SECTION 1

BACKGROUND

TO ABDC-10

CHAPTER 1

CURRENT STATUS AND OPTIONS FOR CROP BIOTECHNOLOGIES IN DEVELOPING COUNTRIES

SUMMARY

In developing countries, there is a need for continued focus on optimizing agricultural output in conjunction with conserving the natural resources base via improved crops and crop management systems. The implications of climate change make it necessary to integrate considerations regarding adaptation, uncertainty, vulnerability and resilience into agricultural research programmes and strategies. The various biotechnologies available have the potential to play a significant role in achieving these aims.

Crop biotechnologies have developed incrementally over the past century, but progress has accelerated greatly over the last two decades leading to many important scientific achievements and impressive technological advances. A wide range of crop biotechnologies is available and some are increasingly used in developing countries, especially tissue culture-based techniques (such as micropropagation), mutagenesis, interspecific or intergeneric hybridization, genetic modification, marker-assisted selection (MAS), disease diagnostics and bioprotection, and biofertilization.

As with other maturing technologies, there have been mixed experiences with crop biotechnologies in developing countries. Genetic modification has had limited but real success in modifying a few simple input traits in a small number of commercial commodity crops, adopted also in some developing countries. The wider application of genetic modification has been slowed down by severe limitations on the kinds of traits available, complex intellectual property rights regimes and regulatory issues, and the often negative public perception. While there have been significant successes in the adoption by farmers of a few first-generation transgenic varieties, there have also been unexpected market setbacks as farmers sought to avoid high seed costs and other restrictions.

The major breeding and crop management applications to date have come from non-transgenic biotechnologies encompassing the full range of agronomic traits and practices relevant to developing countries' farmers. For example, mutagenesis is widely used in developing countries and more than 2 700 mutation-derived crop varieties have been obtained worldwide in the last sixty years, mainly in developing countries. Interspecific hybridization allows the combination of favourable traits from different species and has been used successfully in, for instance, the development of interspecific disease-resistant Asian rice and New Rice for Africa (NERICA) varieties. However, interspecific hybridization programmes can be slow and require a great deal of scientific expertise and skilled labour.

MAS is still at a relatively early stage in its application for key subsistence crops in many developing countries, although it has begun to produce some significant results such as the development of a pearl millet hybrid with resistance to downy mildew disease in India. The costs and technical sophistication required for MAS, however, remain major challenges for developing countries. Micropropagation is used for the mass clonal propagation of elite lines or disease-free planting material. Many developing countries have significant crop micropropagation programmes and are applying it to a wide range of subsistence crops.

Biotechnology also offers important tools for the diagnosis of plant diseases of both viral and bacterial origin, and immuno-diagnostic techniques as well as DNA-based methods are commercially applied for this purpose in many developing countries. Biofertilizers are also being used in developing countries both to augment the nutritional status of crops and as alternatives to chemical supplements.

Biotechnologies such as cryopreservation, artificial seed production, somatic embryogenesis, and other forms of *in vitro* cell or tissue culture are also extensively used for the conservation of genetic resources for food and agriculture in developing countries.

The uptake of biotechnologies in developing countries is increasing gradually but remains patchy. Many biotechnological advances were made in industrialized countries in the private sector, leading to development of proprietary technologies that are often unavailable to scientists in developing countries. Farmers in developing countries, especially small farmers, cultivate crops and face problems that are particular to their cultural and environmental conditions, and have often limited purchasing power to access proprietary technologies. The spillover of research results obtained in industrialized countries by the private sector has therefore had only a limited impact on the livelihoods of subsistence farmers in developing countries. In fact, the most enduring successes to date have come from indigenous public-sector crop research programmes addressing farmer-relevant problems.

Even when there has been strong development of biotechnologies within the public sector in developing countries, they have not always been directed towards – or made available for – improving smallholder livelihoods. In fact, an inclusive process of decision-making about the allocation of resources for the development of appropriate crop biotechnologies was rarely adopted, undermining the successful development of crop biotechnologies. In some cases, even though the technology was sound and the products were potentially beneficial to farmers, there was limited or no adoption due to often-predictable infrastructure or market deficiencies. A promising approach to address such problems is farmer participatory research but this must be coupled with measures to address a wide range of cross-sectoral issues from extension services to seed multiplication programmes.

Biotechnology programmes have been effective where they complemented well-structured conventional plant breeding and agronomy research and development (R&D) programmes. Key factors in the successful development of crop biotechnologies in developing countries have been: appropriate policy development, strengthened research and extension institutions, and enhanced capacities for researchers and technicians. The establishment of cross-sectoral regulatory measures has also been important.

1.1 INTRODUCTION

Despite great advances in agricultural productivity and economic well-being in much of the world over the past 50 years, food insecurity and poverty continue to be serious issues in many regions (FAO, 2008a; 2009a). Moreover, in 2008, the world entered a period of deepening uncertainty and economic downturn that impacted significantly on the future security of food production and distribution systems (Nellemann *et al.*, 2009). The current economic downturn plus the effects of climate change both reinforce the need to extend the effectiveness of crop improvement and management programmes. The key role of crop improvement in increasing food production and in minimizing agricultural land use in developing countries is shown by estimates that, in the 1990s alone, yield gains saved about 80 Mha (million hectares) of land (Nelson and Maredia, 2007). However, if current food production per capita is to be maintained in the face of population growth and climatic uncertainty, 120 Mha (or 12 percent) of additional land might be needed by 2050, mainly in sub-Saharan Africa and Latin America (FAO, 2009b).

Clearly, in developing countries there is a need for continued focus on optimizing agricultural output, together with preserving the natural resources base through improved crops and management systems. The various biotechnologies available will play a part in this process, but there are difficult choices to be made concerning which methods to use for a particular crop or trait in a particular country or region. So, what are the best options for using biotechnological approaches to address global food security? There is no simple one-size-fits-all answer to this question. In many developing countries, staple crops have only recently started to benefit from the scientific plant breeding methods practised in industrialized countries for almost a century. In other cases, some developing country crops are already being improved using newer technologies such as MAS and genetic modification. Thus, there is no straightforward recipe for the use of a particular group of breeding or management methods for a particular crop or within a particular region. Moreover, the rapid pace of scientific progress is making some hitherto relatively complex and expensive technologies both cheaper and easier to access, even for some of the relatively resource-limited breeding and management programmes involving subsistence crops.

Several removable constraints still impede the uptake of modern crop breeding and management by developing countries. These include the privatization of agricultural R&D in developed countries which restricts access to proprietary technologies and limits the possibility of capturing research spillovers (IAASTD, 2009). While constraints relating to intellectual property rights (IPR) are relatively new and apply mainly to advanced biotechnologies, financial, institutional, socio-economical and political barriers have been concerns for many decades. They include basic measures, such as seed supply, bank loans, transport links and market regulations, and their combined effects can negate even the most impressive technology gains (King and Byerlee, 1978; Limao and Venables, 2001). For example, inadequate market infrastructure has limited fertilizer adoption by African smallholders, leading to persistently poor crop yields, low profitability, and chronic food insecurity (Nkonya *et al.*, 2005).

The purpose of this Chapter is to examine options from crop biotechnologies to address food insecurity in developing countries, particularly in the context of deepening economic and environmental uncertainty. Its primary focus is on sector-specific issues relating to biotechnology and their impact on crop breeding, management and genetic resources, but it also considers relevant cross-sectoral aspects such as socio-economic, regulatory, and public-good concerns.

The Chapter is divided into two main Sections – "Stocktaking: Learning from the Past" and "Looking Forward: Preparing for the Future". Under "Stocktaking", Part 1.2 provides a brief definition of the biotechnologies covered here; Part 1.3 documents the current status of application of crop biotechnologies, both traditional and new, in developing countries; Part 1.4 provides an analysis of the reasons for successes/failures of application of crop biotechnologies in developing countries; and Part 1.5 presents some relevant case studies. The conclusions of the stocktaking exercise and a summary of lessons learned are presented in Part 1.6. The "Looking forward" Section comprises three parts. Part 1.7 deals with key, unsolved problems in the sector where the use of biotechnologies could be useful. Part 1.8 identifies a number of specific options to assist developing countries make informed decisions regarding adoption of biotechnologies, while Part 1.9 proposes a set of priorities for action for the international community (FAO, UN organizations, non-governmental organizations [NGOs], donors and development agencies).

A. STOCKTAKING: LEARNING FROM THE PAST

1.2 DEFINING BIOTECHNOLOGIES

One of the challenges in discussing biotechnology is the lack of a consistent definition of the term itself. In this document, the following definition from the Convention on Biological Diversity (CBD) is used: “any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use”.

A distinction is sometimes made between “traditional” and “modern” biotechnologies, and while this may be valid in areas such as fermentation, it is less useful in the field of crop improvement and management. Scientific plant breeding has developed incrementally over the past century by harnessing advances in plant biology, supplemented at times by traditional empirical knowledge (lore), and informed by the principles of Mendelian, and later molecular, genetics. The impact of such biological approaches has been greatly extended by the deployment of a series of increasingly sophisticated biotechnologies, ranging from induced mutagenesis and tissue culture to robotized and fully automated trait selection based on molecular analyses. As described below, some older biotechnologies such as induced mutagenesis and wide crosses which originally dated from the 1920s have now been updated to new and more powerful forms. In the 21st century, biotechnologies are so pervasive in crop improvement programmes worldwide that it is no longer useful to delimit categories like “conventional” and “modern” when discussing crop breeding or management (OECD, 2009). Though a sharp category distinction between non-transgenic and transgenic approaches might be somewhat contrived in breeding terms, and may not be recognized by all crop scientists, such a distinction is nevertheless quite real in terms of legislation and the perception of many policy-makers and consumers.

1.3 CROP BIOTECHNOLOGIES AND THEIR CURRENT STATUS IN DEVELOPING COUNTRIES

Plant biotechnology is a rapidly evolving area encompassing basic and strategic research and its application in agriculture. While new methods and approaches are constantly being developed, an equally important feature is the improvement of existing biotechnologies that makes them cheaper and easier to use. This is especially relevant to developing countries where hitherto expensive and complex techniques, such as MAS or transgenesis, are becoming increasingly accessible. In this Chapter, the technologies are divided into three groups that reflect the three stages of crop development, namely: (i) creation of new genetic variation;

(ii) screening and selection of favourable variants; and (iii) production/management systems for crops or their derivatives. The last category includes plant propagation, nutrition, protection, and genetic resource management/conservation.

For the past 10 000 years, crop productivity has been improved via the processes of breeding and management. Breeding involves the selection by humans of certain genetic variants of a few chosen plant species according to their suitability for exploitation, whether as edible or non-edible resources. The two key prerequisites to both breeding and evolution are variation and selection. Novel genetic variations in wild populations arise from a relatively slow process of naturally-occurring mutation, plus the mixing of genomes that occurs with sexual reproduction. In contrast, science-based breeding as practised over the past century is based on the creation of genetic variation via processes such as induced mutagenesis, hybridization, controlled introgression of traits from diverse populations of the same or different species, and transgenesis. This is followed by the highly regulated reproduction or propagation of selected variants designed to minimize variation in favoured progeny and hence to create a relatively uniform population that is then managed (i.e. cultivated, harvested and processed) for human exploitation.

While so-called "traditional" methods of enhancing variation, e.g. the use of crop landraces, still have great and often untapped potential, the use of newer biotechnologies to create even wider genetic diversity has given breeders unprecedented opportunities for additional crop improvement. This greatly increased potential to create additional genetic variation has been matched in recent years by a revolution in the screening, identification and selection of potentially useful variants using methods such as biochemical and genomic screening, plus molecular MAS. Thanks to continued advances in basic plant research and in genomic and related technologies, there is great scope for further progress in plant breeding, especially in developing countries, during the coming years (Jauhar, 2007; Moose and Mumm, 2008). The major impacts of biotechnologies relate both to breeding new crop varieties and to areas of crop cultivation and management such as the production of propagation materials especially in vegetatively propagated crops (FAO, 2009c); aspects of plant nutrition such as the production and use of biofertilizers (Odame, 2002; FAO, 2005a); the use of symbiotic nitrogen-fixing bacteria and mycorrhizal fungi (Kohler *et al.*, 2008; FAO, 2009c; Yang, Kloepper and Ryu, 2009); aspects of plant protection, including diagnostics and biopesticides (Carpenter *et al.*, 2002; FAO, 2005a; Pender, 2007); and, finally, the conservation and management of crop genetic resources, both *in situ* and *ex situ* (FAO, 2006a).

Here follows a survey of crop biotechnologies, many of which were initially developed in industrialized countries but are now being adapted and increasingly used in developing countries where they are used mainly for commercial crops – though in a few cases they are also being applied to some subsistence crops.

1.3.1 Creation of new genetic variation

The ability of plant breeders to create new genetic variation was enormously increased in the mid-twentieth century by the invention of tissue culture and use of growth regulators (Thomas, Murphy and Murray, 2003). The creation of new genetic variation includes wide crossing with the assistance of methods such as embryo rescue, asymmetric cell fusion, nuclear implanting and somatic embryogenesis. Attempts at wide crossing between distantly related species are frequently frustrated by the incompatibility of their genomes.

Chromosome doubling: This is one of the most important technologies for the creation of fertile interspecific hybrids. Wide-hybrid plants are often sterile so their seeds cannot be propagated. This is due to differences between chromosome sets inherited from genetically divergent parental species, which prevent stable chromosome pairing during meiosis. However, if the chromosome number is artificially doubled, the hybrid may be able to produce functional pollen and eggs and therefore be fertile. Colchicine has been used for chromosome doubling in plants since the 1940s and applied to more than 50 plant species, including the most important annual crops. It has also been used to create seedless fruits and to produce wide crosses and somatic hybrids. More recently, other chromosome doubling agents, all of which act as inhibitors of mitotic cell division, have been used successfully in plant breeding programmes. In some plant species, tissue culture techniques have been used to induce chromosome doubling (Sonnino, Iwanaga and Henestroza, 1988; Cardi, Carputo and Frusciante, 1992). As well as making much wider genetic crosses possible, chromosome doubling has enabled the use of powerful methods such as somatic hybridization and haploid breeding, which have been especially useful in developing countries. To date, dozens of important crops have been improved and hundreds of new varieties produced around the world thanks to chromosome doubling technology.

Tissue culture-based technologies

Tissue culture has been widely used for over 50 years and is now employed to improve many of the most important developing country crops including major staples such as rice and potato, as well as endangered native species (AboEl-Nil, 1996). A brief survey of tissue culture based technologies now follows.

Somatic hybridization: Somatic hybridization is another way of enhancing variation in crop species by importing genes or even whole chromosomes from other species that are not closely enough related for normal sexual crossing (Arcioni and Pupilli, 2004). Although similar in its aims to conventional hybridization, somatic hybridization involves a more radical technological approach. The development of sophisticated microinjection and cell fusion techniques in the 1960s and 1970s allowed researchers to fuse whole cells or parts of cells to create composite cells from unrelated species. The resultant hybrid cells can either be treated with colchicine to induce chromosome doubling, or they spontaneously double the chromosome number during the *in vitro* regeneration process, hence stabilizing the new genome. Finally, the hybrid cells are induced to divide and differentiate into new hybrid plants. Somatic hybridization was introduced into crop breeding programmes in the early 1980s and has been attempted with several developing country crops (Murphy, 2007a).

The main technical hurdle at present is the instability of the new genome combinations from two dissimilar species. To a great extent, somatic hybridization has been replaced over the past decade by transgenesis, which has greater precision, fewer problems with genome instability and a higher overall success rate. However, transgenesis is only of use when there is a known useful gene (or genes) to be transferred. Many useful traits are controlled by as yet unknown sets of genes and can only be transferred into a crop by adding an entire donor genome, or at least a substantial portion thereof. In recent years, breeders have started to return in greater numbers to explore the potential of somatic hybridization, especially in some fruit crops. The reasons for this are threefold. First, transgenesis is not always a quick and easy option for enhancing variation in crops. Second, tissue culture and molecular marker techniques have improved considerably over the past decade, which has increased the rate of success in regenerating genetically stable progeny from such hybridizations. Third, unlike transgenesis, somatic hybridization is not regarded by regulatory authorities as genetic modification. Therefore, varieties produced by this technology are not subject to the same regulatory testing and approval requirements as transgenic varieties, which has created new commercial opportunities for breeders. Although somatic hybridization has not yet been used to a great extent for public-good purposes in developing country crops, this often-overlooked technology has considerable potential and should be kept in mind for the future.

Haploids and doubled haploids: Haploid plants can be produced using anther culture which involves the *in vitro* culture of immature anthers (i.e. the pollen-producing structures of the plant). As the pollen grains are haploid, the resulting pollen-derived plants are also haploid (FAO, 2009c). Doubled haploid plants were first produced in the 1960s using colchicine and today several treatments can be used, including thermal shock or mannitol incubation (Kasha *et al*., 2001). Doubled haploids may also be produced from ovule culture. Breeders value doubled haploid plants because they are 100 percent homozygous and any recessive genes are therefore readily apparent. The time required after a conventional hybridization to select pure lines carrying the required recombination of characters is consequently drastically reduced (Smith *et al.*, 2008). The application of this technique to plant breeding is hindered by the investments in facilities and human resources necessary to produce and to test large populations of doubled haploids. The need to test large numbers of lines can add significantly to the skilled labour requirement and hence lead to increased costs. In the developing world, a major centre of such breeding work is China, where numerous doubled haploid crops have been released and many more are being developed (FAO, 1995). By 2003, China was cultivating over 2 Mha of doubled haploid varieties, the most important of which were rice, wheat, tobacco and peppers (Maluszynski *et al.*, 2003). Improved varieties of durum and bread wheat have also been obtained by applying anther culture techniques in Tunisia and Morocco, respectively (FAO, 2005a).

Sterile plant varieties: Manipulations by plant breeders frequently result in sterile varieties that cannot readily be propagated. Sometimes this is a useful trait and is deliberately engineered by breeders, e.g. in watermelon and citrus crops where consumers demand seedless fruits. Seed sterility is analogous to F_1 or F_2 hybrids or other non-propagable plant types in its utility to commercial seed companies because the farmer cannot use saved seed and therefore needs to repurchase it each year for replanting. One of the most rapid and cost-effective approaches for inducing sterility in a plant is to create polyploids, especially triploids. In most cases, triploid plants will grow and develop normally except for their inability to set seed and therefore cannot be reproduced or propagated, except by the company that owns the parent lines through the use of embryo culture. Alternatively, triploid plants can be regenerated from endosperm tissue, which is naturally triploid. This method has been used to create triploid varieties of numerous fruit crops including most of the citrus fruits, acacias, kiwifruit (*Actinidia chinensis*), loquat (*Eriobotrya japonica*), passionflower (*Passiflora incarnata*) and pawpaw (*Asimina triloba*) (Lee, 1988).

Mutagenesis

This involves the use of mutagenic agents such as chemicals or radiation to modify DNA and hence create novel phenotypes (Donini and Sonnino, 1998). It includes somatic mutagenesis whereby tissue or cell cultures may undergo useful epigenetic modifications provided the resultant traits are stable in future generations. Induced mutagenesis has been practised with great success in crop breeding programmes in developing countries since the 1930s (Ahloowalia, Maluszynski and Nichterlein, 2004), but its scope and utility have recently been greatly enhanced and extended by the new molecular-based technology of targeting induced local lesions in genomes (TILLING, see below). An apparent limitation of mutagenesis versus wide crossing or transgenesis methods is that breeders can manipulate only genes already present in the genome. No new genes can be added by this method. Furthermore, nearly all mutations result in a loss of gene function, meaning that mutagenesis is concerned more with reducing the effects of unwanted genes than increasing the expression of desirable genes. At first sight, this might seem like a serious limitation to the creation of useful new agronomic traits. However, recent genomic studies reveal the surprising fact that during the 10 000-year history of agriculture, loss-of-function alleles were associated with nine out of 19 key episodes in crop improvement and/or varietal divergence (Doebley, Gaut and Smith, 2006; Burger, Chapman and Burke, 2008). Therefore, the past and future potency of mutagenesis for crop improvement cannot be underestimated.

Somaclonal mutagenesis is caused by changes in DNA induced during *in vitro* culture (Durrant, 1962). Somaclonal variation is normally regarded as an undesirable by-product of the stresses imposed on a plant by subjecting it to tissue culture. These stresses include abiotic factors, such as cold, water deficiency, or high salt concentrations; excess or dearth of nutrients; the effects of chemical growth regulators; and infections by pathogens. The stresses of tissue culture can result in single-gene mutations; the deletion or transposition of larger lengths of DNA, including chromosome segments; methylation or de-methylation of genes; and even the duplication or loss of entire chromosomes. Provided they are carefully controlled, somaclonal changes in cultured plant cells can potentially provide a powerful new tool to generate variation for crop breeders (Sala and Labra, 2003). Somaclonal mutagenesis has been used to manipulate traits such as disease resistance, insect resistance, nutritional value, drought and salt tolerance in crops ranging from sugar cane to banana.

Mutagenesis is currently one of the few biotechnologies used much more in developing countries than elsewhere. Both radiation and chemical mutagenesis have been used for crop improvement since the 1930s. During the 1950s, FAO began working with the International Atomic Energy Agency (IAEA) to make irradiation technology more widely available to developing countries in a collaboration that is now known as the Atoms for Food global partnership (FAO and IAEA, 2008). More than 2 700 mutation-derived varieties have been obtained world-wide, generating benefits worth billions of dollars, mainly in developing countries (Ahloowalia, Maluszynski and Nichterlein, 2004; FAO and IAEA, 2008).

TILLING can be viewed as an updated high-tech version of mutation breeding (McCallum *et al.*, 2000a; 2000b). First, mutagenic agents such as alkylating agents or radiation are used as normal to create a population of thousands of mutagenized plants. Next, the second (or M_2) generation of these mutants is screened using a semiautomated high-throughput DNA-based method to detect mutations in genes of interest. Screening involves use of the polymerase chain reaction (PCR) to amplify gene fragments of interest, plus rapid identification of any mutation-induced lesions by looking for mismatches in duplexes with non-mutagenized DNA sequences. The third step is to evaluate the phenotypes of a limited number of selected mutant plants. TILLING is also amenable to automation including high-throughput robotic screening systems, making it especially suitable for large and complex polyploid genomes found in several major crops. As well as screening mutagenized populations, TILLING can be used to screen variation in natural populations in what has been termed EcoTILLING (Henikoff, Till and Comai, 2004).

As with other technologies, TILLING will eventually get cheaper and more accessible, so it can be applied more readily by developing countries. However, the wider applications of this and other new biotechnologies depend critically on how and where they have been developed. For example, chemical/radiation mutagenesis was pioneered in the public sector and was subsequently disseminated around the world. In contrast, other biotechnologies such as maize F_1 hybrids and transgenesis were commercialized by the private sector and, outside the arena of globally traded commodity crops, they have spread more slowly and less widely. In the case of TILLING, it will be important to maintain a balance between protecting the legitimate commercial interests and research investments of the exploiting companies while making the technology available for non-profit, public-good applications in developing countries.

Genetic modification

This is the use of exogenous DNA or RNA sequences to create transgenic organisms that express novel and useful traits in agriculture. It may involve the insertion of copies of endogenously derived DNA or RNA sequences into the same species, e.g. as part of gene amplification or RNA interference (RNAi) based manipulation of gene expression. Unlike other methods for creating variation, there is no limit to the source of the added DNA or RNA; this can be derived from animals, viruses, bacteria, or even from totally man-made sequences. In transgenesis, DNA for stable, inherited transformation is normally added to cells by biolistics or biological vectors (Slater, Scott and Fowler, 2008). In biolistics, DNA is attached to small particles that are propelled into plant tissues. This technique is useful because it can be applied to any plant species, but is relatively inefficient and does not always result in the incorporation of the transgenes into the plant genome (Kikkert, Vidal and Reisch, 2005). Alternatively, DNA can be added in a more controlled fashion by means of vectors such as *Agrobacterium tumefaciens* which are able to insert DNA directly into the genome of a plant cell (Chilton, 1988). Exogenous genes can also be delivered for transient expression using viral vectors, which is faster but less versatile than stable transformation (Marillonnet *et al.*, 2005).

Despite their limitations, each of these methods of DNA transfer can sometimes be more efficient in delivering genes into crops than the non-transgenic biotechnologies such as induced mutations or wide crosses. Tissue culture methods have also been vital in enabling transgenesis. Indeed, even today, more than 25 years after the first transgenic plants were produced, the efficiency of gene transfer in many species (and especially some of the less well studied developing country crops) is still often limited more by the capacity of a plant species/genotype to be cultured and regenerated *in vitro* than by the ability to transfer exogenous genes *per se*.

In some respects, transgenesis is simply a more precise form of wide crossing. The major difference is that the transferred DNA can be derived from a multiplicity of sources. One disadvantage of transgenesis is that for complex multigenic traits, such as drought or salinity tolerance, the genes involved (of which there may be many) have yet to be conclusively identified. This means that breeders currently have relatively few candidate genes available for transfer, although the list of potential genes will continue to grow with further advances in genomics. A further limitation for transgenesis in crop breeding is the current IPR system, whereby several key underpinning technologies are owned by a few commercial companies. As discussed below, this can inhibit the wider development of transgenic crops and is a particular disincentive to their deployment in developing countries (Murphy, 2007a). Additional limitations to the wider adoption of transgenesis include complex and still-unresolved regulatory regimes for the release of transgenic crops plus uncertain public responses in developing countries and/or in potential customer countries (Stein and Rodríguez-Cerezo, 2009; Ramessar *et al.*, 2009).

In response to the problem of restricted ownership of IPR relating to first-generation transgenic crops, there are numerous local initiatives for developing countries to develop their own proprietary biotechnologies, many of which emanate from public-private partnerships (PPPs). For example, in 2009, EMBRAPA, the Brazilian agricultural research organization, applied for final regulatory approval of transgenic herbicide-tolerant soybean varieties, as an alternative to the Roundup Ready® technology owned by Monsanto. In this PPP with the BASF Corporation, EMBRAPA developed locally adapted soybean varieties which are planned for release to farmers in 2011. In addition to its longstanding and successful non-transgenic breeding programmes, the Malaysian Palm Oil Board has a number of partnership programmes, including PPPs, where some of the objectives include the development of transgenic oil palm varieties expressing traits such as improved oil quality and yield, and pest resistance (Murphy, 2007b; Sambanthamurthi *et al.*, 2009). In India, locally-bred transgenic eggplant (*Solanum melongena*) varieties carrying the Bt trait – i.e. containing genes derived from the soil bacterium *Bacillus thuringiensis* (Bt) coding for proteins that are toxic to insect pests – are nearing the final stages of development (Choudhary and Gaur, 2009). The original Bt hybrid stock was donated by its developer, Maharashtra Hybrid Seeds Company, to public research institutes in India, Bangladesh, and the Philippines for use in smallholder targeted breeding programmes in a PPP and North-South partnership (NSP) with Cornell University.

Transgenic crops were first grown on a fully commercial scale in the mid 1990s. The "first-generation" transgenic crops which were grown on an estimated 125 Mha in 2008, are almost exclusively private-sector goods developed in industrialized countries (James, 2008) and tailored to satisfy the needs of their farmers. For over a decade, large-scale commercial transgenesis has been effectively restricted to four commodity crops (maize, soybean, canola/rapeseed and cotton) that collectively accounted for over 99.5 percent of transgenic crop production in 2008. These four crops expressed two transgenic trait classes, i.e. herbicide tolerance (63 percent of genetically modified [GM] crops planted in 2008) or insect resistance (15 percent), while 22 percent had both traits (James, 2008). Although the very narrow range of existing transgenic crops and traits was developed by the private sector primarily for commercial use in industrialized countries, some of them have also been adopted by developing country farmers including many smallholders (Glover, 2007, 2008). For example, the vast majority of soybean output in South America is transgenic and is grown on commercial farms while Bt cotton is grown by an estimated 12 million small and resource-poor farmers in India and China (James, 2008).

One factor that should be taken into consideration with transgenic varieties is that while their transgenic status is normally due to the presence of one or a few exogenous genes, the background genotype is still the product of non-transgenic biotechnologies. For example, the background genotype of Bt cotton grown in India was created by conventional hybridization and backcrossing; and Roundup Ready® soybeans grown in South America have improved yield and quality traits thanks to decades of mutagenesis and wide-crossing programmes. In some cases, such as soybean in Argentina and hybrid maize in South Africa, farmers will be using these varieties not just because of their transgenic traits, but equally (or possibly more) because the varieties also contain other useful agronomic features such as disease resistance or heterosis that were incorporated using non-transgenic breeding methods (Burke, 2004). In other cases, such as Bt cotton in India, the transgenic trait is probably the primary reason for farmer interest in the varieties (Pender, 2007).

Both soybean and cotton are cash crops, and despite their higher prices, transgenic varieties have been widely cultivated in some developing countries. In India, the price of Bt hybrid cottonseed was initially almost triple that of non-transgenic counterparts (Qaim, 2003), but it was nevertheless popular with farmers. However, the high prices led to increased demand for transgenic seed that had been illicitly crossed with local Indian varieties and was available to farmers on the black market. Illicit Bt cotton hybrids were already being sold on the black market across significant areas of the Indian cotton belt for several seasons before the officially approved hybrids were commercialized in 2002 (Scoones, 2005). By 2005, there were reports of black market seeds capturing over 70 percent of Bt cotton sales thanks in part to their being 15–40 percent cheaper than official varieties (Herring, 2006, 2007). Several years later, there were an estimated 200 unofficial Bt cotton varieties, but these were losing popularity due to steep falls in seed prices for official Bt seed (Herring, 2009). Similarly, in China, fully IPR-protected Bt cottonseed imported from the United States initially commanded a price premium of 333 percent in 2001. By 2006, however, non-enforcement of IPR and illicit seed marketing had eroded the price premium to virtually nil (Tripp, Louwaars and Eaton, 2007). Finally, in Argentina, Qaim and de Janvry (2003) report that Bt cotton initially cost from upwards of four to six times more than non-transgenic varieties, resulting in an adoption rate of only 5.4 percent. Within a few years, black market seed was available at one third the official price and these IPR had become virtually unenforceable in Argentina (Qaim and Traxler, 2005).

Therefore, while these examples underscore the popularity of some first generation transgenic crops in developing countries, they also highlight serious problems associated with near-monopoly ownership, anti-competitive IPR regulations and the enforced payment of licence fees (Qaim and Traxler, 2005; Murphy, 2007a). High price differentials and/or licence fees can drive farmers to black-market seed (Qaim and de Janvry, 2003; Perrin and Fulginiti, 2008), or to refuse fee payments as happened with herbicide tolerant soybean in South America (Murphy, 2007a). A possible solution is for developing countries to develop indigenous proprietary biotechnologies which can be made available to farmers at lower cost (Cohen, 2005). Another possibility is for developing countries to invest in the infrastructure to develop extension and seed distribution systems that can provide objective, independent information to farmers regarding the "on-farm" economic benefits and drawbacks from these and other agricultural technologies originating in developed countries and, if farmers are interested, explain how they can gain legal access to such innovations.

Following over a decade of first generation transgenesis which has been restricted to virtually four globally traded commodity crops, the emerging second-generation of transgenic crops includes several examples aimed specifically at subsistence farmers in developing countries. In sub-Saharan Africa, despite relatively low capacity for the indigenous development of transgenesis, several such crops are currently being trialled in joint ventures such as PPPs and/or NSPs (Hartwich, Janssen and Tola, 2003; Smale, Edmeades and De Groote, 2006; Anandajayasekeram *et al.*, 2007). For example, banana is primarily a subsistence crop in rural areas in Uganda, providing some seven million people with food and income. The highest yielding varieties are susceptible to diseases, but since they are sterile, there is limited potential for crossbreeding. In a recent NSP, the National Agricultural Research Organization of Uganda imported transgenic disease-resistant sweet banana plants from the University of Leuven, Belgium (Kikulwe, Wesseler and Falck-Zepeda, 2008). The plants are being field trialled at the Kawanda Agricultural Research Institute for resistance to bacterial wilt and black sigatoka fungal disease. While initial results are promising, the ultimate success of this and similar ventures depends critically on the response of local growers and consumers (Smale, Edmeades and De Groote, 2006).

Other transgenic varieties are at even earlier stages of research and face many years of further development and complex regulatory hurdles before they can be even considered for release. For example, in South Africa the replication-associated protein gene of the severe pathogen maize streak virus (MSV) was used to transform maize plants. Transgenic plants displayed a significant delay in symptom development, a decrease in symptom severity and higher survival rates than non-transgenic plants after MSV challenge (Shepherd *et al*., 2007). Also, a United States based group funded partially by the Rockefeller Foundation and the Centro Internacional de Agricultura Tropical (CIAT) is developing transgenic cassava containing a bacterial ADP-glucose pyrophosphorylase gene for enhanced starch production (Ihemere *et al*., 2006). Other examples currently in the pipeline include: maize for insect resistance and improved protein content; potatoes for viral disease and pest resistance; and rice for disease and pest resistance.

Interspecific hybridization

Wide crossing, or interspecific hybridization, involves hybridizing a crop variety with a distantly related plant from outside its normal sexually compatible gene pool. The usual purpose of wide crossing is not to produce true hybrids, i.e. progeny containing significant parts of both parental genomes, but rather to obtain a plant that is virtually identical to the original crop except for a few genes contributed by the distant relative. In some cases, it may even be possible to use wide crossing to obtain a plant that is almost identical to an elite variety of a crop except for the presence of a single new trait or gene transferred from a different species. The strategy of obtaining useful genes from other species via wide crosses was greatly enhanced by advances in plant tissue culture. A particular challenge was to circumvent the biological mechanisms that normally prevent interspecific and intergenus crosses. The spontaneous rejection of hybrid embryos is normally an important mechanism to ensure the reproductive isolation of populations and to avoid non-viable or debilitated hybrid progeny. Therefore, a high proportion of wide hybrid seeds either does not develop to maturity, or does not contain a viable embryo. To avoid spontaneous abortion, the breeder removes embryos from the ovule at the earliest possible stage and places them into culture *in vitro* (Chi, 2003). Mortality rates can be high, but enough embryos normally survive the rigours of removal, transfer, tissue culture, and regeneration to produce adult hybrid plants for testing and further crossing.

First generation, wide hybrid plants are rarely suitable for cultivation because they have only received half of their genes from the crop parent. From the other (non-crop) parent they will have received not only the few desirable genes sought by the breeder but also thousands of undesirable genes that must be removed by further manipulation. This is achieved by re-crossing the hybrid with the original crop plant, plus another round of embryo rescue, to grow up the new hybrids. This "backcrossing" process is repeated for about six generations (sometimes more) until the breeder ends up with a plant that is 99.9 percent identical to the original crop parent except that it now contains the desirable gene from the donor parent plant. Particularly useful for gene and quantitative trait locus

(QTL) discovery and breeding are the so-called introgression libraries, namely collections of backcrossed families each carrying an introgressed segment (about 10-20 cM) from the donor parent and covering, as a collection, the entire genome (Zamir, 2001). Wide crossing programmes can take more than a decade to complete although MAS and anther culture can also be used to speed up the process. They involve thousands of plants, a great deal of scientific expertise and skilled labour, and success is never guaranteed. Nevertheless, wide crosses have been largely successful in enabling breeders to access genetic variation beyond the normal reproductive barriers of their crops. Some case studies of successes with interspecific crops, including disease-resistant Asian rice and New Rice for Africa (NERICA) varieties are discussed in Part 1.5.

One concern for the future of wide crossing is that many potentially beneficial donor species or local populations of wild plants are being destroyed every year by habitat degradation, industrialization and agricultural expansion. This illustrates the need for an inventory and/or the improved conservation of wild plants that could possibly contribute useful genes to major crops such as those influencing disease resistance. Threats to potentially useful wild relatives of the major Asian crops are particularly serious. Gurdev Khush, former principal breeder at the International Rice Research Institute (IRRI), developer of wide crosses of rice, and 1996 World Food Prize laureate, has described wild relatives as "truly priceless seeds" (Barclay, 2004). Using wide crosses, IRRI has produced new rice varieties that are resistant to the grassy stunt virus, bacterial blight, and blast and tungro diseases. Wide crossing with the wild species *Oryza officinalis* has produced four new rice varieties, each carrying resistance to the brown planthopper which is a particularly serious pest (as well as being a viral vector) in Vietnam (Murphy, 2007a). The new rice varieties reduce pesticide use and also contain resistance to the grassy stunt virus.

The use of the hybrid-plant technologies listed above has been one of the cornerstones of modern crop breeding and is set to benefit further from advances in plant biotechnology. For example, new chromosome engineering techniques are being translated into a greatly improved capacity to effect wide hybridization and hence enable the recruitment of important agronomic traits from wild species into developing country crops (Gupta and Tsuchiya, 1991; Jauhar, 2003; Ceoloni *et al.*, 2005; Singh, 2007). Like TILLING, chromosome engineering can be viewed as a modern high-tech form of an earlier biotechnology. It will be important for developing countries to be in a position to participate in and capitalize on such research advances in the future. This is a good argument for much greater investments in human and physical resources. Indeed, even in a major agricultural research centre like China, there have been recent concerns that insufficient resources are being channelled into R&D to underpin future advances in crop breeding (Chinese Academy of Sciences, 2008).

1.3.2 Screening and selection

In addition to creating new genetic variation, breeders need effective and efficient methods to identify, select and propagate useful variants, and there has been striking recent progress in this area. Examples include the many improvements in efficiency and accuracy in screening and selecting the huge numbers of genetic variants, often numbered in the tens of thousands, created by technologies such as hybridization or mutagenesis. From tandem gas chromatography/mass spectroscopy to automated sequencing and robotized PCR, a host of new analytical and screening technologies can enable breeders to progress from the laborious processing of a few dozen samples per day to routine, rapid, automated, round-the-clock, in-depth analyses of the detailed molecular characteristics of many thousands of plants. Genomics, and genome sequencing/annotation in particular, is a core technology group that is already underpinning improvement in an increasing range of species, including rice, sorghum and oil palm (Kovach and McCouch, 2008; Sakamoto and Matsuoka, 2008; Bolot *et al.*, 2009; Skamnioti and Gurr, 2009).

Marker-assisted selection (MAS)

MAS is a comparatively new screening method with the potential to revolutionize aspects of crop breeding via the use of DNA-derived molecular markers (for a detailed review of MAS in rice, see Collard *et al.*, 2008, and Jena and Mackill, 2008; for cereals in general, see Goff and Salmeron, 2004; and for more comprehensive overviews see FAO, 2007a, Varshney and Tuberosa, 2007a and 2007b, and Xu and Crouch, 2008). MAS can be employed to support any form of crop breeding programme including crossing of traditional land races or within participatory plant breeding programmes with smallholders. Molecular markers are also being used as highly effective research tools to uncover the genetic basis of complex agronomic traits such as drought or salt tolerance and pest/disease resistance (Bernardo, 2008; Cai, Bai and Zhang, 2008; Collins, Tardieu and Tuberosa, 2008). In addition to their increasingly prominent role in the genetic improvement of crops, molecular markers are useful for a host of other agriculturally related applications such as characterizing crop genetic resources, plant gene bank management, and diagnosis of diseases (FAO, 2006a). Using molecular markers, breeders can screen many more plants at a very early stage and thereby save several years of laborious work in the development of a new crop variety. In the case of wheat breeding, for example, it has been estimated that MAS may result in an overall cost saving of 40 percent relative to conventional phenotypic selection, in addition to improved genetic gains (Kuchel *et al.*, 2005).

Hitherto, the use of MAS in crop breeding was largely restricted to a few economically important temperate crops, but the list is now expanding. Public sector initiatives and PPPs have developed cheaper and easier MAS breeding systems (Koebner and Summers, 2003).

MAS technologies have also benefited from more efficient screening methods including PCR, DNA/DNA hybridization, and DNA sequencing (Varshney and Tuberosa, 2007a). Today, most MAS technologies use PCR-based methods, such as sequence-tagged microsatellites and single-nucleotide polymorphisms (SNPs). Molecular marker technology is now being applied to an increasing range of crops and even to domesticating entirely new crops. As well as annual crops such as cereals and legumes (Garzón, Ligarreto and Blair, 2008), MAS has been useful in perennial crops, including subsistence and cash crops in developing countries. Examples include oil palm, coconut, coffee, tea, cocoa, and many tropical fruit trees such as bananas and mangoes. By using DNA markers in conjunction with other new breeding technologies such as clonal propagation, it should be possible to make rapid strides in the creation and cultivation of greatly improved varieties of many of these important tropical crops.

In the medium term, MAS could well evolve into what has been termed "genomics-assisted breeding" (Varshney, Graner and Sorrells, 2005; Varshney and Tuberosa, 2007b). Here bioinformatics-supported genomic and metabolomic resources are key parts of breeding programmes. For example, the immediate wild ancestor of rice, *Oryza rufipongon*, is a genetically diverse species containing alleles that confer agronomically useful unexpected (transgressive) variation when crossed with elite cultivars of *O. sativa.* However, there is currently no way of predicting where to look for such wild alleles. The integration of whole-genome mapping and marker analyses coupled with QTL cloning and EcoTILLING would greatly facilitate a targeted use of wild relatives in breeding (Kovach and McCouch, 2008). Of course, this assumes that such resources and infrastructure are available for the crop in question, which is complex enough in the case of rice despite its small and much studied genome, but may be even more challenging for more genetically complex and less well studied subsistence crops such as cassava or millet.

Despite improvements over the past decade, a major challenge in developing MAS is still the cost and technical sophistication of the initial investment. For each crop, mapping populations must be created, genomic markers assembled, and genetic maps compiled. A cost/benefit analysis by the International Maize and Wheat Improvement Center (CIMMYT) on using MAS in resource-limited public breeding programmes has concluded that each case for developing MAS technology needs to be assessed separately and depends critically on: the nature of the crop including its genomic organization; the availability of requisite technical infrastructure and know-how; and the availability of capital for set-up costs (FAO, 2007b). Such calculations are especially important when developing countries are deciding whether to invest scarce resources in such technologies. Although MAS is becoming progressively cheaper, it is still often relatively expensive compared with alternative approaches for many developing country crops. Prospects for MAS in African breeding programmes have been reviewed by Stafford (2009).

Marker-assisted selection is beginning to produce significant results in the relatively few crop breeding programmes in which it has been deployed, and future prospects here are very good. One example is the development using MAS of "HHB 67 Improved", a pearl millet hybrid with resistance to downy mildew disease, which was approved for release in India in 2005. In 2008, F_1 hybrid seed was produced to sow at least 300 000 ha with HHB 67 Improved, while the 2009 area could exceed 500 000 ha if sowing conditions are favourable (Hash, 2009). Other examples where MAS has been used in the development of new products for farmers include new rice varieties with resistance to bacterial blight in India (Gupta, 2009) and with submergence tolerance in the Philippines (Rigor, 2009). Although most crop research centres of the Consultative Group on International Agricultural Research (CGIAR) and many national organizations are increasingly using MAS in crop improvement programmes, it is still at a relatively early stage in its rollout for key subsistence crops in many developing countries (FAO, 2007c).

1.3.3 Production and management systems

Many developing country crops including cassava, potato, banana, sweet potato and oil palm are mainly vegetatively propagated and tissue culture based micropropagation systems have become especially important for their improvement. Additional production/management-related biotechnologies include the use of biofertilizers and bioinsecticides, plus the use of tools such as molecular markers and cryopreservation for the management and conservation of plant genetic resources. While there are several existing examples of applying these biotechnologies in various developing countries, their true potential for the improvement of food production and reducing chemical inputs has barely been tapped.

Micropropagation

In crops where sexual reproduction is problematic or impractical, vegetative propagation has been used for a long time. More recently, biotechnologies have been developed for mass clonal propagation of elite lines or disease-free planting material by culturing *in vitro* explants such as shoot tips, tuber sections or other cuttings. The regenerated plantlets are subcultured, often on a massive scale, until thousands or millions have been produced for transfer to the field. In this way, cuttings from a single elite tree or disease-free plant can be used for rapid large-scale cultivation. These methods are especially useful for subsistence root and tuber crops such as cassava, potato, and sweet potato as well as for fruit tree crops such as banana and oil palm because they facilitate the production of healthy planting materials at reasonable costs (FAO, 2009c). In the past few decades, the technique of mass propagation has become increasingly useful in breeding programmes, especially for tree crops most of which are too long-lived to be amenable to the approaches developed for annual crops. Mass clonal propagation can be a fast and cheap method for multiplying the best genetic stock in such perennial species.

Today, *in vitro* propagation including micropropagation and somatic embryogenesis, is widely used in a range of developing country subsistence crops, including banana, cassava, yam, potato, sweet potato (*Ipomoea batatas*), frafra potato (*Solenostemon rotundifolius*) and cocoyam; commercial plantation crops, such as cocoa, coffee, oil palm, sugarcane and tea; niche crops, such as artichoke, cardamom, garlic, ginger, and vanilla; and fruit trees, such as almond, cactus, citrus, coconut, date palm, ensete, granadilla, grape, lemon tree, mango, olive, pistachio, pineapple, and plantain (Sharma, 2001; Blakesley and Marks, 2003; Pender, 2007; Smale and Tushemereirwe, 2007; FAO, 2009c). Some of the many countries with significant crop micropropagation programmes include Argentina, Gabon, India, Indonesia, Kenya, Nigeria, the Philippines, Uganda and Vietnam.

Micropropagation is especially useful for vegetatively propagated root crops and it is here that the greatest successes have been demonstrated. For example, disease-free sweet potatoes based on tissue culture have been adopted on 0.5 Mha in Shandong Province in China, with yield gains of 30–40 percent (Fuglie *et al.*, 1999). By 1998, more than 80 percent of local farmers had adopted the technology, generating productivity increases of US$145 million and increasing agricultural income for the seven million sweet potato growers by 3.6 and 1.6 percent, in relatively poor and better-off districts respectively. In India, a scheme enabled potato breeders to integrate micropropagation and virus detection into the initial stages of seed production, leading to an estimated two- to three-fold increase in seed health, and generating more than US$4 million in revenues (Naik and Karihaloo, 2007).

In Kenya, micropropagated disease-free bananas were adopted by more than 500 000 farmers over a 10-year period (Wambugu, 2004). It had been predicted that these new varieties would offer higher financial returns in Kenya than traditional bananas (Qaim, 1999), and this was later empirically verified (Mbogoh, Wambugu and Wakhusama, 2003). In the late 1990s, the Uganda National Banana Research Programme sought to address the decline of cooking banana production in Bamunanika subcounty by introducing micropropagated, high-yielding cultivars. The new cultivars generated socio-economic benefits for the adopters. However, notwithstanding the use of a participatory farmer-to-farmer extension approach, the relatively high capital and recurrent costs of these new cultivars have prevented less endowed households from benefiting (FAO, 2009c).

The use of micropropagated planting materials in Hwedza District (Zimbabwe) enhanced crop yield and economic returns of sweet potato compared with traditionally propagated planting materials (Mutandwa, 2008). In this case the innovation was adopted by 97 percent of the farmers, including both the worst-off and better-off farmers, and contributed to household food security and produced cash surplus (FAO, 2009c). In Vietnam, farmers participated in the micropropagation of new high yielding late-blight resistant potatoes, resulting in a doubling of yields from 10 to 20 T/ha. By producing their own plantlets, farmers have increased yield and incomes, and have set up rural microenterprises specializing in the commercial production of disease-free seed (Uyen *et al.*, 1996).

Disease diagnostics and bioprotection

Biotechnology offers important tools to diagnose plant diseases of both viral and bacterial origin. These tools are of particular value when identification of the causal agent is difficult (e.g. many viral diseases exhibit similar symptoms) and when knowledge of the nature of the pathogen is necessary to develop and apply proper management measures. Immunodiagnostic techniques including enzyme-linked immunosorbent assay (ELISA) and monoclonal antibodies are commercially applied in many developing countries, as well as DNA-based methods (FAO, 2005a). Additionally, diagnostic techniques are routinely used for quarantine systems and the production of seeds and other propagation materials in developing countries.

Bioprotection involves biologically based crop protection systems against biotic threats such as pests and diseases. One example is biological control, which has been defined as: "the use of living organisms to suppress the population density or impact of a specific pest organism, making it less abundant or less damaging than it would otherwise be" (Eilenberg, Hajek and Lomer, 2001). Microbial agents are a form of bioprotection and constitute one of the commonest forms used in developing countries. Often these agents have the additional benefit of substituting chemical pesticides that might be unaffordable and/or environmentally undesirable for use in cash-poor, labour-intensive farming systems. There is a small but growing use of microbial pesticides such as the crystalline (cry) proteins produced by the Bt bacterium and biocontrol agents such as pheromones, growth regulators and hormones. There is also an increasing acceptance of alternative pest control agents via the various forms of integrated pest management (IPM) (FAO, 2005a). For example, Bt sprays are being used in Malaysia to control insect pests of oil palm such as the bagworm group (including *Mahasena corbetti* Tams, *Metisa plana* Wlk and *Cremastopsyche pendula* Joannis) and the rhinoceros beetle (*Oryctes rhinoceros*), and large-scale Bt production facilities have been set up. In India, Bt sprays have also been used successfully at village level in Andhra Pradesh (Puente-Rodríguez, 2007).

Fungi are increasingly used as highly target-specific pest management agents that can often replace chemical pesticides. One example is the desert locust, a sporadic pest that can have a severe impact on food production over wide areas of North Africa. Between 2003 and 2005, conventional control using chemical sprays required 42 million litres of mainly organophosphate pesticides over about 13 Mha. While there were no reported instances of serious animal or human health problems, the cost of safety measures was high and there was significant environmental damage (FAO, 2007d). For these reasons, FAO and other partners have been developing alternative bio-based control strategies. These have involved a combination of *Metarhizium* fungi which are existing pathogens of locusts and grasshoppers, plus the biocontrol agent phenyacetonitrile which is a hormone that affects the swarming behaviour of locusts. One particular isolate of *Metarhizium anisopliae* has been formulated as the proprietary agent Green Muscle® and is produced commercially by a South African company. Recent assessments of these biopesticides underlined the kinds of challenges that also confront the wider deployment of many other biotechnologies (FAO, 2007d and 2007e). These include further R&D to improve product formulation and efficacy in the field; improved production and quality assurance methods; accelerated registration for environmental release; improved awareness, capacity building and training for all stakeholders; and formal incorporation into crop protection strategies. *Metarhizium* strains have been used also as effective control agents against rhinoceros beetle and the Metarhizium Technology Centre in Malaysia has produced nearly 0.5 tonnes of pure *Metarhizium* spores for future crop treatments (Moslim *et al.*, 2006).

Plant nutrition

This category includes the production and use of biofertilizers and the use of nitrogen-fixing bacteria and/or mycorrhizal fungi to improve plant performance. Recent studies have shown that there are numerous plant growth-promoting rhizobacteria that not only enhance nutrient uptake by crops but also induce systemic tolerance to other abiotic stresses such as drought and salinity (Yang, Kloepper and Ryu, 2009). As with biopesticides, the use of bionutrition strategies carries the double benefit of reducing input costs for farmers and preventing nitrate and phosphate accumulation within soils and run-off into sensitive watercourses.

There are numerous examples of the use of these strategies in developing countries both to augment the nutritional status of crops and as alternatives to chemical supplements. For example, it was shown in Thailand that rhizobial inoculants can effectively replace chemical fertilizers for the production of soybean, groundnut and mung bean crops (Boonkerd, 2002). The use of *Rhizobia* in Thai soybean, groundnut and mung bean production between 1980 and 1993 produced estimated accumulated benefits of US$100, US$17 and US$4 million, respectively, for crop producers. However, the performance of inoculants can vary with micronutrient conditions in the field and according to the persistence of bacterial populations in different soils. Some studies have revealed the widely differing effects of inoculants in different locations, even within small areas, and significant variations in their performance over time (Hall and Clark, 1995). Therefore, in addition to agronomic factors, the knowledge and experience of local farmers is important in ensuring the effective application of biofertilizers. In Kenya, the UNESCO Microbiological Resources Centre (MIRCEN) developed a *Rhizobium* inoculant known as Biofix for sorghum crops that has been in use since 1981 (Odame, 2002). Elsewhere in Africa, biofertilizers are being developed for cowpea, groundnut, bambara groundnut and rice (FAO, 2005a).

In Mexico, a *Rhizobium*-based biofertilizer developed by the National University of Mexico for the common bean (Peralta *et al*., 2004) was commercialized in 2003 under the name of Rhizofer. It is sold either on its own or together with spores of the mycorrhizal fungus *Glomus intraradices*, to help the plant acquire soil nutrients and to solubilize phosphates. This commercial package also includes printed material and technical assistance. The biofertilizer has been used mainly in the central and northern regions of Mexico. To date, 20 000 ha from a total of 2 million sown in the country have been biofertilized with reportedly very satisfactory results. The use of this biofertilizer offers important savings in the cultivation of the common bean, and costs significantly less than chemical fertilization. Moreover, it improves soil biodiversity and promotes soil biological activity (Peralta, 2009).

The nutritional status of the soil can also be enhanced by using fungal inoculants to accelerate the breakdown of organic fertilizer. In the Philippines, inoculation of rice straw with the fungus *Trichoderma* reduced composting time to as little as 21–45 days depending on the type of plant residue used (FAO, 2009c). Following the success of this "rapid composting technology" (RCT), the Philippines government set up production units for the fungal agent and actively promoted the production and use of organic fertilizer by farmers' cooperatives, private enterprises and NGOs. An impact study concluded that rice and sugarcane farmers adopting RCT used significantly less chemical fertilizer and had higher yields and higher net incomes (Rola and Chupungco, 1996). For example, rice farmers using both organic fertilizer made via RCT and chemical fertilizer produced 15 percent more than farmers using chemical fertilizer only. Net income gains per ha were about US$171. The main advantages of the substitution of chemical with organic fertilizer were the positive effect on soil nutrient content as well as on soil tilth and texture, making organic fertilizer superior to the chemical fertilizers (Cuevas, 1997).

Genetic resource conservation and management

The need to conserve crop genetic resources is now widely accepted and generally justified for one or more of several reasons such as their importance as raw material for plant breeding to face future changes in market needs, production and environmental/climatic conditions, and their importance as a source of material for scientific research and future germplasm development. They are also part of our cultural and historical heritage, passed down from previous generations. In addition, the characterization of genetic resources goes hand-in-hand with conservation because it is fundamental both to our understanding of what is being conserved and to choosing which genetic resources should be conserved. Characterization can also play an important role regarding issues of ownership as well as access to and the benefit-sharing of agricultural genetic resources.

The key role of biotechnologies in the acquisition, management, conservation, protection, characterization and exchange of plant genetic resources is becoming ever more apparent (Karp, 2002; Peacock and Chaudhury, 2002; FAO, 2006a). Many biotechnologies already discussed here are being employed for germplasm management in the widespread network of public sector seed banks and resource centres across the world (Engels *et al*., 2002; FAO, 2005a; Hunter and Taylor, 2007; Murphy, 2007a). For example, relatively well established technologies such as cryopreservation, artificial seed production, somatic embryogenesis, and other forms of *in vitro* cell or tissue culture are extensively used for the conservation of genetic resources for food and agriculture in developing countries, especially for vegetatively propagated plants which can easily get contaminated with pathogenic micro-organisms. Whereas phenotypes (e.g. yield, growth rate) and morphological traits (coat colour, seed shape) are influenced by both genetic and environmental factors, the use of molecular markers and genomics reveals differences at the DNA level that are not influenced by the environment. These molecular tools are having an increasing impact on the study and management of genetic resources.

1.4 ANALYSIS OF EXPERIENCES WITH BIOTECHNOLOGIES IN DEVELOPING COUNTRIES OVER THE PAST 20 YEARS

As with other maturing technologies and as described in Section 1.3, experiences with crop biotechnologies have been mixed. Although transgenesis is being increasingly deployed, the vast majority of new biotech-derived crop varieties remain non-transgenic. Transgenesis is lagging significantly behind owing to severe limitations on the kinds of traits available, complex IPR and regulatory issues, and often negative public perceptions (Stein and Rodríguez-Cerezo, 2009; Ramessar *et al*., 2009). On the other hand, major successes encompassing the whole range of desirable agronomic traits have been achieved via non-transgenic technologies. In the future, breeders will have the additional benefit of genomic and metabolomic technologies which will contribute to all forms of crop improvement. While there have been significant successes in farmer adoption of a few first generation transgenic varieties, there have also been unexpected market setbacks as farmers seek to avoid high seed costs and other restrictions. In some cases, although the technology was sound and the products were potentially beneficial to farmers, there was little or no adoption due to often predictable infrastructure or market deficiencies. A promising approach to addressing such problems is farmer participatory research (FPR), but this must be coupled with measures to address a wide range of cross-sectoral issues from extension services to civil society programmes. The uptake of biotechnologies is therefore gradually improving but remains patchy.

Some of the main factors affecting the use of biotechnologies in developing countries in the past are highlighted below.

1.4.1 Focus on smallholders

Even where there is strong development of biotechnologies within the public sector, they are not always directed towards improving smallholder crops (Kiers *et al.*, 2008). There have been concerns among some policy-makers in industrialized countries and among others in both the private and public sectors that assisting developing country smallholders with crop biotechnologies might not always address overall poverty reduction (Tschirley and Benfica, 2001; Collier, 2008). However, this thesis has been increasingly challenged and the case for supporting smallholder development as a major mechanism for reducing poverty and food insecurity remains robust (Peacock *et al*., 2004; Lipton, 2006; Hazell *et al*., 2007; FAC, 2009). Indeed, recent data from Vietnam, Africa and elsewhere show that small-scale agriculture can act as an important engine of national economic growth and help generate relative affluence from the bottom up in a society (Gollin, Parente and Rogerson, 2002; Murphy, 2007a; Jama and Pizarro, 2008). In India and South America, transgenic crops such as Bt cotton and herbicide tolerant soybean have also had a positive impact on millions of small farmers (FAO, 2004; Trigo and Cap, 2006; Gruère, Mehta-Bhatt and Sengupta, 2008). Smallholders are responsible for an important share of developing country food production and can play a key role in poverty reduction especially in rural communities. But smallholders cannot be always assisted by biotechnology-driven crop improvements in isolation, so wider cross-sectoral challenges must also be addressed at the same time. For example, it is well known that hunger and food insecurity have much deeper and more complex roots than mere crop yields (Pereira, 2008).

Most new biotechnologies have originated outside developing countries, so improved North-South links to facilitate capacity building and technology flow are especially crucial. Unfortunately, efforts to build enduring links between public sector crop research institutions in industrialized and developing countries have been erratic and only partially effective.

1.4.2 Investments in biotechnological R&D

Investment patterns in biotechnology R&D are highly uneven in developing countries. Care should therefore be exercised when discussing all such countries together (as in this Chapter). For example, China recently invested US$500 million in biotechnologies and is now an acknowledged global leader in agriculturally applied plant genomics (USDA, 2008). Indeed, much of the spectacular economic growth of modern China has been underpinned by huge gains in agricultural productivity that enabled the country to remain self-sufficient in many major crops despite steady increases both in population and in per capita food consumption (IAASTD, 2008). Brazil and India each spend less than one tenth of the Chinese agricultural biotechnology budget, but vastly out-spend the whole of sub-Saharan Africa (e.g. for India, see Sharma, Charak and Ramanaiah, 2003). China, India and Brazil are now recognized as significant global centres of emerging excellence in biotechnology that will soon be on a par with the United States and the European Union (Dutton, 2009). A note of concern here comes from a recent downward revision in estimates of global agriculture R&D spending, especially in developing countries (Beintema and Stads, 2008).

The lack of adequate and sustained investments remains a major limiting factor in most developing countries (IAASTD, 2009). This situation may be exacerbated by the consequences of the current economic downturn.

1.4.3 Biotechnology capacities

Insufficient and unstable investments in R&D are only a part of the problem. A further constraint in developing countries is the limitation of capacity to generate, adapt or utilize potentially beneficial biotechnologies due to limitations in agricultural research systems. Such limitations include:

- absent or inadequate policies for agricultural R&D at government and institutional level (Spielman, Hartwich and von Grebmer, 2007);
- poor scientific, political and public awareness of the opportunities and risks of different crop biotechnologies (Gressel *et al.*, 2004; Cohen, 2005; Pender, 2007);
- inconsistent policy and regulatory regimes regarding issues such as IPR enforcement, the protection of plant and animal health, biosafety, food safety and bioethics (Diao *et al*., 2008; Stein and Rodríguez-Cerezo, 2009);
- deficiencies in economic and physical infrastructures (including trade markets) that impede farmer ability to capitalize on new biotechnologies (Murphy, 2007a; Diao *et al.*, 2008);
- the weaknesses of research institutions that do not allow efficient implementation of research projects;
- insufficiently educated/trained human resources and the lack of appropriate incentive schemes for capacity building, the retention and motivation of staff through competitive career development opportunities.

1.4.4 IPR and other regulatory issues

The status of agricultural IPR in different countries and trade blocks is inconsistent and uncertain (Murphy, 2007a; Gold *et al.,* 2008; Smith, 2008, Yamanaka, 2008). Linked to these IPR problems is the fact that many technology leaders and products (e.g. new crop varieties) are part of private sector bodies with no explicit public good missions. A major challenge is to find ways to facilitate the uptake of agricultural R&D discoveries into developing countries and non-commercial crop staples without compromising the innovative processes that often produce such discoveries. In some cases, this requires balancing the ability to innovate, driven largely by the assurances that IPR provides, with ensuring that access to these innovative technologies is provided to those who need it most.

Many crop biotechnologies originate from discoveries in the public sector but require significant private sector involvement for effective reduction to practice (Hartwich, Janssen and Tola, 2003). Moreover, several aspects of crop biotechnologies, including some key plant transformation and regeneration steps, are subject to private sector IPR, which can significantly limit the freedom to operate of public bodies wishing to develop new crop varieties. This has led to the establishment of a range of PPPs with the broad objective of making the products of existing biotechnologies available to smallholders in developing countries, normally in areas where the private sector has little commercial interest. The private and public sectors should establish a more inclusive intellectual property landscape that recognizes the special needs of subsistence and commercial farmers alike in developing countries.

The rollout of GM crops has at times been inhibited by high transaction costs and complex, inconsistent regulatory requirements (Stein and Rodríguez-Cerezo, 2009), sometimes leading to IPR avoidance and piracy of traits. This could be regarded as a qualified market failure. A comprehensive analysis of IPR and regulation is beyond the scope of this document, and these aspects are covered in much greater detail in Chapters 8 and 9.

1.4.5 Link between biotechnology R&D and plant breeding programmes

It is important to underline that biotechnology can assist and expand, but not substitute, traditional plant breeding programmes. The presence of skilled personnel and adequate facilities for the identification of appropriate parents and segregating materials, as well as the selection of improved lines for their stabilization and agronomic assessment, are essential. Even countries that decide to rely on research results obtained abroad, for instance in neighbouring countries with similar ecological conditions, need capacities for the evaluation, adaptation and adoption of improved lines developed elsewhere. Investments in biotechnology infrastructures and human capacities cannot therefore be made at the expense of conventional breeding or agronomic research and strong breeding programmes must remain at the core of crop improvement.

1.4.6 Farmer involvement in research and breeding

The relevance and uptake of biotechnology advances in crop improvement by smallholders can be improved using participatory research approaches. Participatory approaches to research can lead to more relevant, site-adapted and socially acceptable solutions to real-world problems and technological constraints in agriculture and natural resource management. Research participatory approaches are used in problem identification, planning, implementation and research transfer and/or evaluation. Experiences using FPR for the improvement of crop production have been made in the area of plant breeding and are known as participatory plant breeding (PPB) (Murphy, 2007a), and in IPM, often using farmer field schools.

Recent evaluations of the effectiveness of FPR and PPB have been encouraging (Ashby and Lilja, 2004; Scoones and Thompson, 2009). Small farmers often produce in marginal areas with limited access to knowledge, improved technologies and inputs. Conventional breeding has focused heavily on "broad adaptability" and major traits, resulting in high yielding varieties with pest and disease resistance that produce well when input levels are high, but poorly in the marginal conditions under which cash-poor farmers often operate (Murphy, 2007a). Traits such as resilience to adverse conditions (e.g. water scarcity), ease of harvest and storage, taste and cooking qualities, speed of crop maturation, and the suitability of crop residues as livestock feed, can be of high relevance to small farmers. Involving them in the breeding process from the beginning will help to develop new crop varieties and agricultural practices that are better adapted to the areas where they produce and more relevant to their farming conditions and needs. Examples of participatory approaches in plant breeding are described by Ceccarelli *et al*. (1997 and 2000), Toomey (1999), Almekinders and Elings (2001), Vernooy (2003), and Morris and Bellon (2004).

While participatory research can generate a range of direct and indirect benefits for participants, careful attention needs to be paid to achieving equitable impacts. Participatory approaches must consider power sharing and participant selection, or risk missing important contributions from women and other marginalized groups (Johnson *et al*., 2004). Gender issues can play an important role in many aspects of agriculture (Boserup, 1970), and have been shown to be relevant also for plant breeding/management/processing and the uptake of new technologies (Wambugu *et al.*, 2000; Nguthi, 2007; Smale and Tushemereirwe, 2007; CGIAR, 2008). For example, many traits relevant for the harvesting, threshing, milling and cooking of grains can be more or less invisible even to the men in the local community, and may be overlooked by scientist-breeders. However, these processing-related traits may be of paramount concern to the women who actually carry out such tasks as they prepare food from the crops on a daily basis. The importance of women in the outcome of breeding projects has been shown in several case studies in Côte d'Ivoire, where the selection of inappropriate traits by poorly-informed scientific breeders led to the rejection of new varieties by women farmers (Lilja and Dalton, 1997; Dalton and Guei, 2003; Dalton, 2004).

Modern biotechnologies successfully applied in conventional plant breeding programmes have recently also been introduced using participatory approaches. MAS has been used as part of a PPB approach for developing rice with improved stress tolerance (Steele *et al.*, 2002 and 2004; Witcombe, Joshi and Goyal, 2003), for developing higher yielding maize (Virk *et al.*, 2003) and in small-scale potato crop systems in the Bolivian Andes (Puente-Rodríguez, 2008). Participatory approaches have been used for varietal selection of NERICA rice (see Part 1.5), and for the adaptation and diffusion of NERICA technologies for rice-based production systems in Africa (Somado, Guei and Keya, 2008). Similar schemes are being piloted for other crops and together with more effective extension services, should be considered integral to the process of crop improvement (World Bank, 2007). FPR approaches have also been applied to the production of micropropagated planting materials in many countries including Colombia and Bolivia, and to the production of biofertilizers and biopesticides in Colombia, Ecuador and Peru among other countries, leading to the establishment of micropropagation laboratories managed by farmers.

1.4.7 Technology uptake

Crop varieties and management systems developed by even the most sophisticated new technologies will have little impact on improving food security in developing countries unless they are effectively taken up by farmers on a sustained, long-term basis (Tripp, 2001). Indeed, while modern breeding and crop management technologies can easily take a decade or more to make improved materials available to farmers, it is a telling but often overlooked fact that the widespread on-farm adoption of such technologies can take much longer (FAO, 2007f). Technology uptake, or lack thereof, is an abiding concern for the improvement of food security at small farmer level. For example, it is estimated that simply by applying existing recommended practices of crop management, Ghanaian farmers could double or treble average yields of most staple crops (Al-Hassan and Diao, 2007).

Seed systems

One of the major hurdles to the wide-scale use of improved varieties obtained though biotechnological approaches in developing countries is the weakness of the local seed systems. In many developing countries, the vast majority of seeds used in agriculture are supplied by informal seed systems which include farm-saved seeds, seed exchanges between farmers and seeds purchased from local markets. The informal seed system can, in some instances, play an important role in the conservation of local landraces and other precious genetic resources, and satisfies the demand of low-cost inputs, but the seed supplies often do not meet acceptable quality standards. Seeds of improved varieties obtained by biotechnological means combined with conventional breeding approaches such as MAS-derived varieties, are usually multiplied and distributed through formal seed production and distribution schemes which offer high-standard propagation materials but which often lack the capacity to meet the seed demand for these new varieties and to reach vast numbers of small-scale farmers.

For example, the current demand for seeds of NERICA varieties in West Africa exceeds their supply. Also, the seeds offered by the formal production and distribution systems are frequently more expensive and cannot be accessed by farmers with low purchasing power. In addition to infrastructure, government support within developing countries may consider providing financial incentives to farmers to plant higher yielding varieties that will ultimately bring increased revenue back to the farmer.

Extension services

In a recent report on seed delivery systems in Africa, Guei, Somado and Larinde (2008) stated that: "Most extension services are characterized by a lack of information, technical capacity and logistics for timely delivery of advice to farmers. They have inadequate capacity in terms of personnel and are unable to formulate and implement good and sound technology transfer approaches". Even in comparatively well developed and resourced cropping systems such as oil palm in Malaysia, the effectiveness of extension services to smallholders has come in for criticism (Jalani *et al.*, 2002). Extension services are fundamental to the success of agricultural development, including advice to farmers and local seed production and distribution. Because they are an end-of-pipeline function, extension services are frequently overlooked by researchers, policy-makers and in government budget allocations. Importantly, the linkages between agriculture researchers, extensionists and producers are quite weak, resulting in the poor uptake of innovations, research that fails to reflect smallholder needs, and the delivery of the wrong type of extension education programmes (FAO, 2001). And yet, without a good extension service the introduction of even the best new crop varieties may be delayed or prevented (World Bank, 2007). Some of the problems with extension services include poor human resources, inadequate operational and transportation support, and inappropriate orientation and methodological approaches. Extension agents also have a particularly difficult and often isolated role that may be hampered by poor or inappropriate training, insufficient technical support, lack of motivational incentives, unrealized expectations of farmers and external pressures from third parties such as private seed merchants or NGO representatives.

A report from 39 African countries indicated that nine of them had no extension services at all, while ten more relied on overseas development agencies (Guei, Somado and Larinde, 2008). Even where extension services exist in a country, they are not always able to respond to new crop introductions. For example, when Bt cotton was introduced to India, there was a complete lack of government provision of such services and farmers relied solely upon private seed companies for knowledge dissemination and advice (Solution Exchange, 2007; Gruère, Mehta-Bhatt and Sengupta, 2008). This is clearly unsatisfactory and in the case of Bt cotton in India it contributed to public scepticism about the technology. Clearly, there is a significant structural problem if so many countries do not oversee the provision of national or local extension services to farmers. The case for a qualitative improvement in the status and local management of extension services as an integral aspect of crop development should be emphasized more strongly to governments and policy-makers. The potential for better designed technologies and better technology uptake via well managed and better linked research-extension-producer networks to lead directly to increased food production is demonstrated by the case of potatoes in China. Following a change in government policy in the 1980s, potato cultivation was encouraged in the country. Advanced breeding materials were obtained from the International Potato Center (CIP) in Peru and developed by the Crop Research Institute in Yunnan Province into locally adapted varieties such as Cooperation 88 which greatly outperformed existing varieties. A combination of vigorous extension services and expanding consumer markets led to an increase in the potato-growing area from 2.45 to 4.7 Mha, and in yields from 9.7 to 16 T/ha between 1982 and 2002 (Reader, 2009). This made China the largest potato producer in the world with output reaching 72 Mt or one quarter of the entire global output by 2007 (FAO, 2009d). Improved seed and extension services able to respond to market demand have been cited as factors in the positive economic impact of sweet potatoes at village level in China (Fuglie *et al.*, 1999).

1.5 CASE STUDIES OF EXPERIENCES WITH CROP BIOTECHNOLOGIES

This Part includes several brief case studies of experiences with biotechnologies in developing country crops. In reality, most of them cannot be labelled as full successes or failures because each case may present positive and negative consequences at the same time. Nevertheless, some experiences have brought improved food security to large numbers of people in developing countries such as the African-Asian rice hybrids (NERICA), rice interspecific hybrids in Asia, and mutation breeding. The study of socio-economic impacts of biotechnological innovations in developing countries is still very patchy or limited and few reports are solid and scientifically sound (FAO, 2009c). In most cases it is therefore impossible to draw clear conclusions. In many instances even the more negative experiences can be most accurately described as temporary halts in progress rather than permanent setbacks.

1.5.1 Wide crossing to improve African rice – NERICA

There is little doubt that one of the outstanding recent success stories of African agriculture is the development of a new interspecific form of rice, NERICA. The original NERICA varieties were developed in the 1990s by a team of breeders at the Africa Rice Center, Côte d'Ivoire (Jones *et al.*, 1997a and 1997b; Jones, 1999a and 1999b). NERICA varieties have led to yield increases of up to 50 percent in upland rice crops. These replaced low-yielding, lodging and shattering-prone *O. glaberrima*. While rice tends to be a cash crop for small-to-medium-scale farmers in East and Southern Africa, it is very much a subsistence crop in West Africa where the majority of African rice is produced.

The NERICA lines were created by crossing *O. glaberrima* and *O. sativa*. As these two species do not naturally interbreed, it was necessary to use a range of advanced tissue culture technologies to enable the hybrid plants to survive. In particular, embryo rescue and anther culture methods ensured that crosses survived to produce plantlets to grow on to full maturity. As with many other hybrids of two relatively inbred lines, NERICA varieties display very good degrees of heterosis. For example, they grow faster, yield more, and/or resist stresses better than either parent. Some features of NERICA varieties include: an increase in grain head size from 75–100 grains to 400 grains per head; yield gains from 1 T/ha to 2.5 T/ha and up to 6–7 T/ha with fertilizer application; 2 percent more protein than their African or Asian parents; plus better pest and weed resistance and more tolerance of drought and infertile soils than Asian rice. During the 1990s, about 3 000 lines were developed, many of which have been released and are already being grown by farmers in West African countries. The high-yielding new rice varieties are drought and pest resistant. Their unique adaptation to the growing conditions in West Africa has helped increase yields and has the potential to benefit 20 million farmers (Sarla and Mallikarjuna Swamy, 2005; Kijima, Sserunkuuma and Otsuka, 2006).

The Africa Rice Center has reported the release of NERICA varieties in 30 African countries, and these are now planted in about 0.2 Mha, mainly in Côte d'Ivoire, Guinea, Nigeria and Uganda. Uptake is likely to expand as more varieties are released. In sub-Saharan Africa, over 100 upland varieties are being field tested by the Africa Rice Center in 30 countries and 60 lowland/irrigated varieties are being field tested in 20 countries (FAO, 2009c). Many NERICA varieties are particularly suitable for use in the rainfed upland agrisystems where smallholders lack the means to irrigate or to apply chemical fertilizers or pesticides (Somado, Guei and Keya, 2008). In addition to benefiting rural economies, NERICA has the potential to assist cash-strapped national economies by reducing the cost of food imports. It has been estimated that the introduction of NERICA in Guinea alone led to import savings of US$13 million in 2003 (Harsch, 2004). An evaluation by Obilana and Okumu (2005) discussed the livelihood impacts of NERICA in Benin, Guinea and Mali and concluded: "NERICA rice impacts the whole spectrum of human life problems in the areas of health, nutrition, education, female empowerment, environmental protection, and improved collaboration and partnerships for enhanced development. The impacts in all the three countries are hence the same although they vary in magnitude". By the 2008 season, NERICA varieties were playing a key role in the record rice harvests being enjoyed across Africa (FAO, 2009e).

1.5.2 Wide crossing to improve Asian rice

In Asian rice, wide crosses have been especially effective in addressing serious viral diseases such as the grassy stunt virus to which cultivated rice has little genetic resistance. The virus is transmitted to the plant by a leaf-dwelling brown planthopper, *Nilaparvata lugens.* By the 1960s and 1970s, grassy stunt virus had become endemic in rice crops throughout Asia and threatened food supplies. During a collecting expedition, scientists from IRRI found a tiny population of a wild rice relative from India, *Oryza nirvara*, resistant to the virus. Normally, it would be impossible to cross these two rather different *Oryza* species, but IRRI breeders used tissue culture to produce a crude wide hybrid of this wild Indian plant and Asian rice. Eventually, after many years of repeatedly backcrossing this hybrid with local rice varieties, three new virus-resistant varieties of Asian rice were released in 1974 to subsistence farmers (Barclay, 2004). Despite repeated searching, the original Indian population of virus-resistant *O. nirvara* was never found again and may well have been lost forever. Luckily, some of the useful *Oryza nirvara* genes have been saved by the IRRI scientists, although these genes are now located in the genomes of the three new varieties of Asian rice, *O. sativa*.

1.5.3 Soil bio-inoculants in Kenya

The importance of extension services and overall infrastructure in biotechnology uptake is highlighted by the case of the rhizobial inoculant Biofix in Kenya. Although Biofix has been marketed since 1981 and its effectiveness was clearly demonstrated in field trials within the country, national adoption rates remain relatively low. Explanations include poor distribution systems, lack of product information, insufficiency of extension services, poor access to credit, unsuitable package size, and other constraints (Odame, 1999). The public image of Biofix may also have been tarnished by reports of mixed performance, possibly due to similar factors to those discussed earlier for *Rhizobia* in Thailand (Part 1.3.3). One of these site-specific factors is the need for simultaneous phosphorus provision for certain soil types. Having been identified, this particular problem is now being addressed by the manufacturers with an improved product that contains rock phosphate to counter phosphorus deficiency. In contrast, the uptake rate of Biofix was much higher among smallholders in the Nyeri district of Kenya. Here, there are organized groups of farmers who have ready access to and clear information about the product (Odame, 2002). One factor in the success of Biofix in Nyeri may be peer group encouragement because successful implementation of the technology by neighbours within a local social network is highly visible. Similar peer group-based strategies, such as farmer clubs or societies based on common access to the crop/technology in question are increasingly being used by extension services.

1.5.4 Mutation-bred crop varieties

Public agencies, including the Joint FAO/IAEA Division and universities have been effective proponents of mutagenesis technology and there are essentially no IPR barriers to its deployment for public good crop breeding. Hence, many mutagenized crop varieties have been produced by and for developing countries. More than 2 700 varieties of mutation-bred crop varieties have been released worldwide, mainly in developing countries (FAO and IAEA, 2008). They include all the major staple species (Ahloowalia, Maluszynski and Nichterlein, 2004) and have been cultivated in at least 59 developing countries, mostly in Asia. The largest mutation breeding programmes are in China and India but dozens of other countries are also using the technology (Maluszynski, Szarejko and Maluszynska, 2003; for review see Kodym and Afza, 2003). Widely used mutagenized crops include: Soghat bread wheat in Pakistan, Zhefu rice in Thailand, Shwewartun rice in Myanmar, and Bajra pearl millet in India. In Vietnam, three new varieties of rice with improved food quality and salt tolerance have been developed since 1996. Since their release in the Mekong Delta region, they have increased smallholder incomes by US$350/farmer/year and include some of the top export varieties (FAO and IAEA, 2008).

1.5.5 Bt cotton in India

Cotton is an important commodity crop in India, growing in most agroclimatic zones and providing a livelihood for more than 60 million people working in agriculture, processing, and textiles. According to averaged production statistics between 1997 and 2006, India was the third largest global producer of cotton, but yields were only ranked 70th among the producing countries. This strikingly low-yield performance was caused by factors such as persistent pest problems and lack of irrigation facilities and by issues inherent in small-scale, non-mechanized and resource-poor farming systems. In an effort to increase cotton yields, the Indian government authorized the introduction of transgenic cotton varieties with the Bt insect-resistant trait in 2002, potentially enabling the crop to withstand pests such as the bollworm as well as reducing pesticide requirements (USDA, 2005). Between 2002 and 2008, India rapidly increased its cotton production to over 9 Mha, becoming a major exporter, and in 2007/08 it passed the United States in output to become the second largest global producer of cotton after China. According to the Indian Cotton Advisory Board, Bt cotton was the major factor behind the increased production of cotton from 15.8 million bales in 2001/02 to 24.4 million bales in 2005/06 (ISAAA, 2006). There has also been a significant increase in cotton yields from 300 kg/ha in 1997 to 400 kg/ha in 2003/04, and more than 500 kg/ha in 2006/07 (Gruère, Mehta-Bhatt and Sengupta, 2008).

The uptake of Bt cotton in India has continued to rise as more varieties, both official and illicit, appear on the market. In July 2007, Indian government agencies approved 73 new commercial varieties of hybrid Bt cotton. At that time, a total of 135 hybrid Bt cotton varieties were available on the market plus numerous unofficial varieties (SABP, 2007). It is noteworthy that despite its undoubted commercial success in most states, Bt cotton in India has been surrounded by controversy since its introduction in 2002 (Gruère, Mehta-Bhatt and Sengupta, 2008). Various groups have contested its effectiveness, reporting that farmers have lost income due to lower yields and higher than expected pesticide use, while some groups reported (albeit not in scientific journals and despite contradictory evidence) alleged toxic effects of Bt cotton on livestock health. Others have objected to the high prices for Bt cottonseed charged by seed companies and this has led to widespread unofficial seed trading. It is also the case that the introduction of Bt cotton in India was mediated by company advisors rather than government extension agents, which leaves room to question the partiality of advice received. This has led to assertions of so-called "agricultural de-skilling" as farmers followed their neighbours as part of a "fad" to buy Bt cottonseed (Stone, 2007). However, as discussed above in case study 1.5.3 from Kenya, the follow-my-neighbour strategy is regularly used by extension services in attempts to disseminate new seed or agronomic methods among farmers.

According to other reports, Bt cotton has also been associated with allegations of increased rates of farmer suicide. Although these reports seem to have been disproved, with Gruère, Mehta-Bhatt and Sengupta (2008) concluding that "our analysis clearly shows that Bt cotton is neither a necessary nor a sufficient condition for the occurrence of farmer suicides", the association between farmer suicide and Bt cotton is still widely believed in many quarters. Indeed, the whole topic of the performance and social context of Bt cotton in India is characterized by polarized viewpoints and a dearth of unequivocally reliable evidence. There appears to have been a tendency for supporters of Bt cotton to overstate its benefits and for its many critics to exaggerate its shortcomings, whereas numerous articles instead report a more complex and mixed situation (Qaim and Zilberman, 2003; Bambawale *et al.*, 2004; Rao, 2004; Morse, Bennett and Ismael, 2005; Shah 2005, 2008; Smale, Zambrano and Cartel, 2006; Smale *et al.*, 2006, 2009; Herring, 2007, 2008; Stone, 2007; Glover, 2009).

For example, there is little doubt that the performance of Bt cotton has varied significantly in different regions of this vast country. Average national cotton yield improvements and farmer revenue gains from the use of Bt varieties were in the region of 30–40 percent, and such values were found in the states of Maharashtra and Tamil Nadu. However, there was a decline of 3 percent in both yield and revenue gains in Andhra Pradesh, while farmers in Karnataka reported increases of 70 percent (Raney, 2006). In some cases, these wide variations were due to climatic effects. For example, the initially negative performance of the varieties in Andhra Pradesh was mainly due to severe drought conditions to which the Bt hybrids were not optimally adapted (Qaim *et al*., 2006). An important indicator that does not necessarily correlate with yield/revenue gains is overall profit margins, where the national average increase was 69 percent, but Tamil Nadu reported 229 percent while Andhra Pradesh suffered a decline of 40 percent. To quote Herring (2007): "Bt cottons have been in the field too short a time for definitive assessment of either biological or economic success across so varied an agro-ecology as India; results vary with seasonal variations of pests, weather and local agronomics".

On balance, the limited available evidence supports Bt cotton as a qualified success in most, but not all, parts of India. In several states, it has been very successful and has greatly increased overall national cotton yields and farmer/processor incomes. Moreover, as of 2008 more than 270 Bt cotton varieties were available in India including lines specifically adapted to all the major cotton-growing regions of the country (James, 2008). On the negative side, it has polarized some sections of Indian society and contributed to a somewhat tarnished image of aspects of GM technology. Also, its high technology fees have led to IPR transgressions that might adversely affect the future development of other commercial crops. The wider negative image of Bt cotton in some circles in India might be associated with the provenance of the technology, i.e. it comes from an overseas private-sector source in contrast to many previous, less controversial, crop improvement biotechnologies that have often come from indigenous public-sector sources (Murphy, 2007a). This contrasts with the less controversial locally developed Bt cotton in China. The situation is less clear in South Africa, where modest yield and profit gains were reported from a two-year survey of smallholders (Thirtle *et al.*, 2003), but a later study showed a more complex picture (Shankar and Thirtle, 2005). More recent studies of Bt and herbicide-tolerant maize performance in the KwaZulu Natal region of South Africa over the 2006/07 growing season also revealed a complex picture (Gouse *et al.*, 2009). Some farmers of the GM varieties had substantially higher yields but both GM technologies had very little impact on efficiency, and it was concluded that the tillage system was a key determinant of efficiency levels. As stated by the authors: "The results mostly serve to show how dangerous it is to make any inferences from small sample surveys in one production season".

1.5.6 Micropropagation of oil palm

A risk with mass clonal propagation by micropropagation is the creation of abnormalities during the tissue culture process itself. In the 1980s, a commercial scheme to mass propagate millions of oil palm plantlets from superior breeding lines in Malaysia foundered when the maturing trees were found to have a serious abnormality in their floral development (Corley, 2000). This so-called "mantling" phenotype led to a failure of fruit formation and the trees were effectively useless (Corley and Tinker, 2003). In the case of oil palm, the problem was compounded by the fact that fruits do not normally appear on the plant for about five years. This meant that the abnormalities were not discovered until the trees were already established in mature plantations that had been expensively maintained for several years. At the time, this was a significant setback for Malaysian oil palm development and the desired increases in production were only maintained by an expansion of plantation area. Varietal development and yield gains were also impeded by the slower rates of alternative propagation methods.

More recently, prospects for mass clonal propagation of oil palm have improved significantly. Several private and public sector research programmes have investigated the causes of the mantling phenotype which appears to be due to genotype-dependent epigenetic changes induced by altered patterns of DNA methylation that occur during tissue culture (Tanurdzic *et al.*, 2008). Thanks to this improved understanding of tissue culture/epigenetic interactions, clonal propagation of oil palm has now resumed in some plantations (Wong, Tan and Soh, 1997). Flowering abnormalities still occur, but can often be detected and removed at an early stage leading to much higher success rates in the production of fertile trees. While this technology was primarily developed for commercial plantations, over one third of oil palm yield is generated by smallholders (Vermeulen and Goad, 2006). Globally, there are more than two million independent smallholders cultivating 5 Mha who also stand to benefit directly from such improved clonal lines. The Malaysian example illustrates some of the problems that can arise from tissue culture when manipulations used for plant regeneration cause developmental abnormalities. Despite these setbacks, tissue culture and mass propagation remain immensely valuable for agriculture in developing countries. It should also be stressed that apart from micropropagation, oil palm breeding is showing impressive gains via other biotechnologies. For instance, novel germplasm from Africa and South America is being integrated into Asian breeding lines with the assistance of gene discoveries showing monogenic inheritance for shell thickness, while advanced genomic and MAS methods are now being deployed to address the full range of agronomic traits (Sambanthamurthi *et al.*, 2009).

1.5.7 Biopesticides for control of migratory locusts

Several different biopesticides are available for controlling locusts. Among them, the most tested both in laboratory and in semi-field conditions and used for large-scale field trials (mainly in Africa) as well as in operational conditions (in Australia and China), is a mycopesticide formulated with the spores of the fungus *Metarhizium anisopliae* var. *acridum*. As biopesticides have a slower rate of action compared with conventional chemicals, they are usually sprayed if crops are not under immediate threat or when the environment is particularly sensitive.

For many years FAO has supported environmentally friendly alternatives to chemical pesticides for controlling locusts and has contributed to several field trials. In 2007, the first FAO locust campaign ever carried out using a biopesticide was successfully undertaken in

Timor-Leste (FAO, 2009f). A migratory locust outbreak which had developed since the beginning of the year was threatening maize and rice crops in a huge, inaccessible (only a few roads and no airstrip) and highly sensitive (many water bodies and rivers) area. Upon the recommendation of FAO, the Ministry of Agriculture, Forestry and Fisheries (MAFP) of Timor-Leste agreed to use the biopesticide formulated with the spores of *Metarhizium anisopliae* var. *acridum* (trade name Green Guard®) in aerial and ground spraying operations. Under the framework of an emergency project funded by the Central Emergency Response Fund and implemented by FAO, the *Metarhizium* biopesticide was provided by FAO for aerial spraying operations in May 2007 against in-flight swarms of the migratory locust in the western part of Timor-Leste. They were supplemented in June by localized ground spraying operations against smaller infestations.

The operations were successful and resulted in the quick control of the outbreak, with no further spread of the locust populations (the locust adults were killed before egg laying) and no damage to the rice crops. There were no side-effects on human health or on the very sensitive environment of the Maliana area. It is also important to note that MAFP and FAO carried out a public awareness campaign prior to the aerial spraying operations, providing information about the locust situation and the use of a helicopter and a biopesticide to control the locust populations. More recently, in 2009, similar biopesticides were deployed as part of an international red locust emergency campaign in Eastern and Southern Africa. This was the first time that biopesticides were used against locusts on a large scale in Africa and a massive outbreak in Tanzania was successfully contained. This intervention is estimated to have averted potentially serious damage to the food crops of over 15 million people in the region (FAO, 2009g).

1.5.8 Hybrid sorghum in Africa

Sorghum is one of the most important crops in Africa where two of the main challenges it faces are periodic drought and competition from the often devastating plant parasite Striga or witchweed. Research at the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) in the Sudan resulted in the first hybrid varieties of sorghum for Africa that were both drought tolerant and high yielding. An early variety, Hageen Dura-1, produced 50–100 percent greater yield than traditional varieties and laid the foundations of a commercial seed industry in Sudan. Newer drought tolerant hybrid varieties in Niger have yielded 4–5 times the national average. In an unusual example of South-to-North technology transfer, African breeder Gabisa Ejeta used germplasm he had produced in the Niger and the Sudan to develop elite inbred lines of sorghum at Purdue University to generate commercial sorghum hybrids for the United States and international markets.

However, perhaps the most important sorghum hybrids were the Striga tolerant forms developed in the 1990s and widely disseminated in Africa after 2002–2003. It is estimated that Striga affects 40 percent of arable savannah land and the livelihoods of over 100 million people in Africa (Gressel *et al*., 2004). Ejeta and colleagues used a broad-based research approach involving molecular genetics, biochemistry and agronomy to identify genes for Striga resistance which were then introgressed into both locally adapted and more modern sorghum varieties (Ejeta, 2007). The new sorghum lines were thus broadly adapted to different African ecologies and farming systems and are now grown from Sudan to Zimbabwe. Finally, an integrated Striga management system was developed that has further increased sorghum productivity through a combination of weed resistance, soil fertility enhancement, and water conservation (Ejeta and Gressel, 2007). Meanwhile future research is focusing on identifying other yield-related genes such as early-season cold tolerance (Knoll, Gunaratna and Ejeta, 2008; Knoll and Ejeta, 2008). In 2009, the World Food Prize was awarded to Gabisa Ejeta in recognition of his achievements in improving the prospects of African sorghum farmers (World Food Prize, 2009).

1.6 CONCLUSIONS: LESSONS LEARNED

The preceding parts of this document have provided an overview of the current and past experiences of applying biotechnologies in the crop sector in developing countries. Based on these, a number of lessons can be learned that are summarized below.

Documentation of development, adoption and impact

Assessing the value of biotechnologies for rural development is quite difficult as the information related to their application and socio-economic impact in developing countries is very scant and sometimes inconsistent. Impact studies are often limited to the analysis of the production equation, and fail to pay due attention to the socio-economic effects of the newly introduced technologies.

Investments in biotechnology R&D

- Crop biotechnologies in general have developed incrementally over the past century although progress has accelerated greatly over the last two decades.
- Many crop biotechnologies have been used for the benefit of agriculture in developing countries and all have significant potential for future improvement.
- The most enduring successes to date have come from long-term public-sector crop improvement programmes addressing farmer-relevant problems.
- Farmers in developing countries, especially small farmers, cultivate crops and face problems that are particular to their cultural and environmental conditions and often have limited purchasing power to access proprietary technologies. The spillover from

private sector research in industrialized countries has therefore had limited impact on the livelihoods of subsistence farmers in developing countries.

- An analysis of the past shows that a wide range of existing and emerging problems related to food security can be tackled using crop biotechnologies in combination with other technologies.

Linkages between biotechnology and other agricultural R&D

- The major breeding and crop management successes to date have come from non-transgenic biotechnologies encompassing the full range of agronomic traits and practices relevant to farmers in developing countries.
- Transgenesis has had limited but real success in modifying a few simple input traits in a small number of commercial commodity crops which have also been adopted by some farmers in developing countries.
- Biotechnology programmes were effective when they complemented conventional plant breeding and agronomy R&D programmes and were intimately linked to strong extension programmes.

Policy development and priority-setting

- Even where there was strong development of biotechnologies within the public sector in developing countries, these were not always directed towards or made available to smallholders.
- An inclusive process of decision-making about appropriate crop biotechnologies in the context of scarce resource allocations was rarely adopted in developing countries, undermining the successful development of crop biotechnologies.

Capacity development

Key factors in the successful development of crop biotechnologies in developing countries are: appropriate policy development; strengthened research and extension institutions; and enhanced capacities of researchers and breeders.

Regulation of biotechnology use

- The rollout of biotechnologies was successful when complemented by the full range of cross-sectoral measures to ensure their efficient uptake by smallholders and effective downstream use in well-regulated and fair markets, both local and global.
- The lack of coherent national and international regulatory systems has created uncertainty and possibly reduced investments in biotechnology. This, in turn, has discouraged its adoption and use in developing countries.

Uptake of biotechnologies

- Experience has demonstrated that the uptake of improved varieties or technologies by smallholder farmers does not depend on their performance only, but also on equitable access, adequate infrastructures, appropriate extension capacities and the involvement of all relevant stakeholders.
- There are indications that farmer participatory research, including participatory plant breeding, is a useful approach for connecting high-tech scientists with the most disadvantaged subsistence farmers in developing countries.

Shared access to technologies

- Many resources, technologies and skills relevant for biotechnology development are either currently held by the private sector or are scarcely available to scientists in developing countries.
- A few developing countries have established solid plant biotechnology programmes sustained by substantial investments and have achieved remarkable progress in biotechnology development and adoption.

B. LOOKING FORWARD: PREPARING FOR THE FUTURE

1.7 KEY UNSOLVED PROBLEMS WHERE BIOTECHNOLOGIES CAN HELP

One of the major concerns for the future is the potential impact of climate change on agriculture. Changing temperatures and precipitation patterns will clearly affect the range of crops that can be grown in different regions and their manner of cultivation. In some cases, existing crops might continue to be grown but new varieties would be needed to cope with the changed conditions. Examples might include heat, cold, salt, or drought tolerant varieties of existing crop staples. In other cases, alternative crops may need to be grown or entirely new species domesticated in order to adapt to changed environmental conditions. The occurrence and severity of biotic stresses such as weeds, pests, and diseases will be altered. Once again, breeders will need to develop new stress tolerant varieties, possibly at relatively short notice. Related problems might arise from human impacts, and in some cases these will have similar solutions to those caused by climate change. For example, the lack of water in a region could be due to either drought or diversion by other people, and increased soil salinity could be caused either by climate-related inundation by seawater or by inappropriate irrigation practices.

In this Section, two principal topics are addressed: first, to identify a range of potentially problematic issues that will be important in the future and, second, to examine the role that different kinds of biotechnologies might play in dealing with them. Perhaps equally important is the availability of such biotechnologies and the local capacity for their development and/or exploitation in a particular country or region.

1.7.1 Biotic stresses

Existing diseases, pests and weeds

Historically, breeders have been successful in selecting resistance traits in many of the major crops but such achievements can be offset by the sporadic nature of some important disease and pest threats and the eventual breakdown of resistance, especially during heavy infestations. Many effective chemical treatments and agronomic practices are available to help farmers control fungi and nematodes, but there are no equivalent virus-control agents. The production of virus-free plantlets is effective for avoiding secondary infections (infections transmitted to the next generation crop by the planting materials), but is totally inefficient against primary infections. Therefore, combating viral diseases normally relies on endogenous resistance within the plant itself. In the absence of resistance, viral infections can be particularly devastating to a crop. This has stimulated efforts to engineer viral resistance into transgenic crops. The commercial cultivation of transgenic squash and papaya varieties with virus-resistance genes has already been approved in some tropical regions of developed countries and may soon be extended to some developing countries. In the medium term, the use of transgenesis and MAS to produce virus resistance in crops is a highly promising area, and is one case where this approach may well be the best option for combating this class of crop diseases.

As discussed previously, there are several effective biological strategies to replace or complement the chemical control of bacterial, fungal and nematode pathogens. Examples include IPM and biocontrol, and these approaches will benefit from new advances in biotechnology. In many developing countries, and indeed elsewhere, there are increasing financial, safety, and environmental advantages to such strategies especially given the widespread need for increased sustainability in agricultural practices. Another future option that could carry a similar range of benefits is the development of endogenous resistance to pests and pathogens through genetic modification (Gressel *et al*., 2004) or conventional breeding, possibly assisted by molecular genetics. Technically speaking, and although several promising approaches have been demonstrated, this has been much more problematic to address than viral or insect resistance where single-gene resistance traits are more common. The broader question of engineering plants with increased disease resistance, regarding both what genes to use and how to ensure that they are expressed in the right place at the right time, has been examined by Gurr and Rushton (2005a, 2005b). The severe agronomic impact of pathogens and the limitations of chemical control have stimulated a wide variety of approaches to engineering resistance in crops. For example, in China, the *Xa21* bacterial blight resistance gene has been transferred to five rice varieties (Zhai *et al*., 2000). In India, molecular MAS was successfully used in a backcross breeding programme to introgress three genes (*Xa21*, *xa13*, and *xa5*) for bacterial blight resistance into a local susceptible rice variety (Sundaram *et al.*, 2009). Antifungal agents such as phytoalexins and chitinases have also been expressed in plants (Shah, Rommens and Beachy, 1995). However, in developing fungal resistance within crops it is difficult to produce broad-spectrum durable resistance without transferring huge numbers of genes. In fact, fungi often evolve spontaneously in the field, overcoming the resistance. It is possible that in the longer term, additional transgenic crops resistant to bacterial, fungal and nematode pathogens will be developed but, at present, non-transgenic approaches may often be the more pragmatic option.

As far as resistance to pest insects is concerned, current approaches focus on genes conferring antibiosis or properties that adversely affect insect physiology. This type of resistance may become futile in the long run because insects can develop mechanisms to overcome the resistance. Another possible drawback of antibiosis-based pest resistance is that it can affect target and non-target organisms, damaging the crop-associated diversity. A promising research area is the development of pest resistance based on antixenosis, or plant properties that deter or prevent pest colonization by interfering with their behaviour (van Emden, 2002). Although generally under multigenic control and thus more difficult to manipulate genetically, antixenosis mechanisms are more specific and more environmentally benign. Antixenosis genes have been recently identified and mapped in several plant species, for instance in wheat (Castro *et al*., 2005), but the pathway to practical applications seems quite long.

Newly emerging threats

New crop pests and diseases are constantly emerging and with global transportation and trade can spread rapidly across the world. Some biotechnologies can be used both in surveillance and in breeding programmes to detect and then combat such threats. For example, one of the most serious crop diseases to emerge in recent years is a highly virulent strain of the wheat black stem rust, *Puccinia graminis* (Ayliffe, Singh and Lagudah, 2008; FAO, 2008b). Termed Ug99, the rust first emerged in Uganda in 1998–99, spread around East Africa in the early 2000s, and has now been detected in the Arabian Peninsula and Iran, with a high likelihood of further spread to major wheat growing areas of the Indian subcontinent (Hodson, Singh and Dixon, 2005). This disease has already overcome most of the rust resistance genes bred into wheat over the past 50 years since the early days of the Green Revolution. The US Department of Agriculture's Agricultural Research Service (USDA-ARS) has recently reported the presence of a new variant of the pathogen in Kenya (Comis, 2007). Over one billion people live in potentially affected areas and almost 120 MT of annual wheat production is threatened. The serious threats to food security posed by Ug99 and other emerging crop pathogens will only be satisfactorily addressed by an international effort using all available methodologies. In the case of Ug99, the threat is now being tackled by the Borlaug Global Rust Initiative, a multinational programme whose members include CIMMYT, the International Center for Agricultural Research in the Dry Areas (ICARDA), the Gates Foundation, FAO and USDA-ARS (Kaplan, 2009).

Two key areas where biotechnologies can quickly contribute to combating newly emerging threats are surveillance/detection and breeding for resistance. It has been alleged that the initial detection of the Ug99 outbreak was delayed due to a (perhaps understandable) reduction in the disease monitoring work by CIMMYT after a period of 40 years without rust outbreaks (Stokstad, 2007). In the future, improved molecular kits such as microarray-based systems might enable surveillance to be carried out more cost effectively and extensively, possibly by larger teams of non-experts supervised by smaller numbers of experts. By their nature, new threats are unknown, but the more the relationships between crops and pests/disease organisms in general are understood, the better are the prospects to mount rapid and effective responses. Rapid identification of new pathogens and especially their genome sequences will facilitate the development of control strategies based on previous experience with related disease organisms. Such measures have already been of immense benefit in the case of new human and animal pathogens such as the coronavirus that causes severe acute respiratory syndrome and the virulent influenza A-type viruses. For example, within days of the April 2009 outbreak of influenza A (H1N1) in Mexico, the entire genome sequence of the virus was publicly available online (NIH, 2009).

1.7.2 Abiotic stresses

Abiotic stresses are a particular concern in regions such as the Middle East and parts of Africa where climate change and increasing soil salinization are threatening crop yields in more than 170 Mha of farmland (Ashraf, Ozturk and Athar, 2009). Drought and salinization are already significant threats to agricultural productivity and among the most common causes of sporadic famine in arid and semi-arid regions. Extended episodes of aridity, normally caused by changes in rainfall patterns, were associated with the collapse of numerous civilizations around the world during the past 8 000 years (Murphy, 2007c). The increasing scarcity of water resources and fertile soils is likely to cause human conflicts at local and international levels that will exacerbate food shortages in the affected regions still further. Although abiotic stress is often regarded as a primarily external (i.e. environmental) factor in crop performance, there is also a great deal of untapped genetic variation in responses to such stresses in all the major crop groups (Boyer, 1982; Ribaut and Betrán, 1999; Forster *et al.*, 2000; Ribaut *et al.*, 2000; Harris, 2005; Bänziger *et al.*, 2006). In particular, genetic diversity within crop groups whether in the form of wild relatives or conserved landraces or other genetic resources can be a powerful source of useful variation for abiotic stress tolerance (Singh, Ocampo and Robertson, 1998; Almekinders and Struik, 2000; Langridge, Paltridge and Fincher, 2006). Biotechnology can play a major role here, by enabling the exploration of large germplasm collections without expensive testing against adverse environmental conditions. For example, an international effort to identify genetic loci associated with drought tolerance has recently started under the auspices of the Generation Challenge Programme.

Another potential component of abiotic stress tolerance in crops that has been much neglected by researchers and breeders is the rhizosphere, the soil region around the plant roots. While the structural and inorganic components of the rhizosphere have been well studied, very little work has been done on biological communities such as rhizosphere flora (FAO, 2008c), which can both promote plant growth and reduce the impact of stresses such as drought (Figueiredo *et al.*, 2008), salinity (Zhang *et al.*, 2008), and poor soil nutrition (Shaharoona *et al.*, 2008). While this approach is still in its infancy and has yet to be applied in developing countries directly, it carries the promise of addressing stress tolerance in the context of lower input nutrient management systems that would be highly relevant to such regions (Adesemoye, Torbert and Kloepper, 2008; Yang, Kloepper and Ryu, 2009).

It has been claimed that there is significant potential for transgenesis in modifying stress related traits (Wang, Vinocur and Altman, 2003). However, as researchers in the field have pointed out, our limited knowledge of stress associated metabolism in plants still constitutes a major handicap to effect such manipulations in practice (Vinocur and Altman, 2005). Another problem that farmers and breeders have long been aware of is the synergistic effect of different stresses on crop performance. It is often the combination of such stresses that is so deleterious to the crop in the field, rather than the effect of a single category of stress. However, molecular biologists have tended to focus (for understandable reasons) on single stresses applied in highly controlled environments. Unfortunately for this piecemeal approach, recent studies have shown that the simultaneous application of several stresses gives rise to unique responses that cannot be predicted by extrapolating from effects of stresses given individually (Mittler, 2005). The simultaneous presence of multiple stresses is the norm in open environments, so the success of molecular approaches in addressing them in crops will probably require broader and more holistic approaches than the somewhat reductive strategies employed until now.

Salinity

Salt and nutrient stresses together affect over 100 Mha of farmland, resulting in low outputs, poor human nutrition and reduced educational and employment opportunities (Ashraf, Ozturk and Athar, 2009). Salt tolerance was one of the earliest traits selected by breeders in intensive farming systems. Indeed, in ancient Mesopotamia about 4 200 years ago, Sumerian farm managers switched from emmer wheat to intensive cultivation of more salt tolerant forms of barley in an effort to combat increasing salinization and aridity (Murphy, 2007c). Efforts to select salt tolerant crop varieties, while partially successful, have been hampered by the complexity of the trait and the number of minor genes involved. One problem facing breeders is that crop improvement is often negated by a lack of effective germplasm evaluation during the full growth cycle of the plant (Munns, 2002, 2005; Munns and Tester, 2008). It can also be difficult to ascertain which mechanism of salt adaptation is being expressed in a particular species or developmental stage. Ashraf *et al.* (2008) have listed the following reasons for limited success in tackling salt tolerance: 1) breeding is time consuming and labour intensive, 2) deleterious genes are often transferred alongside desirable traits, and 3) reproductive barriers obstruct the transfer of favourable alleles from wide crosses. In the future, breeding technologies such as MAS and assisted wide crosses will enable breeders to address these challenges with more success than previously. A concerted R&D focus on breeding for salinity traits should be a priority during the next decade.

Salt tolerance has been a particular focus of claims for significant results from transgenic approaches. One of the key prerequisites for success in a transgenic strategy to develop salt tolerance is that it should be regulated as a simple genetic trait, i.e. one involving a very small number of genes. Although such apparently simple genetic regulation has been reported in some laboratory studies (Yamaguchi-Shinozaki and Shinozaki, 2001), it seems more likely that salt tolerance in most crops in the field is a rather complex multigene trait that has evolved differently in several plant groups (Flowers, 2004; Rozema and Flowers, 2008). However, there have been some promising successes in developing salt tolerance in model plants in the laboratory. For example, transgenic tobacco engineered to accumulate elevated levels of mannitol was able to withstand high salinity (Tarczynski, Jensen and Bonhert, 1992). Laboratory and small-scale field studies have shown that the accumulation of compounds, such as betaine or trehalose in transgenic plants may also enhance salt tolerance (Nuccio *et al.*, 1999). Rapeseed plants expressing an *Arabidopsis* vacuolar transport protein tolerated as much as 250 mM sodium chloride (about half the concentration of sea water and enough to kill most crops) without significant impact on seed yield or composition (Zhang *et al.*, 2001). A project to conserve mangrove genetic resources in India is studying and characterizing the genes involved in salinity tolerance from these plants and their associated species which are capable of surviving in highly saline environments. The genes thus isolated were transferred to crops such as rice and initial laboratory analyses have been promising (FAO, 2006b).

Despite these encouraging reports, it is not clear whether such relatively simple modifications will lead to a sustained effect on crop yields in more complex real world cropping systems where osmotic stress is often linked with a combination of other factors such as periodic aridity, mineral/salt buildup and/or erosion. This means that the jury is still very much out on the amenability of salt tolerance in the field to modification by transgenesis (Yamaguchi and Blumwald, 2005). It is known that salt tolerance must be an especially complex physiological trait because there are so many tolerance mechanisms in salt adapted plants in the wild. This should lead to some caution about claims in published studies that the transfer of one or a few genes can increase the tolerance of a wide range of field crops to saline conditions. As stated by Flowers (2004): "It is surprising that, in spite of the complexity of salt tolerance, there are commonly claims in the literature that the transfer of a single or a few genes can increase the tolerance of plants to saline conditions.... After ten years of research using transgenic plants to alter salt tolerance, the value of this approach has yet to be established in the field".

The way forward here is to investigate as many realistic strategies as possible. Nevertheless, given the present state of knowledge it is probably more appropriate to focus limited breeding resources on non-transgenic approaches while supporting research into the physiology and molecular genetics of salt tolerance for potential future application.

Drought tolerance

Like salt tolerance, drought tolerance appears to be controlled by a complex set of traits that may have evolved on numerous occasions as separate mechanisms in different plants and according to the dynamics (i.e. timing and intensity) of water shortages. In the near future, it is likely that aridity will increase in several parts of the world with FAO estimating that by 2025, 1.8 billion people will be living in regions of water scarcity (FAO, 2009h). This will be caused by factors such as localized lower rainfall due to climate change and the diversion of upstream water supplies from rivers, e.g. for dams or irrigation, thus depriving farmers in downstream regions. In the case of rice alone, over 70 Mha are already affected by drought stress (Ashraf, Ozturk and Athar, 2009). Given the predicted increase in long-term aridity, it is surprising that until relatively recently there have been few well resourced attempts to produce drought tolerant crops, even by publicly funded organizations. Such research is complicated by the sporadic nature and hugely varying intensity of drought or aridity episodes in the affected cropping systems. This also highlights the importance of the concept of genotype x environment x management, which is a crucial but highly complex multifactorial relationship that affects all efforts to select for drought tolerance and other abiotic stress traits. An integrated approach taking into consideration several aspects is therefore advisable (FAO, 2008c).

Meanwhile, basic research using reverse genetics and other genomic approaches is beginning to give a few clues about some aspects of drought tolerance mechanisms. For example, it was recently reported that the *erecta* gene, involved in transpiration efficiency, might regulate some of the genetic variation for drought tolerance in the model plant, *Arabidopsis* (Masle, Gilmore and Farquhar, 2005). Although the data are still very preliminary in this case and do not directly relate to major crop systems, the general approach merits further attention. However, as with salt tolerance it may turn out that in a practical field situation many other genes are involved in addition to *erecta* or its equivalents in other plant families.

As with salinity, advanced non-transgenic breeding methods are available to improve the agronomic performance of existing drought tolerant crops in arid regions. Of such crops, one of the most important is pearl millet which is grown on more than 40 Mha in Africa. The similarity in gene order, or synteny, between the pearl millet genome and that of the other major cereals (Moore *et al.*, 1995; Bolot *et al.*, 2009) means that once their loci are identified, drought tolerance traits could potentially be introduced into local varieties via MAS. Another option is to use wide crossing and tissue culture methods to cross millet with one of the other high yielding cereal crop species to create a new drought tolerant, high yielding hybrid species. Breeders have already used such a strategy to create the drought adapted rye/wheat hybrid, triticale, which is a completely new man-made plant species. Further breeding of triticale is now underway to extend its agronomic performance and drought tolerance especially in arid regions (FAO, 2005b). A combination of breeding approaches by ICRISAT and national organizations has generated significant varietal improvements for pearl millet and sorghum. For example, in southern Africa these new varieties occupy 34 percent of the millet area and 23 percent of the sorghum area (CGIAR, 2005). In some cases, farmer participation has been a key element in varietal improvement. One example is the early maturing millets that can enable dryland communities to get through the "hungry season" just prior to the main harvest when the previous year's grain has already been exhausted. Here, Namibian farmers selected a variety that matured 4–6 weeks earlier than traditional millets. Within a few years, the new variety covered half the millet area of Namibia. From an initial R&D investment of US$3 million, a sustainable annual return of US$1.5 million in yield benefits has been achieved (CGIAR, 2005).

At present, the major transgenic work on drought tolerance is being done in the private sector. In some cases, genes are being transferred from other species but companies are reportedly using multipronged approaches involving both conventional breeding and biotechnology. The resulting varieties are likely to carry very specific trait combinations such as enhanced root growth for maize grown under high input conditions (Castiglioni *et al.*, 2008; Edgerton, 2009). These approaches may well highlight possible future breeding strategies or target traits in developing country staples but may not be directly applicable to some of the less intensively managed crops. Also, such approaches are not always realistic in the less well funded context of public sector, public good orientated crop improvement, especially in developing countries. One exception here might be the PPP between Monsanto, the African Agricultural Technology Foundation and CIMMYT, which includes funding from the Gates Foundation and is aimed at developing drought tolerant maize varieties in Africa (Water Efficient Maize for Africa). Other approaches to drought tolerant maize development at CIMMYT are focusing on using genomics and MAS to identify and introgress drought related traits in existing germplasm.

1.7.3 Yield

Maximizing crop yield is probably the most desired aim of any farmer. By increasing yield per ha, more people can be fed from the same area of land. Higher yields also mean that less land is required for crop production, relieving pressure to develop pristine and often environmentally sensitive habitats such as rain forests or species-rich wetlands. It is a telling fact that the great majority of increased crop production over human history has occurred due to the expansion of arable cultivation rather than increased yield per ha. For example, prior to the introduction of scientific breeding techniques in the early twentieth century, grain yields across the world rarely exceeded 2 T/ha, even in the most favourable environments (Ruttan, 1999). The application of Mendelian genetics was an important step forward in realizing yield gains, but some of the most spectacular progress came from new hybrid technologies especially as applied to maize. Following the almost universal adoption of hybrid varieties, US maize yields increased from 1.8 T/ha in the 1920s to 7.8 T/ha in the 1990s (Murphy, 2007c). It has been estimated that at least 60 percent of the increase in maize yields was attributable to advances in breeding with the remaining 40 percent resulting from improved crop management including more effective inputs and mechanization (Duvick, 1997).

These relatively recent biologically-attributable yield gains in commercial grain crops should stimulate greater investment aimed at applying a combination of modern breeding and management technologies to the broad range of developing country crops where yields still remain well below their physiological limits. As noted by Ruttan (1999): "In most developing countries, yields are still so far below existing biological ceilings that substantial gains can be realized from a strategy emphasizing traditional crop breeding combined with higher levels of technical inputs, better soil and crop management, and first generation biotechnology crop protection technology".

Yield traits are increasingly becoming priority targets in developing countries as breeders improve their understanding of the genetics of indigenous crops, and hence their capacity to manipulate these often complex characters. Yield gains of major temperate crops have levelled off in recent years and genetic modification has so far made a limited contribution to the increase in intrinsic yields and to the yield capacity of plants in standard conditions (Gurian-Sherman, 2009). In contrast, the capacity for dramatic yield improvements of many developing countries' crops, especially "orphan" crops, remains largely unrealized (Qaim and Zilberman, 2003). Semi-dwarf cereals were the basis of the Green Revolution of the 1960s and 1970s. However, the identification of these key traits involved the selection of serendipitous variants with little understanding of the developmental processes underlying the traits. Thanks to emerging knowledge of plant development and genomics it is now becoming increasingly feasible to consider the rational redesign of crops (Sinclair, Purcell and Sneller, 2004). For example, gibberellins are important regulators of plant height and hence mutations or gene deletions that either reduce the activity of known gibberellin biosynthetic enzymes or compromise signal transduction pathways involving gibberellins can be confidently predicted to result in the kind of dwarf phenotype seen in modern cereals (Hedden and Kamiya, 1997; Sasaki *et al.*, 2002).

The new understanding of the genetic basis of domestication syndrome traits in many crops, coupled with detailed genomic sequence data and genome synteny in major plant groups, will allow breeders to move key traits between crops or to domesticate new species (Motamayor and Lanaud, 2002; Murphy, 2007c; Weeden, 2007; Burger, Chapman and Burke, 2008; Sang, 2009).

There is a great deal of basic research in industrialized countries of possible relevance to future yield improvements, although robust mechanisms for the application of such research are often lacking, especially in developing countries. Two basic approaches to yield improvements of particular promise are the manipulation of seed development and the manipulation of plant architecture. Crop yields can be increased by developing larger seeds or by manipulating seeds to accumulate more of the desired edible products (e.g. starch or oil) and less of the unwanted products.

Alternatively, plant architecture can be manipulated to maximize yield-bearing structures such as seeds and fruits, and reduce non-productive structures such as excessive branching, thick seed coats, or tall, slender stems. In principle, plant architecture could be redesigned to give higher yielding wheat-like maize plants or dwarf banana, oil palm, or coconut palm trees (Lev-Yadun, Abbo and Doebley, 2002). In order to exploit likely developments in these and other areas of basic plant science for practical crop improvement it will be crucial for research capacities to be built up further in developing countries, and for greater use to be made of molecular markers especially among public sector crop researchers in industrialized countries.

1.7.4 Nutritional quality

Quality traits such as increased nutritional content have been selected by farmers for over ten millennia (Murphy, 2007c). In principle, varieties can be selected/engineered to produce edible parts that contain specified amounts of macronutrients (starch, protein, and oil) and/or micronutrients (vitamins and minerals). The type of starch, protein, or oil in seeds and fruits can also be modified to some extent by both transgenic and non-transgenic methods (Korth, 2008; Newell-McGloughlin, 2008; Slater, Scott and Fowler, 2008). However, more precise manipulations may be possible in the future to produce so-called "designer crops" (Murphy, 2002). For example, there are several cases where the amount or potential nutritional value of seed or tuber protein has been improved by transgenesis although no new crop varieties have yet been commercially released (Chakraborty, Chakraborty and Datta, 2000; Lee *et al.*, 2003; Wang *et al.*, 2003; Popelka, Terryn and Higgins, 2004).

The manipulation of fatty acid composition of oil crops can add to their nutritional and commercial value, and transgenic approaches are extending the range of fatty acids in future crops to include long-chain omega-3 polyunsaturates that cannot normally be synthesized by higher plants (Murphy, 2006). Many, but not all, of these manipulations will involve transgenesis and most of them lie in the medium-to-long-term future rather than being immediate practical options for developing country crop improvement.

Biofortification

Almost all global crop staples are nutritionally deficient in some respect (Murphy, 2007c). This means that when populations are forced to rely on a narrow range of food crops they can suffer from varying degrees of malnutrition, with young children invariably faring the worst. While an ideal solution to this problem is to reduce poverty, hence enabling farmers to purchase a wider range of foods, another approach is to improve the nutritional value of existing subsistence crops. The examples below illustrate some of the methods that are beginning to be used by breeders to increase levels of key nutrients such as vitamins and minerals, in a strategy known as biofortification (Nestel *et al.*, 2006; Gilani and Nasim, 2007; Hirschi, 2008; Mayer, Pfeiffer and Beyer, 2008; Stomph, Jiang and Struik, 2009). Several vitamin-enhanced fruit varieties for Asia and Africa, including a high-carotene tomato for adaptation to semi-arid areas of West Africa are being developed (AVRDC, 2009).

The HarvestPlus consortium focuses on the three dietary micronutrients recognized by the World Health Organization (WHO) as particularly limiting in many subsistence populations in developing countries, namely iron, zinc and vitamin A. HarvestPlus has breeding programmes utilizing all available biotechnologies including MAS and genomics for six of the most important staple food crops, i.e. rice, wheat, maize, cassava, sweet potato and common beans (Cakmak, Graham and Welch, 2004). In addition to enhancing micronutrient levels in selected crops, its objectives are to assess the bioavailability of micronutrients in foods actually consumed by the population to facilitate farmer uptake of the varieties and measure their long-term nutritional impacts (HarvestPlus, 2007). The Vitamin A for Africa (VITAA) programme is focused on vitamin A in the sweet potato (CIP-VITAA, 2008).

Sweet potato is the fifth most important global crop on a fresh weight basis and is especially important in Africa. Traditional white varieties have little vitamin A and over 3 million children in the region suffer from vitamin A-related blindness. Vitamin A deficiency is also a leading cause of early childhood death and a major risk factor for pregnant women. New orange-fleshed varieties with high vitamin A levels obtained through conventional plant breeding schemes could potentially replace white sweet potato varieties that had previously been favoured by farmers throughout Africa (Low, Walker and Hijmans, 2001; Tumwegamire *et al.*, 2004). One future challenge is to provide enough planting material (normally as bundles of vine cuttings) to meet the high levels of farmer demand. Micropropagation can assist in this respect. Other targets are to improve post-harvest handling and food-preparation methods at community level to ensure retention of beta-carotene (provitamin-A) levels, and to assess the impact of orange-fleshed sweet potatoes on the health status of HIV/AIDS-affected communities.

The best known transgenic approach to biofortification is "golden rice", developed in the 1990s by a Swiss/German public-sector group (Ye *et al.*, 2000). This rice variety has yellow rather than white grains due to the accumulation of beta-carotene, which is normally absent from polished rice grains. More recently, an improved version of golden rice has been developed with a reported 23-fold increase in provitamin-A levels (Paine *et al.*, 2005). The development of laboratory versions of golden rice was just the start of a lengthy process of backcrossing into local varieties and field tests that has already lasted a decade. In 2005–07, the original golden rice trait was crossed into the popular IR64 variety at IRRI, and outdoor field trials of 20 potential breeding lines started in 2008. Field trials of the improved golden rice variety show five times more provitamin-A than the original lines (IRRI, 2008). A further challenge will be to ensure that newly expressed provitamin-A can withstand processing, storage, and cooking, while remaining bioavailable after consumption.

1.7.5 Narrow genetic basis of crop production

Since the beginning of agriculture, more than 7 000 species of plants have been cultivated or collected. Many remain important to local communities where exploiting their potential is crucial to achieving food security, but nowadays it is estimated that only 30 crops provide 95 percent of human food energy needs and just four of them – rice, wheat, maize and potatoes – provide more than 60 percent. The domestication of new crops by advanced breeding methods is an exciting prospect for broadening the genetic base of crop production and extending the potential of agriculture to provide food and other materials in the climatically uncertain times that lie ahead. Recent advances in genomics and the manipulation of complex traits have clear applications in the domestication of new crops (Varshney, Graner and Sorrells, 2005; Varshney and Tuberosa, 2007b). Emerging understanding of the genetic basis of domestication traits will aid their manipulation via advanced methods such as MAS (Murphy, 2007c). This will accelerate breeding programmes aimed at improving agronomic performance and enable the faster and more reliable multiplication of seeds or plantlets for dissemination to growers. For example, Bioversity International has recommended that partially domesticated or undomesticated tropical fruits are used as alternative sources of vitamins.

In a recent survey of southeast Asian fruits, ten candidate species with high vitamin A levels were found, including durians (*Durio* spp.), milk apple (*Syzygium malaccense*), rose apple (*S. jambos*), and button mangosteen (*Garcinia prainiana*) (Khoo *et al.*, 2008). Some of these fruits could be grown as cash crops. Their further improvement, and that of other newly domesticated plants with great potential in developing countries, would be greatly facilitated by biotechnologies such as MAS (Murphy, 2007a). From records of indigenous cultures, at least 1 650 tropical forest species are potential horticultural crops. Many of these plants are already adapted to areas unsuitable for existing crops and could therefore extend local food-producing capacity without interfering with existing crops.

1.7.6 Sustainable and environmentally friendly crop production

Intensive agriculture using primarily human and animal inputs has been practised in various regions of the world for well over four millennia. Examples include irrigated barley/wheat production in ancient Mesopotamia, paddy rice in East Asia, and the milpa system in the Americas (Murphy, 2007c). Over the past century, however, the availability of cheap energy and raw materials has facilitated a massive expansion of intensive farming across the globe that does not depend on biological inputs. In particular, the introduction of inorganic fertilizers and new crop varieties bred for efficient fertilizer response have been the cornerstone of the Green Revolution which largely alleviated the crisis in food security in developing countries during the 1960s and 1970s (Murphy, 2007a). During the past century, intensive arable farming has spread globally as more and more land has been brought into cultivation. It is now generally agreed that humankind is approaching limits both in the amount of land available for future agricultural expansion and in the sustainability of intensive, high input, fossil fuel dependent farming systems. But there remains a fundamental tension between understandable concerns for the long-term sustainability of crop production with the lowest feasible environmental footprint and the undoubted requirement for higher yields to feed expanding and increasingly urbanized populations, especially with the added uncertainties of climate change and a possible consequent reduction in usable arable land. This complex and interrelated set of challenges can be addressed, at least in part, by biotechnologies in combination with other approaches.

In the recent past, environmental and sustainability concerns about cropping systems have frequently been the drivers for technology-based solutions. Examples already discussed include IPM or biocontrol to replace pesticide inputs, and biofertilizers or legume intercropping to replace inorganic nitrogen inputs. Such methods are widely used in developing countries but there remains great scope for their refinement and extension to a wider range of crop types.

The replacement of inorganic inputs by biological agents can have multiple benefits such as reduced energy use, enhanced environmental credentials (e.g. the reduction or elimination of input residues), lower costs and improved safety for farmers who would no longer need to purchase or handle so many chemical inputs. The use of advanced breeding technologies to create significant yield gains, especially if these can be achieved without greatly increasing inputs, has clear environmental implications because it reduces pressure to bring more land into cultivation. Clearly, many of these developments remain aspirational at present but the fact remains that biotechnologies can play a greater role in enhancing the sustainability and mitigating the environmental impact of farming. One emerging area that will become increasingly important in the future is that of agro-ecological system dynamics as applied to breeding strategies and technological interventions. This area relates especially to the implications of climate change and the manner in which adaptation, uncertainty, vulnerability and resilience are viewed. A useful critical discussion of this area with a commentary on biotechnology-based strategies is provided by Thompson and Scoones (2009).

Decisions about introducing more sustainable and/or environmentally friendly crop production methods have sometimes thrown up both threats and opportunities that can be addressed via biotechnology. For example, the voluntary implementation in Malaysia of a no-burn policy when replacing ageing oil palm trees led to an increase in infestation rates by the virulent fungal pathogen, *Ganoderma boninense*, which causes basal stem rot (Bridge *et al.*, 2000).

Public sector researchers in Malaysia and Indonesia responded by developing new molecular technologies for the early detection of this problematic disease and innovative microbial agents for its effective treatment (Flood, Bridge and Holderness, 2000; Soepena, Purba and Pawirosukarto, 2000; Panchal and Bridge, 2005; Bréton *et al.*, 2006; Paterson, 2007; Sundram *et al.*, 2008).

1.7.7 Conclusions

- There is a wide range of existing and emerging problems related to food security that can be tackled by crop biotechnologies in combination with other technologies.
- Key areas include pest/disease control, salt/drought tolerance, crop yield/quality, and the sustainability and environmental impact of crop production.
- The knowledge gained from basic plant research will underpin future crop improvements but effective and robust mechanisms for the rapid and effective translation of research discoveries into public good agriculture remain to be developed.
- Maximum benefit will be derived if robust plant breeding and crop management programmes have ready access to all the modern crop biotechnologies, both transgenic and non-transgenic, to address food security issues. This will require additional investments in capacity building for R&D in developing countries.
- Technology implementation alone is not sufficient to address such complex questions as food security. Biotechnologies will make new options available but their uptake and effective exploitation will rely on an intricate web of cross-sectoral factors.

1.8 IDENTIFYING OPTIONS FOR DEVELOPING COUNTRIES

Based on the overview and previous analyses contained in this Chapter, a number of specific options can be identified to assist developing countries make informed decisions regarding the adoption of biotechnologies in the future, such as when and if they should employ one or more crop biotechnologies and, if they decide to use them, how to ensure the successful application of the chosen biotechnologies to enhance food security in the future. The options identified are grouped under the same eight headings as the lessons learned from the past (Part 1.6).

Documentation of development, adoption and impact

Developing countries should undertake national-level documentation and analysis of the adoption and socio-economic impacts of biotechnological innovations for crops to advise policy-makers on the cost/benefit implications of biotechnology applications. This includes the collection of data, studies, etc.

Investments in biotechnology R&D

- Developing countries, possibly working in regional groups, should build up indigenous research, development, and advisory capacities for the generation, assessment and adoption of appropriate biotechnologies.
- Adequate, consistent, stable investments should be ensured from indigenous resources to public sector biotechnology R&D.

Linkages between biotechnology and other agricultural R&D

- Investments in biotechnology R&D cannot be made at the expense of current spending in other research fields.
- Biotechnological research should be linked more effectively to strong and well resourced R&D programmes on crop breeding.

Policy development and priority-setting

- Countries should develop expertise to ensure they can make sovereign decisions about adopting biotechnologies and carry out their own independent, broad- based risk/benefit analyses.
- Countries should prioritize research activities to address the greatest food security needs, with special reference to the needs of smallholders.
- Countries should ensure the appropriate involvement of relevant stakeholders in decision-making processes.

- Decisions on crop biotechnology tools to address the problems of smallholders should reflect the appropriateness and socio-economic impacts of the tools.
- Independent public sector organizations should engage and communicate more effectively with society at large about the role of all crop improvement/management biotechnologies for food security.

Capacity development

Countries should develop the biotechnology capacities of national agricultural research systems in their three dimensions (policy development, institutional set-up and human capacities).

Regulation of biotechnology use

- All countries should be encouraged to establish consistent and transparent, evidence-based decision-making processes to regulate crop biotechnology R&D and its application.
- Biotechnology-related regulations should be developed in harmony with other national regulations, especially those relating to plant and animal health and food safety. For this purpose, the adoption of the biosecurity[1] approach is strongly encouraged.
- While it is essential that decisions on adopting biotechnologies are ultimately based on verifiable scientific evidence, public participation should, where appropriate, form part of the decision-making process.
- Developing countries can often act more effectively in regional groups when engaging with international trade and conventions.

Uptake of biotechnologies

- Biotechnology development strategies should be strongly linked with strategies for its widespread dissemination.
- Stronger extension services, with expertise in modern agronomy and linked with participatory crop improvement programmes, should be an integral part of national/regional agricultural support structures.
- Seed production and distribution systems should be enhanced.

Shared access to technologies

- Effective and equitable mechanisms for PPP should be established where appropriate.
- Developing countries should consider, where appropriate, sharing technologies, skills and knowledge with each other by means of South-South collaboration platforms or mechanisms.

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[1] A cross-sectoral national approach to the management of biological risks associated with food and agriculture, including plant and animal health, food safety and biosafety of GMOs.

1.9 IDENTIFYING PRIORITIES FOR ACTION FOR THE INTERNATIONAL COMMUNITY

The international community, including FAO and other UN organizations as well as NGOs, donors and development agencies, can play a key role in supporting developing countries by providing a framework for international cooperation and funding support for the generation, adaptation and adoption of appropriate biotechnologies. Below is a set of Priorities for Action that will assist the international community in playing this role, grouped under the same eight main headings as parts 1.6 and 1.8.

Documentation of development, adoption and impact

International agencies should systematically collect and systematize documentation on development and adoption of crop biotechnologies and analyze their socio-economic impacts in developing countries. This includes compiling statistics, establishing and maintaining biotechnology application databases, studies, etc

Investments in biotechnology R&D

Donors and international funding agencies are encouraged to dedicate an appropriate share of their assistance projects to promoting and strengthening public biotechnology R&D in developing countries.

Linkages between biotechnology and other agricultural R&D

- Technical assistance in biotechnology R&D cannot be done to the detriment of present spending in other research fields.
- Technical assistance in biotechnology R&D should always support effective and intimate links to strong plant breeding, agronomic research and extension programmes.

Policy development and priority-setting

- The international community should assist developing countries in strengthening capacities for biotechnology policy development and long-term planning.
- The international community should assist developing countries to enhance the capacities of national agricultural research systems to involve relevant stakeholders in decision-making processes.
- International organizations should inform more effectively society at large about the role that biotechnologies for crop improvement/management have in food security.
- International R&D organizations should develop innovative approaches for the appropriate inclusion of the public in decision-making processes in developing countries.

Capacity development

The international community should help developing countries enhance the biotechnology capacities of national agricultural research systems in their three dimensions (policy development, institutional set-up and human capacities).

Regulation of biotechnology use

- The international community should continue its efforts to assist developing countries in establishing robust national regulatory frameworks in areas such as biosafety, food safety, plant health protection, the protection of intellectual property and the protection of traditional knowledge.
- The international community should promote the adoption of the biosecurity approach to assist in the framing of holistic and integrated biotechnology regulation.
- The international community should assist developing countries in enhancing their institutional capacities for regulatory development and enforcement.
- Regulatory procedures should be regionally and/or internationally harmonized to facilitate international trade and scientific collaboration. When requested, FAO and other international agencies should continue to offer a meeting place for governments to discuss common governance measures.

Uptake of biotechnologies

- Biotechnology knowledge and expertise should be included in extension, educational and advisory services to facilitate uptake by farmers and the spread of reliable public knowledge about crop biotechnologies.
- Development agencies should assist developing countries in enhancing seed production systems to facilitate farmers' utilization of the fruits of crop biotechnologies.

Shared access to technologies

The international community should facilitate effective mechanisms for South-South collaboration including:

- the training of scientists and technicians;
- joint research projects (pooling complementary resources to work on projects of common interest);
- the sharing of technologies, techniques, protocols and materials;
- the sharing of information relevant for biotechnology development and adoption;
- assistance in the establishment of mechanisms for the dissemination to developing countries of biotechnologies developed in industrialized countries (North-South collaboration, PPPs).

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CHAPTER 2

CURRENT STATUS AND OPTIONS FOR FOREST BIOTECHNOLOGIES IN DEVELOPING COUNTRIES

SUMMARY

The forestry sector differs from the crop or livestock sectors in a number of important ways. First, forest trees are highly heterozygous long-lived perennials with late sexual maturity and a lengthy regeneration cycle which places high priority on retaining genetic diversity as an insurance policy against rapid change. Second, most forest tree species have narrow regional adaptation so the numbers of species used for planting are much higher than for food crops. Third, forest trees serve as keystone species in dynamic ecosystems so managing against loss translates into more than tree survival. Fourth, forest trees are largely undomesticated although a few species have had some population-level improvement for one to four generations.

For management of naturally regenerated forests, DNA-based and biochemical markers are available for a growing number of tropical species. Today, findings are available to guide operational forest management plans including in developing countries, but only for a very limited number of the hundreds of tree species that are managed in naturally regenerated tropical forests. This area of forest biotechnology continues to expand, moving from tools development into more hypothesis-driven knowledge acquisition. Such research inquiry is a powerful source of pertinent knowledge for protecting tropical forests. This research is also moving from molecular markers into genomics. Biotechnology tools such as molecular markers and the field of genomics are therefore providing important knowledge about naturally regenerated tropical forests and important insights into the nature of the entire tropical forest ecosystems including the relationship between forest trees and the microbial communities with which they interact, which can influence the strategies employed for managing tropical forests.

For planted forests, although there is some overlap the range of biotechnologies used is generally quite different from that used for naturally regenerated forests. Plantations can have different types of management systems (e.g. intensive, semi-intensive) and use different types of genetic material (e.g. wild material, genetically improved trees). Depending on the level of management intensity and the genetic material used in the planted forest, different groups of biotechnologies can be used. For simplicity, three different groups of biotechnologies can be identified according to the type of planted forests, ranging from the least sophisticated to the most advanced.

A first group of biotechnologies is suitable for the least intensively managed planted forests, and includes a range of vegetative propagation methods (including micropropagation based on tissue culture), biofertilizers and genetic fingerprinting using molecular markers. It could also be complemented by conventional technologies, such as early-stage tree improvement programmes.

A second group of biotechnologies can be used for planted forests that provide industrial raw materials on a large planting scale. The single species used for plantations may be indigenous or exotic, but these plantations are intensively managed. This group of biotechnologies includes somatic embryogenesis (a tissue culture technique), molecular markers and quantitative trait locus (QTL) analyses, whole genome sequencing and functional genomics. A third and most sophisticated group of biotechnologies includes backward and reverse genomics approaches, whole-genome sequencing, low-cost vegetative propagation and genetic modification of forest trees. To date, the only report of commercial plantings with genetically modified (GM) trees is for poplar on 300 to 500 ha in China. However, most tree species used in planted forests have been successfully modified at the experimental level, and traits that have been the subject of extensive research include stem shape, herbicide resistance, flowering characteristics, lignin content, insect and fungal resistance.

Many developing countries currently have biosafety regulations for agricultural crops, including fruit-trees, although many others lack such frameworks and the capacity to implement them. There are no regulations, however, specific to the use of GM forest trees. Although policies and regulations adopted for agricultural crops are also likely to be used for forest trees, they present special challenges (long time frames and life spans, wild resource, major constituents of an ecosystem). Forests are not only trees, and forest ecosystems are more fragile, longer-lived and less closely controlled than crop fields. Decision-making is complicated by the fact that while agriculture is primarily viewed as a production system, forests are generally viewed as a natural system, important not only for the conservation of biodiversity but also for social and cultural values. Thus, the use of GM forest trees is viewed more as a political and environmental issue than as a technical or trade issue.

2.1 INTRODUCTION

In recent decades, forest biotechnology has grown into a dynamic portfolio of tools, moving beyond research into global trade and development. This portfolio concept is consistent with the *sensu lato* definition of biotechnology put forth in Article 2 of the UN Convention on Biological Diversity (CBD) "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use." This is the definition used in this and the other FAO background documents prepared for ABDC-10. The following is a brief description of the state of the world's forests and some factors shaping forestry and forest biotechnology.

2.1.1 Forest and tree resources management - state of the world's forests

Forests and other wooded areas perform key economic and ecological functions. Not only do they provide goods and livelihoods but they also protect soils, regulate water and absorb carbon. Forests also shelter much of the world's biodiversity. FAO's most recent review on the overall status of forest resources, the Global Forest Resources Assessment (FAO, 2006), indicate that the world has just under 4 billion hectares (ha) of forests, covering about 30 percent of the world's land area. It also reveals that production of wood and non-wood forest products is the primary function for 34 percent of the world's forests and that more than half of all forests are used for wood and non-wood production in combination with other functions such as soil and water protection, biodiversity conservation and recreation.

Only 5 percent of forests in the world are in plantations, with the balance found in natural or semi-natural, largely unmanaged and undomesticated forest stands. Planted forests are expanding and their contribution to global wood production is approaching 50 percent of the total. In 2004, the production of industrial roundwood was 1.6 billion cubic meters, representing some 45 percent of the global wood production, and forest products trade reached a total value of US$327 billion. More than half the wood biomass consumed globally – and well over 80 percent in developing countries – is burned as fuel. About 1.6 billion people rely heavily on forest resources for their livelihoods (World Bank, 2001). Sixty million indigenous people living in the rain forests of Latin America, Southeast Asia and West Africa depend heavily on forests; 350 million people living in, or next to, dense forests rely on them for subsistence or income; and 1.2 billion people in developing countries use trees on farms to generate food and cash. Forest and tree resources are managed in different main types of systems, which are presented in Table 1. The intensity of management varies very much between primary natural forests and productive industrial plantations.

FAO (2006) indicates that the world's forested area is shrinking, particularly at tropical latitudes (Table 2). Only a few countries have seen a net increase in forested land area, and these include China, Vietnam, Cuba, Uruguay, Chile, United States and most of Europe, west and east. Forested land area is not increasing in tropical regions where biodiversity and growth rates per ha (not shown) are highest. This table points to a few of the factors shaping forest biotechnology opportunities.

TABLE 1

CHARACTERISTICS OF MAIN TYPES OF FOREST AND TREE RESOURCES MANAGEMENT

Naturally regenerated forests		Planted forests				Trees outside forests
Primary	Modified natural	Semi-natural		Plantations		
		Assisted natural regeneration	Planted component	Productive	Protective	
Forests of native species, where there are no clearly visible indications of human activities and the ecological processes are not significantly disturbed	Forests of naturally regenerated native species where there are clearly visible indications of human activities	Silvicultural practices by intensive management: • weeding by intensive • fertilizing • thinning • selective logging	Forests of native species, established through planting or seeding intensively managed	Forests of introduced and/or native species, established through planting or seeding mainly for production of wood or non-wood goods	Forests of introduced and/or native species, established through planting or seeding mainly for provision of services	Stands smaller than 0.5 ha; tree cover in agricultural land (agroforestry systems, home gardens, orchards); trees in urban environments; and scattered along roads and in landscapes

TABLE 2

FORESTED AREAS AND ANNUAL RATES OF CHANGE FOR THE WORLD'S FORESTED LAND COVER BY REGION

Forest area	Land area (1 000 ha)	Land area (percent)	Annual change 2000-2005 (percent)	Forested countries with highest net increase
Africa	635 412	21.4	-0.62	Rwanda, Egypt
Asia and Pacific	734 243	25.8	+0.09	China, Vietnam, New Zealand
Europe	1 001 394	44.3	+0.07	Bulgaria, Spain
Latin America and Caribbean	859 925	47.3	-0.51	Uruguay, Chile, Cuba
North America	677 464	32.7	-0.01	United States
West and Central Asia	43 588	4.0	+0.03	Uzbekistan
World	3 952 025	30.3	-0.18	

Source: FAO (2006)

Rapid loss of forested areas is coming from changes in land use. In addition to deforestation, existing forests are being degraded by pathogens and pests, fire, atmospheric pollution, extreme weather events, climate change and unsustainable forest management practices.

2.1.2 Factors shaping forests, forestry and forest biotechnology

The following factors shape global opportunities, condition investment decisions and drive research priorities for forest biotechnologies. They also point to important differences in the use of biotechnologies compared with the crop or livestock sectors.

- Forest trees are highly heterozygous, long-lived perennials with late sexual maturity and a lengthy regeneration cycle which places high priority on retaining genetic diversity as an insurance policy against rapid change (Namkoong, Barnes and Burley, 1980).
- Most forest tree species have narrow, regional adaptation, so species numbers used for planting are orders of magnitude higher than those for food crops (Pautasso, 2009).
- Forest trees serve as keystone species in dynamic ecosystems, so managing against loss translates into more than tree survival (Whitham *et al*., 2006). Survival for colonizing forest tree species often depends on the presence of specific symbiont microbial species (Bonfante and Anca, 2009).
- Forest trees are largely undomesticated although a few species have had some population-level improvement for one to four generations.
- Most of the world's forests have public ownership (Agrawal, Chattre and Hardin, 2008).
- A forest tree is utilized for multiple purposes, not a single product. A single log can be used for sawtimber, paper and pulp. Waste products from papermaking are sold in secondary markets. Pulping waste is a rich source of industrial solvents, livestock feed, lubricants and consumer products such as artificial vanillin and medication.

Against this context, the purpose of this Chapter is to review the state of biotechnology and its impact on forest activities. It addresses this first by looking at the past and then by looking forward. In looking at the past, Part 2.2 provides an overview of the history and status of application of conventional technologies in forestry with special attention to developing countries. Part 2.3 documents the current status of application of forest biotechnologies in developing countries. Part 2.4 provides an analysis of successes and failures of forest biotechnologies in developing countries, while Part 2.5 presents a small number of case studies. In looking forward, Part 2.6 addresses key issues in the sector where forest biotechnologies could be useful, Part 2.7 identifies options for developing countries and Part 2.8 presents priorities for action for the international community.

A. STOCKTAKING: LEARNING FROM THE PAST

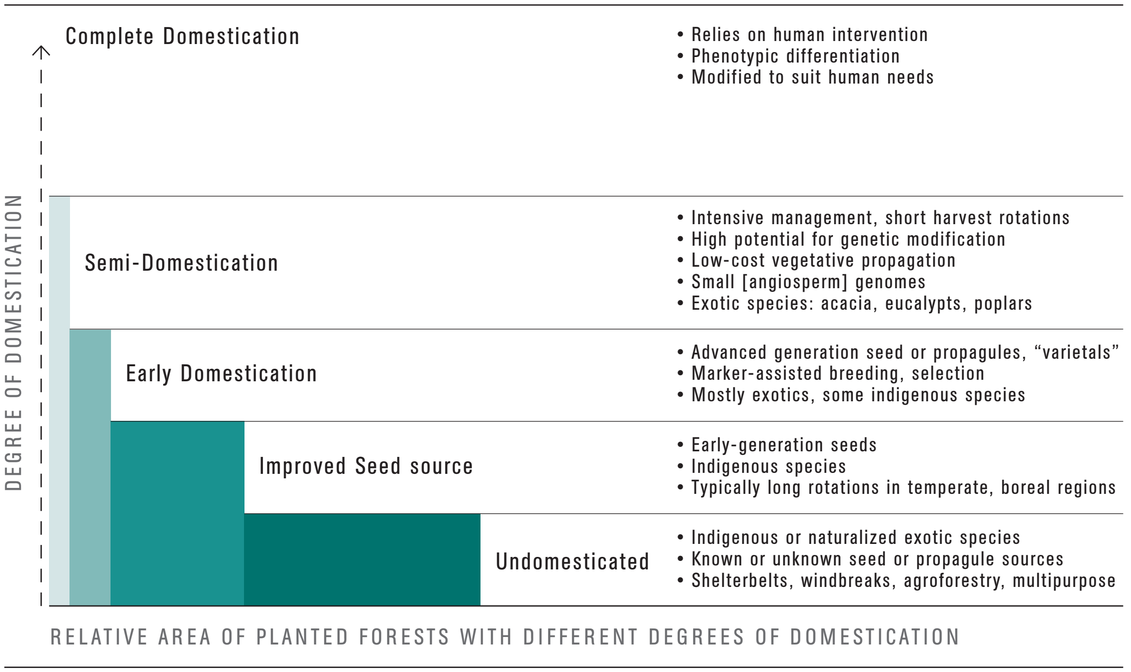
2.2 OVERVIEW OF CONVENTIONAL TECHNOLOGIES IN DEVELOPING COUNTRIES

Oddly, planted forests are not domesticated forests. To explain this, consider the definition of domestication put forth by Allard (1960): "Domestication is the bringing of a wild species under the management of humans". Another definition of domestication is when a plant or animal is modified for human use to the point where it relies solely on human intervention for its survival. Under either definition, even the most intensively managed forests are only semi-domesticated (Figure 1). This is seen as an opportunity by many authors, who advocate using advanced biotechnologies to accelerate domestication for the benefit of wood production (Robinson, 1999; Campbell *et al*., 2003; Boerjan, 2005; Tuskan, 2007).

In any case, forest biotechnology applications have historically been developed for the benefit of planted forests. But today forests are still planted from undomesticated reproductive material, as explained below. Planted forests compose 5 percent of the world's forested areas and a few forest tree species are in the early stages of domestication (Nelson and Johnsen, 2008) but even so, they are semi-domesticated at best (Figure 1). Forest biotechnology applications are specific to each type of forest.

FIGURE 1

TYPES OF PLANTED FORESTS SORTED BY DEGREE OF DOMESTICATION



A brief overview follows of some main applications of conventional technologies in the forestry sector in developing countries.

Forest tree improvement

Forest tree improvement spread as a concept in the twentieth century, well after the advent of quantitative genetics and World War II. The primary goal was to identify and select wild seed sources suitable for planted forests. Few recurrent breeding programmes developed from this. Breeding cycles were lengthy, in part because population level improvement was essential. Forest tree improvement proceeds along a separate trajectory from agriculture.

Namkoong, Barnes and Burley (1980) wrote on their opening page: "Tree breeding is now an accepted activity in approximately half of the countries of the world…the breeding strategy has stopped at the first generation concepts of selection, progeny tests and clonal or seedling seed orchards". Three decades later, this still holds true. The decision to settle for a known seed or propagule source can be traced to shortfalls in the long-range stability, funding and continuity of efforts required to sustain any forest planting programme: political instability, policy shifts, timber surplus, land sales, warfare, famine, drought, extreme weather events, lost manufacturing capacity and shift in global markets. Rarely has the decision to halt a tree improvement programme rested on the choice of forest tree species, but shortfalls here include forest disease and pest outbreaks, poor wood quality and even a surfeit of seed production.

Tree improvement for indigenous species gained momentum after World War II, mostly in Europe, Canada, Australia, New Zealand and the United States when reliable and well-adapted seed sources were needed for massive planting programmes. The next step, making selections in natural stands that served as seed parents, was viewed as a radical practice that contrasted with natural regeneration, dysgenic logging and the occasional haphazard seed collection. These early programmes were government-led.

A few tree-improvement programmes matured into recurrent forest tree breeding programmes. Given large land and financial requirements, these became enduring public-private partnerships among governments, universities and timber companies. Vegetative propagation was used only in the early years, provided that the species could be propagated easily at a low cost. Whether seedlings or cuttings, the idea of a known/tested source of germplasm rapidly spread to Southern Hemisphere countries such as Argentina, Brazil, Chile, China, Colombia, the Congo, India, Malawi, South Africa and Zimbabwe, where introduced and indigenous forest species alike grew much faster than in the Northern Hemisphere. Notable among these were some of the world's most successful exotic species today: *Pinus radiata*, *Eucalyptus* spp. and *Acacia* spp.

Southern Hemisphere tree improvement was founded on naturalized introductions, imported exotic species and a few indigenous species. Its link to markets and manufacturing grew with global trade. Multinational timber corporations could grow timber more cheaply in some Southern Hemisphere countries and this spurred closer connections between forest research initiatives in developed and developing countries. Planted forests and tree improvement programmes have reaped considerable benefits from globalization.

Recurrent tree breeding

Recurrent tree breeding refers here to the application of Mendelian genetics principles within a given silvicultural system for the purpose of improving the genetic quality of the forest. Its goal is to improve the genetic value of the population while maintaining genetic diversity. This advanced generation or recurrent breeding programme refers to population level improvement, not to the development of breeds or inbred lines. Few of the many forest tree species planted today have been subjected to even a single generation of population level improvement. This is a subtle but important point when comparing advances in forest biotechnology with advances in crop or livestock biotechnology. Forest tree breeders weigh the importance of genetic gain against the importance of sufficient genetic diversity, the avoidance of inbreeding depression and long-term uncertainty.

As such, the breeding programme requires highly skilled experts, considerable investment funds and continuity of effort, because it continuously provides the best individuals for planting with each new breeding-testing-selecting cycle (Balocchi, 1997; White and Carson, 2004). Selections are placed in a production population which can be a small indoor or outdoor orchard. For some programmes only a few seeds are needed for multiplying via vegetative propagation. Either seed or propagules may be sold or planted as "varietals" although each is highly heterozygous. To date, forest tree breeding programmes do not develop inbred lines or hybrid crosses as is the case with crop breeding.

In any breeding programme, the selection goal needs to be well defined. One important trait to consider in breeding programmes, be they conventional or biotechnology-based, is wood formation (Plomion *et al*., 2000; Plomion, Pionneau and Baillères, 2003), which drives profit margin through age of harvest and product recovery.

For conifers, annual rings within a single tree generate differences in market value, and so much attention has centred on how to alter this aspect of wood formation. For example, the early corewood rings for *Pinus* spp. are less valued than the outer rings owing to their different warping and pulping qualities. Annual rings laid down at older ages compose so-called mature wood. Finding the genetic controls for wood quality at early and later stages of development is a critical step for conifer plantations because higher quality wood in the early rings would lower the age of harvest or the "rotation age". The rotation age is the earliest age in the tree's lifespan at which harvest becomes profitable. Most forest trees can live decades or even centuries beyond the rotation age.

Even in the most intensively managed forest tree programmes, tree improvement has not followed the same path as the crop sector. Genetic gain is carefully balanced against genetic diversity. Unlike their crop counterparts, forest tree breeders attach great importance to maintaining genetic diversity for population level improvement. Genetic diversity is seen as an insurance policy against catastrophic loss beyond a single generation. Forest tree breeding programmes, so integral to molecular applications of forest biotechnology, work on long timelines as a biological necessity.

This biological imperative to balance genetic gain against genetic diversity has not only given rise to forest tree programmes that do not resemble those for crops or livestock, but also to novel solutions. One common approach in tree improvement programmes is to safeguard genetic diversity (Tanaka, Tsumura and Nakamura, 1999; FAO, 2001). Grafted archives are often established at multiple locations. Unlike agricultural crops, these are needed because there are no repositories to insure against the loss of indigenous forest tree species. The payoff for these backup collections often comes when these archives provide germplasm for disease resistance, catastrophic weather events or a change in market demands. Another and more cost-efficient method has been the multiple population breeding strategy which uses divergent selection and multiple populations for a 2-for-1 programme conserving genetic diversity at the same time as making genetic gain (Eriksson, Namkoong and Roberds, 1995; Williams, Hamrick and Lewis, 1995). In this respect too, the forest biotechnology portfolio follows a separate path from crops and livestock.

2.3 CURRENT STATUS OF APPLICATION OF FOREST BIOTECHNOLOGIES IN DEVELOPING COUNTRIES

Forest biotechnology can contribute to improving productivity and reducing vulnerability of forest ecosystems to disease, degradation and human disturbance. The challenge continues to be to ensure sufficient genetic gains while maintaining genetic diversity at the ecosystem and landscape levels. To date, forest biotechnology has provided knowledge on how to mitigate the effects of forest fragmentation on genetic diversity, and on how to promote gene flow by managing tropical forest ecosystems for pollination, seed dispersal and soil symbionts.

An overview now follows of applications of biotechnologies in naturally regenerated tropical forests and in planted forests. Some of the biotechnologies overlap, although the forest systems differ considerably.

2.3.1 Naturally regenerated tropical forests

Today, most molecular marker systems are DNA-based systems such as microsatellites (Brondani *et al*., 1998; Yazdani *et al*., 2003) or amplified fragment length polymorphisms (AFLPs) (Cervera *et al*., 2000), although biochemical markers such as isozymes continue to provide important insights into tropical forest ecosystems (e.g. Brown and Moran, 1981; Hamrick, 2004). Molecular markers have been used for decades and are extensively reviewed in FAO (2007).

Molecular marker methods are available for a growing number of tropical hardwood species such as *Aucoumea klaineana*, *Bagassa guianensis, Entandrophragma cylindicum*, *Hopea odorata*, *Hymenea courbaril, Dryobalanops aromatica*, *Neobalanocarpus heimeii*, *Koompasia malaccense* and the endangered *Shorea lumutensi* (Born *et al*., 2006, 2008; Garcia *et al*., 2004; Hamrick and Murawski, 1990; Lacerda, Kanashiro and Sebbenn, 2008; Lee *et al*., 2000, 2002, 2003, 2004a, 2004b, 2006; Lee and Krishnapillay, 2004; Lim *et al*., 2002; Naito *et al*., 2005; Ng, Lee and Koh, 2004; Ng *et al*., 2006; Sebbenn *et al.,* 2008; Silva *et al*., 2008). Today, findings are available to guide operational forest management plans in developing countries, but only for a very limited number of the hundreds of tree species that are managed in naturally regenerated tropical forests. This area of forest biotechnology continues to expand, moving from tools development into more hypothesis-driven knowledge acquisition (Table 3). Such research inquiry is a powerful source of pertinent knowledge for protecting tropical forests.

TABLE 3

HYPOTHESIS-DRIVEN MOLECULAR MARKER APPLICATIONS FOR INDIGENOUS TROPICAL FORESTS WHICH ARE NATURALLY REGENERATED

Topics	Region, biota or taxa	Reference
Life history and potential for resilience to climate change	Tropical forests	Hamrick, 2004
Phenology	Neotropics	Clark, 2004
Silvicultural diversity	Tropical forests	Finkeldey and Ziehe, 2004
Selective logging	*Shorea megistophylla*	Murawski, Dayanandan and Bawa, 1994
Organellar DNA diversity	*Cedrela odorata*	Cavers, Navarro and Lowe, 2003
Forest fragmentation	Many tree species	Nason and Hamrick, 1997; Young and Clarke, 2000
Genetic bottlenecks	*Pinus maximartinezii*	Ledig *et al.*, 1999
Reproductive biology	*Dunalia arborescens*	Cruz, 1981
Fitness by life cycle stage	*Platypodium elegans*	Hufford and Hamrick, 2003
Outcrossing rates	*Cordia alliodora*	Boshier *et al.*, 1995
Genetics of invasiveness	*Pinus* spp.	Richardson and Petit, 2006

The hypotheses were tested using DNA-based forest biotechnology tools in combination with other information sources such as meteorology, ecology and/or taxonomy

TABLE 4

EXAMPLES OF USE OF GENOMIC DATA IN FORESTRY

Research areas	Region, biota or taxa	Reference
Phylogeny, phylogeography, nuclear DNA diversity	Agroforestry *Leucaena* spp.	Hughes, Eastwood and Bailey, 2006
Speciation and the study of mechanisms which generate biodiversity	Neotropical forest genus *Inga*	Richardson *et al.*, 2001
Rapid species identification via DNA barcoding	Worldwide	CBOL Plant Working Group, 2009
DNA-based Phylogeny Tree of Life Project	Worldwide	Burleigh and Matthews, 2004

This research community is also moving from molecular markers into genomics. Genomics refers to sequencing DNA either from the nuclear genome or from plastid and mitochondrial organelles. Unlike other areas of forest biotechnology, genomics data are often found in the public domain, usually internet databases (see review in Dean, 2006) and this affords the opportunity for DNA-based computational biology research. This availability of DNA sequencing data brings a distinct advantage to worldwide research on tropical forests.

To date, genomics data are yielding new insights into comparative biology for tropical forests (Table 4). Perhaps the application of most immediate use is an international plant barcoding project under the Consortium for the Barcode of Life (CBOL) to identify genes that can be used to distinguish between plant species[1].

More recent applications from DNA sequencing are emerging for the study of naturally regenerated tropical forests. This emerging use of genomics has been applied to several areas of inquiry, including phylogeny, which refers to comparing two or more DNA sequences from related forest trees with their near relatives to infer past divergence and speciation events. DNA sequences can be assumed to diverge in a steady-state, linear manner such that they serve as a molecular clock (Table 3). A closely related area of inquiry is phylogeography, which refers to using DNA-based sequence data to infer the history and formation of one or more taxa (Table 4).

Genomics has yet to provide its full benefit: it is a growth area for the forest biotechnology portfolio. DNA sequencing can encompass well-characterized genes, entire chromosomes or even entire genomes. Not only are related taxa being compared but interrelationships among components of entire forest ecosystems can be studied. Taxonomy, complemented by phylogeny, has now given way to phylogeography and phylogenomics, where functional genes are compared across taxa (Eisen and Fraser, 2003; Burleigh and Matthews, 2004). DNA sequence data are available for comparative analyses via Internet databases (Table 5).

1 http://barcoding.si.edu/plant_working_group.html

Biotechnology tools such as molecular markers and genomics can therefore provide important knowledge about naturally regenerated tropical forests and important insights into the nature of the entire tropical forest ecosystems, including the relationship between the forest trees and the microbial communities with which they interact, which can influence the strategies employed for managing tropical forests.

Mycorrhizae are symbiotic associations that form between the roots of plant species and fungi. The hyphae (thread-like structures that are part of the body of the fungi) spread through the soil, taking up nutrients such as phosphorus and absorbing water, and transporting them to the plant root. In return, the fungi receive sugars from the plant (FAO, 2008a). Trees colonized with fungal symbionts are therefore likely to be more resistant to microbial pathogens and less stressed by drought. These benefits hold particular relevance for tropical forest ecosystems, given that drought and pathogen increases are predicted under climate change.

Genomics-based research is elucidating how this symbiotic complex functions. First, not all fungal symbionts have the same mechanisms, as genomics knowledge is confirming. The two major types of associations are ectomycorrhizae (EM) and vesicular-arbuscular mycorrhizae (VAM). While both buffer the tree host against diseases and abiotic stress, EM is more desirable for slowing forest degradation (Connell and Lowman, 1989) and for hastening re-colonization of abandoned land (Viera, Holl and Peneireiro, 2009). To this end, Connell and Lowman (1989) hypothesized that EM would confer a greater advantage to their host species than VAM.

TABLE 5

SOME EXAMPLES OF RELEVANT DNA SEQUENCE DATABASES

Database	URL
NCBI Taxonomy Browser Entrez Site Map	www.ncbi.nlm.nih.gov/ www.ncbi.nlm.nih.gov/Taxonomy/taxonomyhome.html/ www.ncbi.nlm.nih.gov/Entrez/ www.ncbi.nlm.nih.gov/Sitemap/
EMBL-EBI UniProt Site Map EMBL-Heidelberg Bioinformatics Tools	www.ebi.ac.uk/ www.ebi.ac.uk/uniprot/index.html www.ebi.ac.uk/services/index.html www.embl.de/services/bioinformatics/index.php
DENDROME Treegenes	http://dendrome.ucdavis.edu/ http://dendrome.ucdavis.edu/treegenes/

Source: adapted from Dean (2006)

Analysis requires specialized software, also available at some of these sites

The symbiont complex is more than the forest tree's roots and the fungal symbiont. Symbiont EM fungi also have specific bacterial associates which together form complexes with the host tree's roots (Bonfante and Anca, 2009). Together, this fungal-bacterial complex with the tree's roots confers benefits within the roots and surrounding area. Genomic sequencing of some fungal symbionts has been completed (Kuhn, Hijri and Sanders, 2001) and this is leading the way towards an emerging field known as community genomics which uses DNA sequencing tools to unravel these and other complex interactions within an entire forest ecosystem (Whitham *et al*., 2006). This plethora of DNA sequencing methods not only applies to a single species or its near relatives, but also can provide insights into a tropical forest ecosystem. Its potential is already emerging for testing ideas about paleoecology and community ecology.

2.3.2 Planted Forests

Although there is some overlap, the biotechnologies used for planted forests are generally quite different from those used for naturally regenerated forests. It is also important to emphasize that there are different kinds of planted forests. Plantations can have different types of management systems (e.g. intensive, semi-intensive) and use different types of genetic material (e.g. wild material, genetically improved trees). Depending on the level of management intensity and the genetic material used in the planted forest, different groups of biotechnologies can be used. For simplicity, three different groups of biotechnologies can be identified according to the type of planted forests, ranging from the least sophisticated to the most advanced.

2.3.2.1 Basic forest biotechnologies

This group of biotechnologies is suitable for the least intensively managed planted forests and includes a range of vegetative propagation methods such as tissue culture, biofertilizers and genetic fingerprinting using molecular markers. It can also be complemented by conventional technologies such as early-stage tree improvement programmes. For these least intensively managed planted forests, the tropical forest restoration staircase (Chazdon, 2008) is the example that illustrates this type. This starts with planting reliable and well-adapted seed or propagule sources for reforestation. Poorly adapted, dysgenic plantings cannot hope to achieve such outcomes as restoring soil fertility for crop or forestry use, payment for ecosystem services, timber production or biodiversity recovery (Quesada *et al*., 2009). In this first stage of planted forests, forest biotechnologies contribute to the health and quality of indigenous tropical forests and of exotic species.

Vegetative propagation of forest tree species

This covers a wide range of techniques which are useful for the rapid multiplication of genotypes. This has been useful for species which produce few or recalcitrant seeds or seedlings and for multiplying selected genotypes in a short period of time. It is also among the most ancient of forest applications, dating back eight centuries in China (Minghe and Ritchie, 1999). In India, there are about 8.9 million ha of teak forest, much of which is propagated by tissue culture (Tiwari, Tiwari and Siril, 2002). The National Chemical Laboratory in Pune and the Tata Research Institute in Delhi produce up to a few million teak plantlets annually. Phytosanitary measures also require tissue culture when moving germplasm from one country to another. This reduces the spread of plant viruses. Some of the disadvantages are the high costs of maintaining a tissue culture laboratory and quality control. Without quality control, one often sees the occurrence of somaclonal variations and deformed plantlets.

Micropropagation is the development of clonal lines from small tissue samples such as buds, roots or embryos extracted from seeds (Yanchuk, 2001) and some examples are provided in Table 6. The principles and achievements relating to plant tissue culture and micropropagation have been well reviewed by FAO (1994, 2004) and Yanchuk (2001). Thorpe, Harry and Kumar (1991) listed over 70 angiosperm and 30 gymnosperm tree species for which successful methods for the production of plantlets have been reported. Almost two decades ago, Le Roux and van Staden (1991) listed over 25 species of *Eucalyptus* alone. This, therefore, is a maturing part of the forest biotechnology portfolio.

TABLE 6

A FEW OF THE MANY FOREST TREE PLANTATION SPECIES WHICH HAVE BEEN MULTIPLIED THROUGH TISSUE CULTURE ON A COMMERCIAL SCALE IN DEVELOPING COUNTRIES

Countries	Species
India	*Tectona grandis*, *Anogeissus latifoglia* *Bamboo* spp.
Indonesia, Malaysia and Vietnam	*Acacia mangium* and *Acacia mangium* x *Acacia auriculiformis* hybrids
India, Vietnam and South America	*Eucalyptus* spp.
Chile	*Pinus radiata*
Brazil, Indonesia, Malaysia and Thailand	*Tectona grandis*

Between 2002 and 2004, FAO commissioned four studies to investigate the extent and patterns of research and application in biotechnologies in forest trees worldwide. Results from the studies indicate that Asia accounts for 38 percent of the activities in forest tree micropropagation, followed by 7 percent in South America, 3 percent in Africa and 2 percent in Oceania (FAO, 2004). As expected, micropropagation of tree species is active mostly in countries with significant tree planting programmes (Galiana *et al*., 2003; Watt *et al*., 2003; Goh and Monteuuis, 2005; Goh *et al*., 2007). While a large number of tree species (78 to 80) have been used for vegetative propagation research, little of this effort continues. Most halt at the laboratory stages (94 percent), so few even get as far as the field-testing stage (5 percent). Less than just 1 percent of the species developed clonally and tested have reached the commercial application stage (FAO, 2004).

Biofertilizers

Soils are dynamic living systems that contain a variety of micro-organisms such as bacteria, fungi and algae. Maintaining a favourable population of useful microflora is important from a fertility standpoint. The most commonly exploited micro-organisms are those that help in fixing atmospheric nitrogen for plant uptake or in solubilizing/mobilizing soil nutrients such as unavailable phosphorus into plant available forms, in addition to secreting growth promoting substances for enhancing crop yield. As a group, such microbes are called biofertilizers or microbial inoculants.

The use of biofertilizers has yielded positive results for indigenous forest species in the eastern Madagascar littoral forests as well as for exotic forest species including eucalypts, acacia and cypress (Kisa *et al*., 2007; Duponnois *et al*., 2007, 2008; Ouahmane *et al*., 2007; Remigi *et al*., 2008). Other symbionts that are being considered include nitrogen-fixing bacteria such as *Rhizobium*, and *Azolla*, blue-green algae and mycorrhizal fungi (Caesar, 2009). In addition to the least intensively managed planted forests in developing countries, biofertilizers have also proved useful in forests under more intensive management.

Genetic fingerprinting with molecular markers

All types of molecular and biochemical markers have been used for decades in these early-stage tree improvement programmes. A few examples are as follows:

- measuring genetic diversity of breeding population accessions between indigenous provenances and naturalized landrace origins;
- testing paternity contributions to offspring grown in field tests;
- verifying genetic identity during vegetative propagation.

2.3.2.2 Intermediate forest biotechnologies

The second group of biotechnologies can be used for planted forests that provide industrial raw materials on a large planting scale. The single species used for plantations might be indigenous or exotic, but the plantations are intensively managed.

Somatic embryogenesis

Somatic embryogenesis (SE) is a tissue culture technique that can also be used for the micropropagation of forest trees, where a small group of vegetative cells which are stem-cell like, are induced on culture media to undergo tissue differentiation to form a somatic embryo. The somatic embryo goes through a maturing process before being "germinated" for planting (Tartorius, Fowke and Dunstan, 1991).

Regeneration through SE has been reported for over 50 woody species encompassing over 20 angiosperm families, and at least a dozen conifer species (Wann 1988; Attree and Fowke, 1991; Tartorius, Fowke and Dunstan, 1991; Watt *et al*., 1991; Park, Barret and Bonga, 1998). Potential multiplication rates particularly from cell suspension cultures are very high. Additional advantages include the amenability of the process to handling in automated bioreactors and the possibility for mechanized delivery of the emblings (plants propagated from SE) through synthetic seed technology. SE is also ideally suited for efficient genetic transformation procedures because of the single cell origin of embryos. The advantages of SE in comparison with micropropagation by *in vitro* cuttings, especially with regards to multiplication rate and genetic modification, explain why large research investments have been made towards developing this technique. Although successes have been reported in some commercial species, there are still major obstacles to the large-scale operational application of the technique to forest trees. Most of the reports (Table 7) demonstrate that the results obtained are still in the experimental stages and are yet to reach the commercialization phase.

TABLE 7

SPECIES IN WHICH SOMATIC EMBRYOGENESIS IS AT THE EXPERIMENTAL STAGE

Country	Species reported	References cited
Chile	*P. radiata, P. taeda*	Park, 2002; Jones, 2002; Lelu-Walter and Harvengt, 2004
Brazil and India	*Eucalyptus globulus, E. grandis* and *E. dunnii*	Pinto *et al*., 2002; Watt *et al*., 2003
India	*Tectona grandis* *Bamboo* Sandal	Krishnadas and Muralidharan, 2008 Godbole *et al*., 2004; Shali and Muralidharan, 2008 Rathore *et al*., 2008
Bangladesh	*Gmelina arborea, Artocarpus chaplasha, A. heterophyllus, Azadirachta indica* and *Elaeocarpus robustus*	Sarker, Islam Rafiqul and Hoque, 1997; Roy, Islam and Hadiuzzaman, 1998

Moreover, SE is a costly high-precision operation usually funded through multinational timber companies which own or lease land. Only the most elite selections are propagated using SE, where the genetic gains from recurrent breeding are maximized through the high-volume propagation of a single genotype.

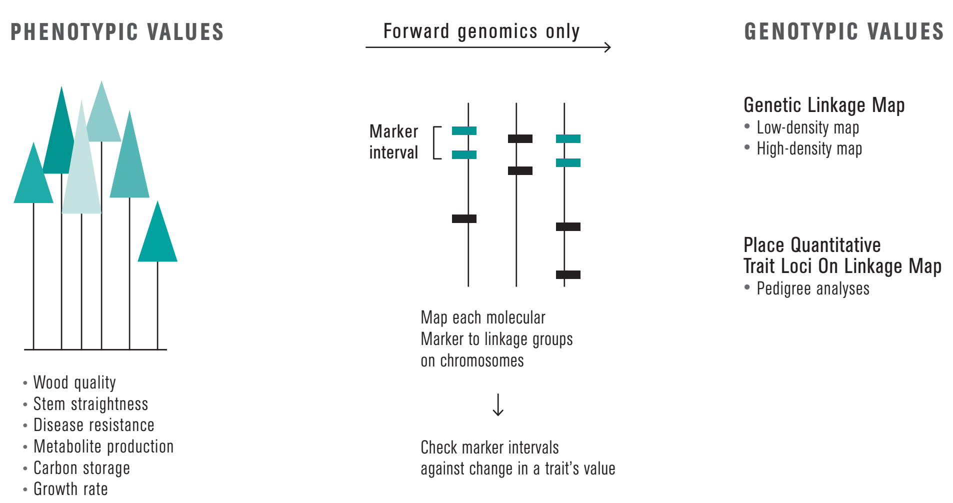
Molecular markers, maps and QTL analyses

As part of this high precision operation, molecular markers also take on new functions. Breeding and selection in the recurrent breeding programme can be optimized by localizing chromosomal regions which influence the trait of interest.

No longer used only for genetic fingerprinting, markers are now used to find associations between traits and chromosomal regions. Forest trees, as perennial plants, have an added temporal dimension which can be challenging (Gwaze *et al*., 2003) even for a single pedigree. If a marker interval is found to change the trait value then it becomes known as a quantitative trait locus (QTL) or a QTL haplotype, delineated by the relative position of two molecular markers. A QTL haplotype is not a gene but a single chromosomal segment inherited from either the maternal or paternal parent. It can include one or many genes exerting some degree of influence over a phenotypic trait.

FIGURE 2

FORWARD GENOMIC METHODS



Source: modified from Grattapaglia and Kirst (2008)

Finding QTL for forest trees is more costly and more computationally demanding than for most crop and livestock species because forest tree pedigrees are outcrossing and highly heterozygous (Devey *et al*., 2003; Williams and Reyes-Valdes, 2007; Williams, Reyes-Valdés and Huber, 2007). Large pedigrees are rare with few generations and the populations have no breed structure or strong degrees of differentiation. However, numerous reports have cited the identification of QTL for major traits ranging from growth to wood quality and disease resistance in both Northern and Southern Hemisphere countries for a cadre of forest tree species. Moving from the genetic map to the physical map is more feasible with small hardwood genomes such as poplar and eucalypts. For species with large genomes, molecular cytogenetics technology or placement of dye-tagged DNA segments from known genes on a fixed chromosome squash is proving to be a useful bridge technology (Doudrick *et al*., 1995).

Translating QTL identification into marker-assisted selection (MAS) is moving into the realm of commercial applications. Choosing MAS requires a cost-benefit analysis as described for *Pinus radiata* (Wilcox *et al*., 2001) and this is used for poplars, *Eucalyptus* spp., *Pinus radiata* and a few cases of temperate-zone *Pinus* spp. especially those planted as an exotic. MAS has led to some novel breeding strategies when applied to forest trees (e.g. El-Kassaby and Lstiburek, 2009).

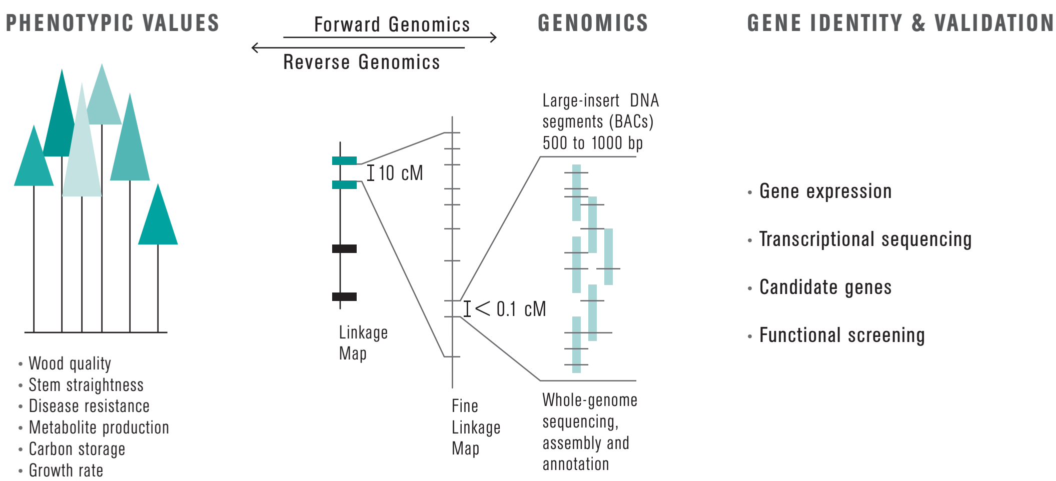
The selection of QTL haplotypes is not straightforward because a given pedigree can be segregating for more than one or even two QTL haplotypes of interest, which can result in ambiguous genetic models for QTL inheritance. But MAS is operational, lending yet another level of forest biotechnology precision to plantation forestry. Figure 2 shows how large numbers of molecular markers are assayed on gels for segregation patterns, then placed on a genetic map. Each individual now has a known genetic fingerprint, a collection of marker intervals or haplotypes – and some trait measurements. QTL haplotypes can be identified from these elements.

However, as mentioned earlier, finding QTL in single pedigrees is an arduous process for forest trees. Other methods for identifying QTL have since been developed or borrowed from other biological systems. These include association genomics which was developed for humans and other mammals (reviewed by Darvasi and Shifman, 2005) but these methods are well suited for forest trees (Brown *et al*., 2004). Association genomics is a population level QTL detection method that is only effective if enough gametic disequilibrium is present in the population. This has indeed been the case for several intensively managed forest trees in both Northern and Southern Hemisphere regions.

Trait measurements constitute the phenotypic value of an individual tree. Trait-based genomics approaches such as QTL mapping are known as forward genomics (Figure 2). The trait measurements for each individual can be compared with its marker haplotypes.

FIGURE 3

FORWARD AND REVERSE GENOMIC METHODS



Source: modified from Grattapaglia and Kirst (2008) and Grattapaglia *et al.* (2009)

This is known as co-segregation between linked molecular markers and a putative QTL haplotype. While forward genomics is trait-based, the reverse genomics approach (Figure 3) is gene-based. Reverse genomics identifies, tests and validates specific genes controlling the trait of interest. Together, they provide an integrated picture of which genes or chromosomal segments are influencing the trait of interest and the degree of independence among these genes. The most sophisticated forest biotechnology portfolios at this time use both forward and reverse approaches but these are limited to *Eucalyptus* spp, *Populus* spp. and *Pinus* spp.

Whole genome sequencing projects for forest tree species

For hardwood species such as *Eucalyptus* spp. or *Populus* spp., adding reverse genomics is rapid and feasible because genome sizes are in the same range as those for rice, tomato and *Arabidopsis* (Wakamiya *et al.*, 1993). Conifer genomes, by contrast, are larger than any commodity species in agriculture. The poplar genome was the first forest tree species to be sequenced in its entirety (Tuskan *et al.,* 2006). The *Eucalyptus* genome initiative for whole-genome sequencing is an even larger effort that is being coordinated between 130 scientists in 18 countries including Brazil and South Africa. Sequencing the pine genome has less momentum given its enormous size, almost seven times larger than the human genome. A number of groups are completing part of the pine genome at present. A total of 100 large chromosomal segments (also known as bacterial artificial chromosomes or BACs) from *Pinus taeda* are presently being sequenced at the Joint Genome Institute in the United States.

The impetus for sequencing these forest tree genomes tends to come from large-scale wood production in intensively managed plantations worldwide, but forest health has also provided an equally compelling case. One of the side benefits of a large-scale DNA sequencing project is a rich store of new molecular markers such as single nucleotide polymorphisms (SNPs).

Functional genomics

In recent years, sequencing entire genomes has shifted emphasis from analyzing sequence data to the elucidation of gene function, also referred to as functional genomics. Gene function is inferred by using sequence alignment-based comparisons, identifying homologues between and within organisms, transcript profiling to determine gene expression patterns for small numbers of transcripts and yeast two-hybrid interaction analysis for identifying metabolic pathways, gene networks and protein complexes.

It is often conducted using microarrays which refer to the parallel assessment of gene expression for tens of thousands of genes. It works on the principle of competitive hybridization between complementary DNA (cDNA) strands. This approach can identify candidate genes for quantitative traits in forestry, a form of reverse genomics. As an example, cDNA microarray technology generated a transcript-level profile of wood forming tissues (differentiating xylem) for a pedigree composed of individuals from a *Eucalyptus grandis* x *E. globulus* F_1 hybrid x *E. grandis* backcross population (Kirst *et al*., 2004). Microarrays are information rich sources of information about genes controlling the trait of interest.

Proteomics

Just as a genome describes the genetic content of an organism, a proteome defines the protein complement of the genome. Proteomics includes the identification of proteins in cells or tissues and the characterization of their physio-chemical properties such as post-translational modifications, function and expression level. Proteomics is a powerful tool for studying proteins and their modifications under different developmental stages and/or in response to various environmental stimuli.

In the cell, proteins form transitory or stable complexes as part of pathways and act within protein networks. These protein-protein interactions can be used to unravel the various interactions. After processing and modifications, a single gene may express between one and a few dozen different protein products. A combination of methods is required to characterize expressed proteins (or proteomes) fully.

A standard procedure is two-dimensional gel electrophoresis as the separation method followed by mass spectrometry analysis of the separated and enzymatically digested proteins. The peptide mass fingerprints typically obtained by mass spectrometry are matched against sequence databases using dedicated bioinformatics tools. The whole procedure can be automated and robotized for high throughput purposes. The aim of this technique is to evaluate the modifications of protein expression with respect to genetic, environmental and developmental factors. The question is which quantitative variation of proteins is responsible for which quantitative phenotypic variation. The application of two-dimensional gel electrophoresis coupled with mass spectrometry in forest tree genomics to map the expressed genome has been well reviewed by Plomion, Pionneau and Baillères (2003).

2.3.2.3 Advanced forest biotechnologies

This uses the most sophisticated forest biotechnology portfolio yet. It includes recurrent tree breeding, backward and reverse genomics approaches, whole genome sequencing, low cost vegetative propagation and genetic modification of forest trees. The latter is the focus of this part.

To date, the only report of commercial plantings with genetically modified (GM) trees is for poplar on 300-500 ha in China (Xiao-hua *et al.,* 2003; FAO, 2004). However, most tree species used in planted forests have been successfully transformed at the experimental level, and results have demonstrated the correct expression of new genes in these plants (Walter *et al*., 1998; Bishop-Hurley *et al*., 2001).

Benefits from genetic modification can arise in particular from the transfer of traits from species as wide apart as bacteria or other plants that are not readily available either in the breeding population or in the forest tree species as a whole. Traits that have been the subject of extensive research for genetic modification include stem shape (taper and “roundness”), herbicide resistance, flowering characteristics, lignin content, insect and fungal resistance (Li *et al*., 2003; Grace *et al*., 2005; Punja, 2001; Shin *et al*., 1994; Tang and Tian, 2003).

The potential environmental benefits of such technology (Gianessi *et al*., 2002) include new means to combat pathogen and pest outbreaks. Some intensively managed tree improvement programmes have been investigating the use of gene transfer methods for many years. An example is the introduction of the *Cry1Ac* gene from the bacteria *Bacillus thuriengensis* (Bt) into radiata pine, where the ultimate goal is to enhance resistance to the pine shoot tip moth (Grace *et al*., 2005). Less attention has been given to other applications of GM forest trees such as environmental remediation, land reclamation and mercury sequestration. Forest trees (conifers and hardwoods) are useful for land reclamation purposes even without genetic modification, so the potential value is considerable.

As mentioned earlier, a small area of GM poplar is also planted on a commercial scale in China. China has a highly productive forestry plantation programme with six national forest planting programmes. To date, at least seven million ha have been planted with fast growing poplars (FAO, 2008b).

The first successful transformation was done on *Populus nigra* with the *Cry1Ac* gene in 1993. This tree was used in field testing as early as 1994 and was subsequently deployed in further pilot plantings. In 2000, the Chinese regulatory authority permitted the establishment of about one million trees on 300 ha (Hu *et al*., 2001). This was followed by a smaller release with a hybrid poplar clone transformed with both *Cry1Ac* and *PI* genes (Xiao-hua *et al*., 2003). The toxicity of this transformed clone was greatly enhanced as the GM plants contained two insect resistance genes. Subsequently, the transformation of poplars for disease resistance and tolerance to environmental stresses has been achieved, though these are still at the laboratory stage (Xiao-hua *et al*., 2003).

Genetic modification is part of the reverse genomics approach that is used to evaluate gene function but its commercialization is shifting investment from the public domain into proprietary areas. As noted by FAO (2004), a notable trend is that the "numbers of publicly funded projects appear to be waning, while privately funded projects appear to be increasing, judging by field trials established in recent years". This is a capital intensive effort requiring long-term continuity of funding, scientists and infrastructure. Developing a GM genotype on a commercial scale first requires a well established gene transfer technology (Walter *et al*., 1998). Each GM genotype must then be vegetatively propagated on a large scale before shareholders can expect a return on the steep initial investment.

The issue of GMOs has received considerable attention over the last decade in scientific and non-scientific circles and from policy-makers worldwide. The focus of attention has been on the crop sector which is where most GMOs have been commercialized. In 2008, an estimated 125 million ha were cultivated with GM crops compared with just 400 ha of Bt poplars in China, with 20 000 seedlings prepared for planting in 2009 (James, 2008). If or when further GM forest trees are released commercially this situation may change. A regulatory framework to govern research and the applications of GM forest trees is essential. The issue goes beyond the country level because pollen flow and seed dispersal do not respect national boundaries. National and international regulatory systems should contain provisions for preliminary risk assessments, monitoring and control and for liability and redress.

Many countries currently have regulations for agricultural crops including fruit trees, although many developing countries lack such frameworks and the capacity to implement them. There are, however, no regulations specific to the use of GMOs in forestry. Although policies and regulations adopted for agricultural crops are also likely to be used for forest trees, forest trees present special challenges (they have long time frames and life spans, they form a wild resource and are major constituents of an ecosystem). Forests are not only trees, and forest ecosystems are more fragile, longer-lived and less closely controlled than crop fields. Decision making is complicated by the fact that while agriculture is primarily viewed as a production system, forests are generally viewed as natural systems, important not only for the conservation of biodiversity but also for social and cultural values. Thus the use of GM forest trees is viewed more as a political and environmental issue than as a technical or trade one (El-Lakany, 2004).

2.3.3 Summary

Based on the current analysis, Table 8 attempts to summarize and compare the current status, key issues and future perspectives for a number of conventional approaches and biotechnologies in developing countries. The different technologies differ in respect of public acceptance, the technical capacity and infrastructure/materials required for their use and costs. For the near future, it is predicted that the potential impact is high for tree improvement, genomics, DNA barcoding and biofertilizers. To complement this information, Table 9 summarizes the anticipated contribution of forest biotechnology applications to natural and planted forests for developing and developed countries based on the worldwide survey commissioned by FAO (2004).

TABLE 8

CURRENT STATUS OF SOME CONVENTIONAL TECHNOLOGIES AND BIOTECHNOLOGIES, AND FACTORS INFLUENCING THEIR APPLICABILITY IN THE FORESTRY SECTOR IN DEVELOPING COUNTRIES

Emerging forest biotechnology applications	Extent of use	Public and government acceptance	Current technical capability for using technology	Current technical capability for adapting or developing new technology	Infrastructure and/or materials and tools available for using technology	Relative cost	Skills required for application	Potential for generating impact (time frame < 10 years)
Tree improvement	High	High	High	Low	Medium	Medium	Medium	High
Recurrent tree breeding	Low	High	Low	High	Medium	High	High	Medium
Molecular markers	Medium	High	Medium	Medium	Low	Medium	Medium	Medium
Genomics	Low	High	Low	Low	Low	Medium	High	High
Bioinformatics	Medium	High	Medium	Medium	Medium	Medium	High	Low
Genetic modification	Low	Low to medium	Low	Low	Low	High	High	Low
Biofertilizers	High	High	High	High	Low	Low	Low	High
Comparative phylogeny	Low	High	Medium	Medium	Low	Medium	High	Low
DNA barcoding	Low	High	Medium	Medium	Medium	Medium	Low	High

TABLE 9

ANTICIPATED CONTRIBUTION OF FOREST BIOTECHNOLOGY APPLICATIONS TO NATURAL AND PLANTED FORESTS WORLDWIDE

Applicable forestry component	Spatial scale	Development elements relevant to biotechnology	Broad technologies						
			Molecular applications						Regeneration
			Bioinformatics	Diversity measurement	Gene discovery	Genetic modification	Biosensors	Product verification	
Natural populations	Tree–population	Genetic resources characterization	X	X	X				
	Population	Mating system/gene flow		X					
	Population–landscape	Conserving diversity		X					
	Population–landscape	Silvicultural impact assessment		X					
Breeding populations	Tree	Selection	X	X	X				
	Tree–population	Mating designs		X					X
	Tree	Testing	X	X	X			X	X
	Population	Diversity management		X	X				
Production populations	Population	Mating system	X	X					X
	Population	Gene flow	X	X				X	X
	Population–landscape	Silvicultural impact		X			X		X
Regeneration	Stand	Natural		X	X			X	X
	Stand	Planted		X	X	X		X	X
Domestication	Population	Native species diversity	X	X	X		X	X	
	Population	Exotic species suitability	X	X	X		X	X	
Gene conservation	Population	Diversity assessment	X	X					
	Population	Gene flow/contamination		X			X		X
	Tree	Reproduction		X	X		X		X
Forest health	Tree–stand	Risk/hazard assessment	X	X			X		
	Tree	Resistance screening	X	X	X	X	X		X
Processing/ Value added	Logs	Pulp processing	X		X	X	X	X	
	Logs	Wood treatment	X		X	X	X	X	

Source: adapted from Table 2.4.2 in FAO (2004)

2.4 ANALYSIS OF SUCCESSES AND FAILURES OF FOREST BIOTECHNOLOGIES IN DEVELOPING COUNTRIES

To date, the use of biotechnologies has been beneficial only at very advanced stages of selection and improvement programmes. Unlike crops, where the number of species to choose from is relatively limited, an immense diversity at both the interspecific and intraspecific level is used in forestry. Thanks to this important diversity, the early stages of classical selection (exploration, collection, testing of genetic resources) provide important gains. By way of example at the species level, *Acacia crassipcarpa*, which is currently the main plantation species in swamp areas was "unknown" as a plantation species only 20 years ago. At intraspecific level, coordinated, multilocational provenance trials have shown sometimes 200 percent variation in adaptive traits among populations across the natural range of distribution of the same species. Individual variation within populations is also very important, and selection at this level also yields important initial gains in particular through clonal development (the traditional rooting of cuttings).

For most species and forest tree management systems, advances registered in developing countries until now have been made without any incorporation of biotechnologies. There are very good examples of advanced tree breeding programmes using biotechnology tools in developing countries too, but they refer to a small part only of the forest area (although their share of timber production is relatively high).

One main reason for failure is an inadequate assessment of the real costs and benefits of using biotechnology tools in given conditions (the level of improvement and the intensity of management), often under pressure from providers. As a result, expectations are not met and unjustified costs are high. This is a common risk in the early stages of development of new technologies. The same problem occurred during the development of clonal forestry a few decades ago. The development of protocols for the mass vegetative propagation of eucalyptus (rooting cuttings) was a real breakthrough in the 1970s, making it possible to take advantage of outstanding individuals from highly heterogenous interspecific hybrid progenies (the genetic gain could not be captured otherwise). The first large-scale plantations and gains in the Congo and Brazil were very impressive. But a perverse side-effect was that insufficiently informed programmes (or projects that were under pressure from active clonal forestry promoters) overestimated the benefit from vegetative propagation and neglected all the necessary but time consuming and demanding basic work (systematic species and provenance exploration and testing, individual selection and breeding, etc). This resulted in disappointments and misconceived strategies in some cases.

Much still needs to be done along the lines of upgrading the skills of researchers by ensuring that they receive higher education or appropriate higher level training to be able to plan, develop and execute proper tree improvement programmes. Sufficient financial resources also need to be committed at the national level to ensure that such programmes are carried out successfully with the final aim of producing improved and bred reproductive material.

In developed countries, the applications of advanced forest biotechnologies have developed faster than predicted by Robinson (1999) a decade ago. A shift in technology transfer models has contributed to this success. In particular, this has come from the engagement and contributions of many Southern Hemisphere governments and universities. These institutions have contributed funding, talent and impetus to virtual forest research consortia in areas such as whole genome sequencing and other genomic applications. This contrasts with the older technology transfer models which characterized early tree improvement programmes. Unlike tree improvements, the consortia are less formally structured within a government. These grassroots scientific exchanges often include one or more government partners, and they are hastening forest biotechnology in interesting ways that bear little resemblance to traditional models of technology transfer. The advances being made in developed countries are also relevant to the progress in the application of forest biotechnologies in developing countries.

An analysis of forest biotechnology successes and/or failures leads to the following seven observations:

Forest biotechnology applications are developing along a separate path from crop biotechnology

Policy-makers tend to put forest biotechnology and crop biotechnology on the same plane, but the benefits, goals, risks and deliverables are distinctly different. This points to an important knowledge deficit about forestry biotechnology that needs to be addressed.

Forest biotechnology is now expanding to a wide range of forest types

The forest biotechnology portfolio *sensu lato* appears to be growing beyond its utility to forest plantations. Tropical forest complexity, health and recovery are also benefiting from forest biotechnologies in the form of genomics and its panoply of related methods. This has new relevance for tropical forests given the major current focus on slowing climate change.

That forest biotechnology applications have rapidly expanded in the past 5–10 years is also apparent from FAO (2004) which indicates that 64 percent of research and application activities in forest biotechnologies worldwide were focused on only six genera (*Pinus, Populus, Eucalyptus, Picea, Quercus* and *Acaci*a). As discussed earlier, this is no longer the case. In this respect, genomics can be seen as a technology spillover, no longer restricted to planted forests but being used also for the management of naturally regenerated tropical forests.

Forest biotechnology has advanced over the past decade during favourable economic conditions. This is expected to change. The next decade may see slower progress because the forestry industry itself has some inherent problems which may be accentuated by the global financial crisis. Like other research and development (R&D) areas, this downturn could reduce forest biotechnology investment at a critical time and shape how developing countries choose to invest in forest biotechnology. These problems are unique to the forestry context, as summarized by Robinson (1999).

Plantation forestry has less flexibility in tailoring its raw materials delivery due to long lead times

This means that tailoring raw materials for markets that are years or even decades into the future is a high-risk proposition. Historically, this is a point which has not been well understood by biotechnology leaders in the agricultural biotechnology or pharmaceutical industries (Robinson, 1999).

This suggests that it might be timely to re-examine the role of biotechnology within the wood manufacturing processes rather than modifying the raw material supply years in advance of market demand. This emerging field of science is known as molecular wood biotechnology. Biotechnology benefits to date have included energy savings, waste reduction, remediation of toxic chemicals (see reviews by Breen and Singleton, 1999; Mansfield and Esteghlalian, 2003; Ahuja, Gisela and Moreira, 2004). Perhaps the best known example is the use of microbial (fungal) enzymes that degrade lignin, a component of the plant cell wall. The use of microbial enzymes is a time-honoured method that has been applied in pulping processing since 1975. Economic feasibility studies have shown that recent microbial biotechnology applications can raise mill productivity by 30 percent (Mansfield and Esteghlalian, 2003). The genetic improvement of fungi, bacteria and other microbes is a faster way of improving the efficacy of pulping processes and degraded mill waste than attempting to modify the raw materials of forest trees.

The private forestry sector is cautious about investing in forests and forest biotechnologies on lands which are not wholly owned

This holds true both for forest biotechnology and for intensive plantation management. As noted earlier, most forests are not privately owned. A related issue is that for-profit licensing for genetically enhanced forest trees tends to have been a tricky business model in the past due to long timelines, low investment rates and public ownership of forests as a worldwide norm (Robinson, 1999). Thus forestry and its research, including tree breeding, are now more vulnerable to funding reductions and loss of continuity than before the financial crisis.

In most developing countries, the industrial sector is dominated by foreign firms that do not often solicit or require research input from local research establishments, as they rely on research conducted in their countries of origin. The situation, however, is different for the agriculture, forestry and horticultural sectors, where research is heavily supported by public research institutions. This scenario does not bode well for the development of biotechnology because commercial biotechnology has its roots in academia. Researchers in universities and research institutes carry out nearly all the basic research from which biotechnologies and biotechnology processes are developed. Thus, private venture capital companies which could help supply equity capital in support for development of local biotechnology are lacking. Besides, local firms are very unlikely to invest their already limited financial resources in long-gestation projects when interest rates are often higher if the funds are kept in banks.

However, there are interesting experiences of genetic improvement cooperatives that have pooled the resources of various private companies and universities to establish a single genetic improvement programme to benefit all participants. This model was applied successfully in Chile where the state forest service, the main forest companies and a university created a cooperative. Most of the advances in biotechnologies both in pines and eucalypts were made by this consortium.

Costs and consequences of expanding the range of forest biotechnologies

To the above stresses and strains, one must add the cost of expanding the forest biotechnology portfolio itself. Such an expansion can also generate financial strain. Burdon (1992) considered how molecular-based forest biotechnology would fit with classic breeding programmes. He foresaw severe institutional strain "…without skilful and sensitive management various competitive forces can subvert the safe and successful application [of molecular-based methods]". He was also concerned that this internal tension could imperil the collaboration within and between organizations which had already brought so much success to tree breeding. That "proprietary technology is very tempting…" added yet another source of strain on forest tree breeding. Managing forest biotechnology appropriately requires strategic oversight.

Roller-coaster R&D funding

Another point is that forestry, and its R&D budget, have always had a "roller-coaster ride" (Robinson, 1999). Managing against the vagaries of a roller-coaster budget makes the success of forest biotechnology to date even more impressive. This is true also for government sponsored research. Unstable raw material costs, fixed labour and overhead costs coupled with small, uneven profit margins all mean that the scale of forestry operations tend to become ever larger to clear net profits. The roller-coaster ride is an external force which threatens the stability and continuity required for long term research on long lived forest species.

Infrastructure and capacity constraints

In most developing countries, the use of biotechnology has been mostly limited to using tissue culture for the multiplication of selected clones. While some form of master plan for the development of biotechnology is present, there have been no real efforts to popularize this technology in the countries, mainly because of socio-economic factors. The introduction of biotechnology to developing countries has been by means of multilateral or bilateral collaboration. Experts from the collaborating (often developed) countries have visited and worked in the developing countries as short- or long-term experts and counterparts. They have helped establish laboratories and equip them with the relevant facilities to carry out research. While work continues during the period of collaboration, it slows down considerably once the collaboration phase is over. There are several reasons for this:

- The local counterparts are not adequately trained to continue the work independently once the collaboration ends.
- Once the collaboration period is over and the experts have returned home, the work in the laboratories slows down considerably as a result of financial constraints or the lack of technical knowledge.
- When equipment breaks down, it takes a long time to be repaired or purchased due to lack of funds.
- The purchase of chemicals needed for the work can be delayed as a result of a shortage of funds or the need to wait for them to be imported into the country.

In spite of these shortcomings, countries such as Vietnam have successfully developed elite clonal hybrids of *Acacia mangium* x *Acacia auriculiformis* for planting programmes. There are currently 127 000 hectares under clonal acacia hybrids cultivation (van Bueren, 2005) and the planted area continues to increase each year. With the recent rapid growth of the economy in the country, the situation looks poised to change as the government commits more funds towards education, training, research, skilled manpower development and infrastructure development. The biotechnology agenda is also being given priority in the national development plans of countries like Vietnam, Laos and Cambodia.

2.5 CASE STUDIES OF APPLICATIONS OF FOREST BIOTECHNOLOGIES IN DEVELOPING COUNTRIES

2.5.1 Eucalyptus plantations in Brazil

More than 700 species of eucalyptus are found in Australia but their performance as a plantation species is far greater elsewhere (Borralho, 2001) and especially in Brazil.

The Aracruz Cellulose's plantations in Brazil are perhaps the most widely cited success story. The company won the coveted Wallenberg Prize for its intensification efforts. This operation comprises a total of 300 000 ha of eucalypts of which half are produced by low cost vegetative propagation (Aracruz Cellulose, 2008).

In support of this intensive plantation effort, Brazil has a large-scale eucalyptus genomic research initiative that is known as the Genolyptus Project or the Brazilian Network of Eucalyptus Genome Research (Grattapaglia, 2004). The Genolyptus Project builds on the international whole genome sequencing effort. It aims for a genome wide understanding of the molecular basis for wood formation in *Eucalyptus* and is coupled with ongoing tree breeding programmes.

The project's talented team of scientists is generating a suite of biological and computational resources to discover, sequence, map, validate and understand the underlying variation of genes and genomic regions of economic importance in *Eucalyptus* with a focus on wood formation and disease resistance (Grattapaglia *et al.,* 2009). The project is based on a partnership among agencies within the Brazilian federal government through the MCT–Fundo Verde Amarelo. The academic/research sector is represented by seven universities and the Brazilian Agricultural Research Corporation (EMBRAPA). Industry is represented by twelve forestry companies. The Genolyptus Project could be considered a good example of how genomics can be successfully integrated with traditional breeding programmes to return value in a reasonably short time. This project also represents a good model of how universities, government agencies and private enterprises can work together to benefit different categories of stakeholders.

2.5.2 Clonal propagation of teak in Malaysia

Teak, *Tectona grandis*, is widely planted in many countries in Asia, South and Central America and Africa. A fifteen-year collaboration between the Sabah Foundation Group (Malaysia) and the Centre de Coopération Internationale en Recherche Agronomique pour le Developpement (CIRAD, France), exploiting molecular markers and micropropagation, has led to the availability of superior quality planting material both for the local market as well as for export (Goh *et al*. 2007; Muralidharan, 2009a). The candidate trees for producing the superior clones were selected with reference to intrinsic wood qualities (e.g. natural durability, shrinkage, sapwood percentage, etc.). Simple sequence repeat markers were developed to determine the genetic background and diversity in order to reduce inbreeding and ensure the genetic fidelity of the clones mass produced by tissue culture. There is now widespread demand for these clones globally. In addition, a clone identification form provides detailed information on each clone, including the DNA fingerprinting profile.

2.5.3 Micropropagation applied to tree breeding of fast-growing forest tree species in Latin America

Biotechnology was introduced in Latin America in the 1980s. Networking has been very important for the research community there. By December 2008, there were 5 467 researchers in 738 agricultural biotechnology laboratories in 32 countries in the Technical Co-operation Network on Agricultural Biotechnology in Latin America and the Caribbean (REDBIO), based at the FAO Regional Office in Chile. The network has been in operation since 1991 to develop biotechnology for the sustainable use of regional genetic resources, promote the safe and responsible application of the technologies – especially in fragile environments, and enhance the regional development of new strategic technologies such as molecular genomics. It also encourages the application, whenever feasible, of advanced biotechnology tools in integrated crop management and sustainable production systems.

In terms of planted forests, the largest areas are in Brazil (7 million ha, 4.1 million of which are industrial man-made forests). Chile has 2.25 million ha of planted forest areas, practically all for industrial purposes; Uruguay has about 0.75 million ha; Argentina has 0.7 million ha; Venezuela, 0.5 million ha; Cuba, 0.4 million ha; Peru, 0.3 million ha; and Colombia and Mexico have about 0.2 million ha each. In the other countries of Latin America and the Caribbean the reforested area is less than 100 000 ha per country. The estimates of the current yearly forestation rate vary from 386 000 to 520 000 ha (FAO, 2006). Practically all the planted forests have been established on abandoned agricultural lands where erosion is prevalent, with the overwhelming majority being established with fast-growing exotic species in the *Eucalyptus* and *Pinus* genera. Many of these planted forests have been established by clonally propagated elite plants in the case of *Eucalyptus* or through somatic embryogenesis in the case of the *Pinus* species.

2.5.4 Bioprotection in Kerala, India

At the Forest Protection Division of the Kerala Forest Research Institute, India, investigations into control of a serious insect pest of teak viz. the teak defoliator (*Hyblaea purea*), have been carried out for several years. A *Hyblaea purea* nuclear polyhedrosis virus (HpNPV) isolated from natural populations of the insect larvae resulted eventually in a very effective biological control method. A permanent preservation plot where the pest outbreak was kept under control over several years with regular spraying of the HpNPV formulation clearly demonstrated the benefits in terms of increased volume of timber compared with the control plots. Research then went into the rearing of the insect larvae in the laboratory on an artificial diet and the mass multiplication of the virus, followed by the formulation of the pesticide incorporating UV protectants and other adjuvants, and finally the spraying technique in the planted forests. Almost two decades of research finally culminated in a successful solution to a serious problem. Nevertheless, the technology has remained in the laboratory and there is no indication that it will make it to the standard package of practices of the teak plantings immediately. Since most teak in India today comes under the control of State Forest Departments, acceptability by the forestry professionals is important. Some farmers had shown interest and willingness to use the product in their plantations, and the initial response showed that the technology was effective. The case study demonstrates that research in forest biotechnology has a much better chance of producing results when conceived, developed and implemented in a broader framework that involves not only scientists and technologists but also at every stage the forestry professionals who work at the field level and, at some level, policy-makers who eventually have to give their approval (Muralidharan, 2009b).

B. LOOKING FORWARD: PREPARING FOR THE FUTURE

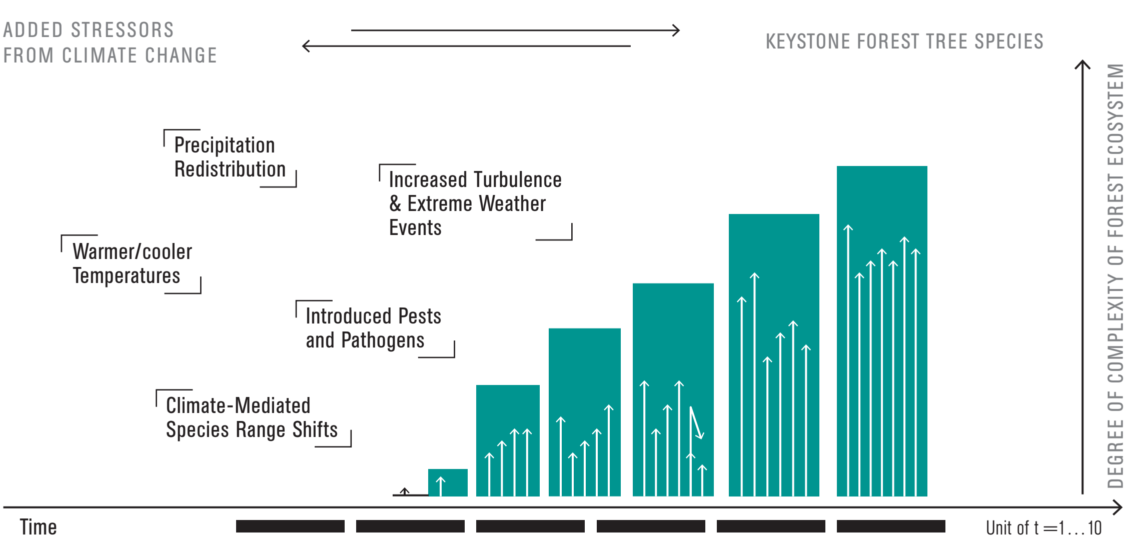
2.6 KEY ISSUES WHERE FOREST BIOTECHNOLOGIES COULD BE USEFUL

2.6.1 Adaptation to climate change

Forests, particularly tropical forests, play a central role in climate change and this is expected to shape the direction of forest biotechnology research in new ways. At the heart of the matter is how to ease forest adaptation. Forest adaptation is the foundation for all other forestry policy solutions aimed at slowing climate change (Hamrick, 2004; Millar, Stephenson and Stephens, 2007; Aitken *et al*., 2008). In addition, all forestry policy solutions, i.e. reducing emissions from deforestation and degradation (REDD), forestry offsets, biofuels and biomass depend on the health and resilience of forests while adapting to climate change (Clark, 2004). Thus, forest adaptation deserves a closer look as predictive models for climate change effects become more regional. Already, predicted range shifts and assemblage mixing are being published to some degree but no two regions will experience climate change in the same way. Tropical forests are especially vulnerable to climate change (see Figure 4). Climate change related problem-solving will dominate forest R&D, particularly for tropical regions.

FIGURE 4

A SCHEMATIC DIAGRAM OF A FORESTED ECOSYSTEM WHICH IS ADJUSTING TO CLIMATE CHANGE



Thinking about forest tree adaptation under climate change has led to formulation of the concept of assisted migration (Aitken *et al*., 2008; Marris, 2009). Assisted migration refers to the practice of matching seed source to location, assuming a different climate in the future. This is an important concept given that forest trees are so narrowly adapted.

As climate change models are becoming more regionally predictive, range shifts for indigenous forest trees are expected. Seed sources and provenances can be matched for optimum growth under these future site conditions (Aitken *et al.,* 2008). The issue is more critical at higher latitudes where forest rotation ages span 50–100 years, which is well within the realm of expected climate change by 2050.

With regard to biotic and abiotic stresses expected under climate change scenarios, the development of biotechnology tools for resistance to pests, tolerance to climatic extremes, bioremediation and carbon sequestration will be more relevant in the near future both for naturally regenerating and for planted forest tree species.

2.6.2 Sustainable management of forest genetic resources

Genetic diversity provides the fundamental basis for the evolution of forest tree species that has enabled forests and trees to adapt to changing conditions for thousands of years. Adaptation has resulted in a unique and irreplaceable portfolio of forest tree genetic resources. Fires, deforestation, new pests and diseases, and other factors are increasingly threatening forest genetic resources. The vast majority of forest genetic resources remain unknown and underutilized although the sustainable use of forest genetic diversity has great potential to contribute towards addressing new challenges and maintaining economic, social and cultural values, as well as providing environmental services and benefits. The field of forest genetic resources is undergoing significant changes. Traditionally, the sector has been concerned with technical issues of genetic conservation, tree improvement and seed supply for wood production. The scope of genetic management, however, is now expanding as the demand for products from forest species is increasing and diversifying (timber, fibre, fruits, resins and other non-wood products), which is contributing to food security and poverty reduction of rural populations. The emerging uses of forest genetic resources must be assessed to achieve sustainable use of these resources. Advances in biotechnology are rapidly enabling the improved use of genetic resources, and potentially greater economic and social contributions resulting from forest genetic resources. Biotechnology developments will also provide improved tools to enhance the effectiveness of conservation and development measures (knowledge about life-history traits and genetic diversity is lacking or inadequate for most tree species to define and implement conservation strategies).

2.7 IDENTIFYING OPTIONS FOR DEVELOPING COUNTRIES

Based on the stocktaking exercise carried out here, a number of specific options can be identified for developing countries to help them make informed decisions regarding the adoption of biotechnologies in the forestry sector in the future.

Biotechnologies should be integrated with conventional technologies

Forest biotechnology as a whole lacks strategic oversight to ensure the integration of its parts (Burdon, 1992). No policy exists that would ensure that tree breeding and molecular-based components of forest biotechnology work together in a complementary fashion. This is a problem because biotechnologies such as molecular markers and mass propagation methods can be useful only if stable conventional forest breeding programmes are in place.

Promote public-private partnership at national level

Effective public-private partnerships are a key factor in most successful cases of the development and implementation of forest biotechnologies, especially as regards industrial wood production and processing. It is therefore an important strategy to be considered by developing countries.

Improve information and communication strategies for biotechnologies

Public access to good and updated information on forest biotechnologies is very important in developing countries. Benefits from their use can be optimized if the end users know how to utilize them properly. Consolidated information and education mechanisms should be put in place to allow communication between the relevant sectors of society. Attention should be given to issues relating to the meaningful adoption of biotechnologies including socio-economic implications, efficiency, costs and benefits and environmental impacts.

2.8 IDENTIFYING PRIORITIES FOR ACTION FOR THE INTERNATIONAL COMMUNITY

The international community, including FAO and other UN organizations as well as NGOs, donors and development agencies, can play a key role in supporting developing countries by providing a framework for international cooperation as well as funding support for the generation, adaptation and adoption of appropriate biotechnologies. A set of Priorities for Action is given below that will help the international community fulfil this role.

Improve access to peer-reviewed scientific information about forest biotechnologies in developing countries

Even with Internet access, peer-reviewed journal and books continue to be central sources of information for scientists. Subscription costs for the best available scientific knowledge have risen exponentially, putting it out of the reach of many institutions even in the most science-literate developed countries. While open-source journals are a step in the right direction, publications in traditional forestry outlets such as proceedings, conferences and government printing office publications are declining. Today, forest biotechnology is adversely affected by barriers to knowledge acquisition. These barriers, when coupled with publication bias (defined as the propensity to forego publishing negative results), can only slow scientific progress.

The international community is already acting to reduce these barriers. For example, FAO is coordinating the Access to the Global Online Research in Agriculture (AGORA)[2] programme, providing free or low-cost access to scientific journals in the fields of food, agriculture (including forestry), environmental science and related social sciences. A sister programme called Online Access to Research in the Environment (OARE)[3] also covers both forestry and biotechnology and its goal is to improve access to scientific research in developing countries by providing high quality, timely, relevant, environmental and related science journals and other scientific content for free or at nominal cost. OARE is an international public-private consortium coordinated by the United Nations Environment Programme (UNEP), Yale University and leading science and technology publishers. Such initiatives from the international community should be encouraged and strengthened.

Build capacity for understanding forest biotechnology issues at all levels

For most policy-makers, scientists and even students, forest biotechnology is a form of agriculture. As discussed earlier, however, this is not the case. At best, it is a tribute to those who have developed capacity for agricultural biotechnology, but applying agricultural biotechnology to trees will not optimize the benefits to be obtained from forestry resources. Agricultural biotechnology does not constitute the best form of knowledge for forests. Forest biotechnology is an area that is separate from crop and livestock biotechnology and requires its own capacity building. Capacity building initiatives in forest biotechnologies from the international community should be strengthened in view of this important observation. The capacity building initiatives should include training in emerging tools such as bioinformatics and computational biology for tropical forest studies. Intensive educational efforts for bioinformatics courses would benefit professionals and scientists in developing

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2 www.aginternetwork.org.
3 www.oaresciences.org.

countries. This skill set provides capacity for testing hypotheses using available information from DNA sequences and related databases. In addition to educational workshops, this action will also require upgrades of computing infrastructure and perhaps bandwidth in some cases. A wealth of data is being produced by whole genome DNA sequencing consortia, the Tree of Life project, the Consortium for the Barcode of Life and a host of other independent initiatives.

Review the status and potential of forest biotechnologies for developing countries

It is clear from this Chapter that the forestry sector in developing countries is in a very dynamic situation and facing a number of important challenges and opportunities for which biotechnologies can play a significant role. FAO commissioned a series of studies in 2002–2004 to investigate the extent and pattern of research and application of forest biotechnologies worldwide (FAO, 2004). These studies have informed and influenced policy-making in developing countries, providing good indicators and possible predictions of trends in forest biotechnologies around the world. Such global surveys are important, and the international community should continue to provide periodic reviews of the status and potential of forestry biotechnologies in developing countries. The reviews should cover synergies with other biotechnology sectors such as applications of biotechnology to micro-organisms to improve wood manufacturing processing, as well as with other fields of technology that may be useful such as nanotechnology, information technology and synthetic genomics that may converge to the benefit of wood products manufacturing. Another potential area for convergence is the combination of genomics tools with geographic information systems (GIS). Using GIS to track rare alleles, gene flow or expressed proteins is another area that deserves a closer look. Technology advances are delivering finer resolution at both the landscape and molecular ends of this molecule-to-landscape spectrum, and this will no doubt provide interesting ways to study all forest ecosystems.

Encourage North-South collaboration

As mentioned earlier in this Chapter, the application of forest biotechnologies has advanced faster in developed countries than originally predicted (Robinson, 1999). As much of the research refers to processes and/or tree species that are relevant to developing countries, these advances are of major potential relevance to developing countries as well. The international community should act to ensure that the results of research and application in forest biotechnologies in developed countries are made accessible to developing countries.

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CHAPTER 3

CURRENT STATUS AND OPTIONS FOR LIVESTOCK BIOTECHNOLOGIES IN DEVELOPING COUNTRIES

SUMMARY

Conventional technologies and biotechnologies have contributed immensely to increasing livestock productivity, particularly in developed countries, and can help to alleviate poverty and hunger, reduce the threats of diseases and ensure environmental sustainability in developing countries. A wide range of biotechnologies are available and have already been used in developing countries in the main animal science disciplines, i.e. animal reproduction, genetics and breeding; animal nutrition and production; and animal health.

In animal reproduction, genetics and breeding, artificial insemination (AI) has perhaps been the most widely applied animal biotechnology, particularly in combination with cryopreservation, allowing significant genetic improvement for productivity as well as the global dissemination of selected male germplasm. Complementary technologies such as monitoring reproductive hormones, oestrus synchronization and semen sexing can improve the efficiency of AI. Embryo transfer provides the same opportunities for females, albeit on a much smaller scale and at a much greater price. Molecular DNA markers can also be used for genetic improvement through marker-assisted selection (MAS) as well as to characterize and conserve animal genetic resources. Use of most molecular marker systems depends on the polymerase chain reaction (PCR), which is an important technique for amplifying specific DNA sequences. AI is practised at some level in most developing countries, primarily in dairy cattle and peri-urban areas where complementary services including milk marketing are available. The high cost of liquid nitrogen for cryopreserving semen often restricts its use far from cities. AI is usually used for crossbreeding with

imported germplasm rather than for breeding with males of local breeds due to the paucity of animal identification, recording and evaluation programmes. Lack of systems for identifying superior animals together with weak technical capacity precludes the use of more advanced technologies such as embryo transfer or MAS. Application of molecular markers has generally being limited to genetic characterization studies, usually through international cooperation.

Biotechnologies for animal nutrition and production are often based on the use of micro-organisms including those produced through recombinant DNA technology. Fermentation technologies are used to produce nutrients such as particular essential amino acids or complete proteins or to improve the digestibility of animal feeds. Microbial cultures are used to increase the quality of silage or to improve digestion, when fed as probiotics. Recombinant bacteria have been developed to produce specific enzymes and hormones that improve nutrient utilization, which can increase productivity (e.g. somatotropin) and/or decrease environmental impact (e.g. phytase). Fibre-degrading enzymes are also used to increase animal productivity and decrease environment pollutants. Although data are scarce, amino acids and enzymes appear to be the most prominent and widespread nutrition-related biotechnology products used in developing countries, and India and China have developed local industries to produce them. Various factors have limited the use of many other biotechnologies. For example, silage production is not common, thus precluding the use of microbial cultures. The uptake of recombinant somatotropin has been affected by low public acceptance, inadequate good quality feed and the low genetic potential of animals in developing countries. Fermentation of lignocellulosic materials to improve the quality of crop residues and forages has not been very effective.

Biotechnologies in animal health are used to increase the precision of disease diagnosis as well as for disease control and treatment. Monoclonal antibodies are used in immunology-based diagnostic methods including enzyme-linked immunosorbent assays. Since these methods may not allow the distinguishing of vaccinated from infected animals, molecular approaches that detect specific DNA sequences and that rely mainly on PCR are now often preferred although their use is mainly restricted to the laboratories of research institutions and larger governmental diagnostic laboratories. Vaccination is widely used as a cost-effective measure to control livestock diseases as exemplified by the soon-to-be-confirmed eradication of rinderpest. Recombinant vaccines offer potential advantages over traditional vaccines in terms of specificity, stability and safety but few recombinant vaccines are being produced commercially and their use in developing countries is negligible. The sterile insect technique is usually applied as part of an area-wide integrated pest management approach and has played a vital role in the eradication of the tsetse fly population in Zanzibar and in the control of screwworms in several countries.

3.1 INTRODUCTION

The challenges facing the global community in food and agriculture are enormous. According to the most recent report on the State of Food Insecurity in the World, there are now about one billion undernourished people (FAO, 2009a). Livestock contribute directly to the livelihoods of nearly one billion of the world's population. Livestock provide protein and minerals for human consumption, manure for crop production, fibre and leather for industrial uses, and draught power. Beyond their roles in providing food and inputs for agriculture and industry, livestock provide security to farmers in developing countries, especially in emergencies such as crop failures. To many of the resource-poor smallholder farmers and landless livestock keepers, animals are a living bank, facilitating both income distribution and savings. In addition, by consuming crop residues and by-products and through well-managed grazing, livestock production contributes positively to the environment, particularly in mixed crop-livestock production systems. Thus, livestock are important sources of income and employment, contributing thereby to poverty alleviation and enhancing the household food security of farmers.

Livestock production is one of the fastest growing agricultural sectors in developing countries, where it accounts for more than a third of agricultural GDP. It is projected soon to overtake crop production as the most important agricultural sector in terms of added value (FAO, 2006a). Many developing and transition countries have realized high economic growth in recent years. This, coupled with an increasing population, an expanding urban population and growth in personal incomes, is altering the lifestyle and purchasing patterns with respect to food products. Global food protein demand is shifting from plant proteins to animal proteins. Using data from 2000 as a baseline, it is projected that the demand for animal products will nearly double by 2030 and that a large proportion of this increase will be in developing countries and from monogastric animals (FAO, 2002).

This increasing demand for livestock products, termed the "Livestock Revolution", is creating opportunities for improving the welfare of millions of poor people who depend on livestock for their livelihoods and could become a key means of alleviating poverty. It has been observed that in addition to providing benefits to farmers and the animal product industry, the rapid growth in livestock production has stimulated demand for, and increased the value of, labour, land, and non-agricultural goods and services, resulting in overall economic growth. However, increasing land degradation, global warming, erosion of animal and plant genetic resources, livestock-mediated environmental pollution, severe water shortages and the threat of emerging infectious diseases pose several new challenges to sustainable animal production and food security, particularly in developing countries (FAO, 2006a; Belák and Gay, 2007; World Bank, 2009). Meeting the increasing demand for animal products, while protecting natural resources and the wider environment, is therefore one of the major challenges today.

Technological innovations have been drivers of social and economic change. They have played a pivotal role in enhancing the quality of life and the safety of animals and humans. In the last four decades there has been an unprecedented surge in the development of biotechnology in animal production and health, with gene-based biotechnologies becoming most prominent in the last decade. While the vast majority of these technologies has been developed and utilized in developed countries, they have the potential to alleviate poverty and hunger, reduce the threats of diseases and ensure environmental sustainability in developing countries. Some of the technologies have a long history of successful use, others have been used with varied success, and many more are at different stages of development and commercialization.

A number of fundamental questions can be asked about livestock biotechnologies in developing countries: To what extent are they being used today?; what are the reasons for their success (or failure)?; what emerging challenges can be addressed through their application?; what options do individual developing countries and the international community have for enabling developing countries to make informed decisions on the use of appropriate biotechnologies to enhance food security? This Chapter tries to address these critical questions.

A. STOCKTAKING: LEARNING FROM THE PAST

3.2 CONVENTIONAL TECHNOLOGIES IN DEVELOPING COUNTRIES

Since the Second World War, all branches of the animal sciences – animal reproduction, genetics and breeding; animal nutrition and production; and animal health – have benefited substantially from the application of various technologies in developing countries. Although the benefits of technologies in the fields of animal genetics and breeding and animal health have produced large economic benefits – induced primarily by the adoption of artificial insemination (AI), disease diagnostics and vaccines – the role played by advances in animal nutrition should not be underestimated. Indeed, without the provision of adequate nutrition, the benefits of animal improvement programmes could not have been realized. Good nutrition is also necessary for the proper functioning of the immune system which helps keep animals healthy and productive.

The technologies used in animal nutrition have been diverse, much more so than in the other two sectors. In the early 20th century, locally available resources – mainly a mixture of crop residues, grasses and some easily available low-cost protein sources such as brans, kitchen waste and oil cakes – were used for feeding ruminants. Since the 1960s, with increased knowledge of mineral, protein and energy metabolism, concepts of balanced animal feeding emerged and several new technologies were developed. In developing countries the focus has been on enhancing the efficiency of utilizing crop residues and other roughages through urea ammoniation treatment and optimizing rumen fermentation by ameliorating nutrient deficiencies (mainly nitrogen and minerals) in low quality roughage. Approaches used included adding minerals, nitrogen in the form of non-protein nitrogen and tree leaves to roughage based diets; chopping and soaking roughages in water, which increases intake, is also being practised.

Productivity in peri-urban dairying and other commercial livestock units has been increased by using compound balanced rations of locally available ingredients; mineral mixture supplementation including the use of urea-molasses mineral blocks; the production, conservation and use of green fodder; the enrichment and densification of crop residues; the production of by-pass proteins, by-pass fat and chelated amino acids. For poultry and pigs, the nutritional provisions have shifted from the use of backyard feed resources to balanced feeding using conventional feed resources, especially on commercial farms. However, improving animal productivity has also hinged on striving for greater environmental stability. Imbalanced feeding results in the release of excess nitrogen, phosphorus and other nutrients into the environment, thereby causing pollution. Environmental pollution due to excessive feeding is particularly serious in intensively managed farms.

In the area of animal reproduction and breeding, cytogenetics has played an important role. Karyotyping technology is used to screen animals for chromosomal aberrations to assess subfertility and infertility in dairy animals. In some developing countries, open nucleus breeding systems and progeny testing programmes involving proper recording and analysis of necessary information for reliable decision making along with population and quantitative genetics have led to the development of highly productive animals when provided with the proper nutritional inputs and suitable housing and management. The basis of these systems is predicting the breeding values of the animals using phenotypic and genealogical information. Technologies such as AI and pregnancy diagnosis have been extensively used to transfer the improved germplasm to developing countries although natural mating is still the most common practice for breeding farm animals in such countries.

Since the early 20th century, the focus in animal health has been on the eradication of infectious diseases by slaughtering infected animals and in some cases, also associated animals. Recently vaccination has been used. Vaccination is the introduction (often by injection) of biological material into an individual to increase its immunity to a given disease. Its first use is attributed to Edward Jenner in the late 1700s. The biological material typically resembles the disease pathogen and prepares the immune system to react to subsequent infections. In the 1940s, the advent of antibiotics revolutionized the treatment of common diseases and these also encouraged surgical interventions. During the last decades, productivity-reducing subclinical diseases such as those caused by internal parasites have been treated with various antibiotics and drugs. For some livestock species, antimicrobials were also used as growth promoters. This last practice has not been without controversy and it is believed that misuse has contributed to drug resistance in parasites and bacteria.

The concepts and analytical techniques of epidemiology and their careful application have been a very significant factor in disease prevention in the last four decades. The availability of statistical methods, software and computing power allowed handling a large body of datasets, resulting in effective and fast decision-making and a better understanding of diseases. Epidemiology allowed for the simultaneous evaluation of the effects of various environmental, host and pathogen-related factors on disease incidence and transmission. Information on the effectiveness of vaccines under field conditions was also assessed by epidemiological methods. Other conventional techniques such as the clinical pathological analysis of specimens for the diagnosis or confirmation of diseases in farm animals and serological screening for various infectious agents have contributed significantly to monitoring and control programmes for many transboundary animal diseases. Traditional diagnostic tools such as virus neutralizing tests and virus isolation have a long history and remain the "gold standards" for serological and virological investigations. These have been invaluable tools for diagnosis of diseases. Vaccines developed through traditional approaches have also had a major impact on the control of foot-and-mouth disease (FMD), rinderpest and other epidemic and endemic viral, mycoplasmal and bacterial diseases.

3.3 ANIMAL BIOTECHNOLOGIES: DEFINITIONS AND HISTORICAL PERSPECTIVE

Biotechnology has been practised since the beginning of animal husbandry. The evaluation and selection of different breeds started with the domestication of animal species around 12 000 years ago which was led by the wish to obtain traits dictated by social, nutritional and environmental needs with no understanding of the molecular processes involved. In 1919, Karl Ereky, a Hungarian engineer coined the term "biotechnology" and described it as the process by which products could be synthesized from raw materials with the aid of living organisms. In this and the other FAO background documents for ABDC-10, the definition of biotechnology follows that of the Convention on Biological Diversity (CBD), i.e. "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use". A brief history now follows of the biotechnologies identified for discussion in this Chapter and their definition.

3.3.1 Biotechnologies in animal reproduction, genetics and breeding

The advent of AI in the 1930s represented the start of a revolution in traditional animal breeding. The subsequent discovery in the 1950s that glycerol could act as a cryoprotectant for semen removed practical barriers to the use of AI, expanding its potential exponentially. Prolonged storage of spermatozoa in a deep frozen state allows a single male to mate with thousands of females without restrictions imposed by geography and time. These developments were followed by oestrus synchronization, multiple ovulation induction and embryo transfer (ET), sperm and embryo sexing, and *in vitro* embryo production and cloning by nuclear transfer. In addition, recent developments in molecular markers coupled with the use of bioinformatics opened the possibility for identifying genomic variation and major genes for genetic improvement of livestock. The ongoing move to use molecular markers in conjunction with reproduction technologies such as AI and *in vitro* production of embryos is likely to accelerate further genetic change to obtain animals with desired traits.

Artificial insemination: Semen is collected from donor male animals, diluted in suitable diluents and preserved in liquid nitrogen. Fresh or frozen diluted semen is manually inseminated into the reproductive tract of an ovulating female to achieve pregnancy.

Sperm sexing: Depending on the species, X chromosome-bearing sperm contain 2–5 percent more DNA than sperm bearing the Y chromosome. Different sperm have distinct emission patterns when stained with a fluorescent dye and exposed to light. This difference allows the sperm to be separated by a flow cytometry machine. The sorted sperm can subsequently be used for AI to obtain offspring of the desired sex.

Progesterone monitoring: A highly specific antibody is used to measure the concentration of progesterone (the antigen) in blood or milk. This is particularly useful for identifying animals that are anoestrous or non-pregnant, improving the efficiency of AI. Radioactivity (radioimmunoassay – RIA) or fluorescence (enzyme-linked immunosorbent assay – ELISA) are used for quantification. The concentrations of many molecules of biological or agricultural interest can be measured using such procedures.

Oestrus synchronization: This is the process of bringing female animals into oestrus at a desired time by using a progesterone-releasing intravaginal device, intravaginal progesterone sponges, progesterone ear implant or prostaglandin treatment. The systematic administration of a combination of hormones such as gonadotrophins, prostaglandins, progesterone or oestradiol is also used. It assists in large-scale use of AI and can decrease the amount of labour used to monitor cattle for oestrus.

Embryo transfer: ET is the transfer of an embryo from one female to another. A donor animal is induced to superovulate through hormonal treatment. The ova obtained are then fertilized within the donor, the embryos develop and are then removed and implanted in a recipient animal for the remainder of the gestation period. The embryos can also be frozen for later use. Multiple ovulation and embryo transfer (MOET) increases the scope to select females – whereas AI limits selection to males – but its success depends upon the accurate identification of superior females and its application requires greater technical expertise and infrastructure than AI.

Embryo sexing: Heifers are preferred by the dairy industry and bulls by the beef industry. The pig industry generally prefers females due to higher quality and lower cost of production. Y chromosome probes are used for sexing the embryos. Karyotyping antibodies specific for male antigens and X-linked activity enzymes are also used for embryo sexing, but the use of Y chromosome specific probes seems to be the most reliable and practical method.

In vitro fertilization (IVF): Unfertilized eggs (oocytes) from ovaries of live donor animals are gathered by a technique referred to as "ovum pickup". The oocytes are matured in an incubator and then fertilized with sperm. The resulting zygotes are incubated in the laboratory to the blastocyst stage. The fertilized embryos can be transferred fresh or can be frozen. Sexed semen can be used to obtain embryos of the desired sex, which is more efficient and less complicated than the Y chromosome probe-based approach.

Cryopreservation: This refers to the storage of valuable genetic material (e.g. sperm, oocytes, embryos, somatic cells) in deep-frozen form in liquid nitrogen (-196 ^{o}C) for preservation and later use.

Cloning: The replication of DNA and other molecules and of genetically identical cells to produce an identical organism are all examples of cloning. Clones of entire organisms can be produced by embryo splitting or nuclear transfer including nuclei from blastomeres, somatic cells and stem cells.

Recombinant DNA technology: Simple changes in the DNA sequence of an organism's genome can have profound effects on its phenotype. Excision of a gene or even a single nucleotide can silence or "knock out" a gene, preventing it from being fully translated into the corresponding protein. In addition, because the DNA of all organisms is effectively the same molecule in terms of chemistry, insertion of one or more new genes into animal, plant or microbial cells is possible through various genetic tools. The microbes or animal cells hosting the transgenes become minute factories producing large quantities of the gene product. When recombinant DNA is inserted into the germ line of an animal, the result is a transgenic animal that is capable of passing the transgene on to its progeny.

Molecular markers: A DNA marker is an identifiable DNA fragment or sequence that can be used to detect DNA polymorphism. Molecular markers have a number of uses including estimation of population histories and genetic relationships within and between animal breeds (molecular characterization), as well as the determination of parentage. Markers that have a statistical association with a phenotypic trait can be used to select animals for the desired phenotype (MAS). Molecular markers may also be used to increase the efficiency of the introduction (introgression) of genes from one breed into another through repeated backcrossing of a recipient breed. Finally, although not an application for reproduction and breeding, DNA markers can be used to follow production streams containing particular components of interest, such as tracing animal products to their site of origin.

Different types of markers are available, including: a) restriction fragment length polymorphisms (RFLPs), in which DNA is cut with a specific nucleotide sequence using bacterial restriction enzymes yielding fragments of different lengths which are then separated on a gel; b) random amplified polymorphic DNA (RAPD) and amplified fragment length polymorphisms (AFLPs) involving the use of restriction enzymes and the polymerase chain reaction (PCR); c) minisatellites, which are regions of DNA with polymorphisms in the number of repeated nucleotide sequences of around 25 bases in length; d) microsatellites, which are DNA repeats in tandem at each locus, the tandem repeats usually being two to five bases long; and, e) single nucleotide polymorphisms (SNPs), which are single base changes in DNA. SNPs are the basis of DNA chips which have thousands of complementary DNA fragments arranged on a small matrix and are capable of scoring large numbers of loci simultaneously. Sequence analysis of either specific DNA fragments or entire genomes can also be carried out.

3.3.2 Biotechnologies in animal nutrition and production

A number of products from biotechnological processes are added to animal feeds to increase the efficiency of production.

Nutrients: L-amino acids produced through fermentative processes are used for correcting amino acid imbalances in diets. Industrial production of amino acids using biotechnological approaches began in the middle of the last century. The biotechnological processes – fermentation and enzymatic catalysis – led to a rapid development of the market for amino acids due to the economic and ecological advantages these biotechnologies offered. Essential amino acids such as L-lysine, L-threonine, L-tryptophan, L-phenylalanine and L-cysteine are produced either using high performance mutants of *Corynebacterium glutamicum* or recombinant strains of *Escherichia coli*.

Enzymes: In the present context, enzymes are proteinaceous biocatalysts, generally of microbial origin, that improve feed nutrient availability by enhancing the digestibility of macromolecules and decreasing antinutritional factors. An additional advantage is a potential decrease in environmental pollutants from livestock production systems. Some examples are phytase, glucanase and xylanase. The first phytase preparation was launched in the feed market in 1991. Phytases that enter the market are produced from microbial strains that are either derived through mutation or by using recombinant DNA technology. Some of the phytase preparations authorized in the European Union (EU) are produced by recombinant strains of *Aspergillus niger*, *A. oryzae* and *Trichoderma reesei*. Other enzymes such as glucanase, amylase and xylanase, which are also products of microbial fermentation, have been used in monogastric diets for decades. For many years the use of exogenous enzymes in ruminants was discouraged because of the perception that these enzymes would be hydrolyzed quickly by rumen microbes. However, studies conducted in the 1990s showed that adding exogenous enzymes to ruminant diets also has the potential to increase productivity.

Ionophores: These are compounds that translocate ions across biological membranes and consequently disrupt the transmembrane ion gradient. An example is monensin, an antimicrobial compound that is produced in large amounts by *Streptomyces cinnamonensis*. In 1971, monensin was originally introduced into the poultry industry as an anticoccidial agent. Some countries have approved its use in the diets of swine and ruminant animals, particularly dairy cows and beef cattle.

Single cell protein: This is the microbial biomass or extracted proteins obtained from processes in which bacteria, yeasts, fungi or algae are cultivated in large quantities. It can be used as protein supplements in animal feed.

Solid state fermentation: A method for biological treatment of lignocellulosic materials to improve their digestibility and facilitate their enzymatic hydrolysis or to produce enzymes for various applications.

Probiotics and prebiotics: Probiotics are live micro-organisms which may confer health and production benefits to the host animal when administered in adequate amounts. These are usually from the *Lactobacillus* and *Bifidobacterium* families for monogastric animals, while *Aspergillus oryzae* and *Saccharomyces cerevisiae* are generally used for ruminants. Since the 1920s, foods containing probiotic microbes (*Lactobacillus acidophilus*) for human consumption have been marketed in Japan. *Lactobacillus acidophilus* use in the United States reached its peak around the middle of the1930s and then faded. Since the late 1950s there has been steady interest in the study of probiotics for animals and humans. Prebiotics are non-digestible food ingredients that beneficially affect the host by selectively stimulating the growth and activity, or both, of specific microbial flora in the colon. Examples are inulin, fructo-oligosaccharide and resistant starch.

Silage additives: The nutritional quality of ensiled forages depends in part on the success of the fermentation process. Microbial inoculants and enzymes have been developed for addition into the silage at the time it is put into storage. These additives generally function by stimulating the fermentation process.

Recombinant metabolic modifiers: Since the 1920s, it has been known that injecting hypophyseal extracts stimulates tissue growth and milk secretion, and growth hormone was eventually identified as the primary source of this effect. During the 1990s, recombinant somatotropin produced by bacteria was licensed in various countries for the stimulation of production in dairy cows, swine and horses. Many countries have not approved its use.

3.3.3 Biotechnologies in animal health

Before the advent of recombinant DNA technology, the diagnosis and immunological prevention of infectious animal diseases was largely based on the use of whole pathogens or their physically resolved fractions. In many instances these crude methods were inefficient. Great improvements were obtained with the development of the ELISA, which has been the most popular diagnostic tool for animal diseases. Many ELISA systems now use recombinant antigens for detection of antibodies, which impart higher sensitivity, specificity, safety and acceptance compared with the use of whole pathogens. Additional major strides were made in pathogen detection after the discovery of PCR. Monoclonal antibodies and PCR have played an important role in the development of a number of diagnostic kits.

Diagnostics

Monoclonal antibody-based diagnostics: Monoclonal antibodies are produced by fusing two kinds of cells. One is an immune system cell that produces antibodies, the other a cancer cell. The fused cell inherits the ability to produce antibodies from the immune cell and the ability to reproduce indefinitely from the cancer cell. Kohler and Milstein were the first to develop a technique for the production of monoclonal antibodies in 1975 and were awarded the Nobel Prize in 1984. Monoclonal antibodies have a number of applications such as in diagnostic tests for animal diseases and progesterone assays for the reproductive management of livestock. Monoclonal antibodies have become common and essential tools for applying ELISA-based methodologies (e.g. antigen-capture ELISA and competitive ELISA), as well as Western blotting and immunochemistry techniques.

Polymerase chain reaction: PCR was developed in 1985 by Kary Mullis who received the Nobel Prize in 1993 for discovering the chemistry of this reaction. PCR increases the number of DNA molecules in a logarithmic and controlled manner. It results in the *in vitro* production of a large quantity of a desired DNA fragment from a complex mixture of heterogeneous sequences. PCR can amplify a selected region of 50 to several thousand base pairs into billions of copies. Molecular biology has been revolutionized by PCR. After amplification, the target DNA can be identified by many techniques such as gel electrophoresis or hybridization with a labelled nucleic acid (a probe). Real-time PCR, or quantitative PCR (qPCR), detects and measures the accumulation of a replicated DNA fragment during the amplification reaction. It enables quantification of the DNA and RNA (through cDNA production) present in a sample. For detection of RNA (for example the RNA of viruses), a cDNA copy of the RNA must first be made using reverse transcriptase. The cDNA then acts as the template for amplification by PCR to produce a large number of copies of cDNA. This method is called reverse transcriptase PCR (RT-PCR).

RFLP and related DNA-based approaches: DNA or RNA is isolated from the sample material (and if the starting material is RNA, a cDNA copy is prepared), the nucleic acid is digested with appropriate restriction enzymes into smaller pieces, and the fragments are then separated by electrophoresis to form bands for which the position is dictated by molecular weight. The pattern obtained on the gel (fingerprint) can be compared with known reference materials. This technique has been extremely useful in epidemiology, enabling comparison of isolates of a particular pathogen. This technique can also be combined with PCR to offer a much greater sensitivity for the identification of pathogens and is especially useful when the pathogen is available only in small numbers or is difficult to culture. Sequence analysis can also be conducted for more precise phenotype and genotype analysis.

Recombinant vaccines

Recombinant vaccines are produced from cloned genes via recombinant DNA technologies, and can generally be assigned to one of three types: DNA vaccines, marker vaccines and virus-vectored vaccines.

DNA vaccines: This refers to the direct inoculation of a eukaryotic expression vector encoding antigenic protein into an animal, resulting in the *in situ* production of the encoded antigen with the host's tissue to produce an immune response. It also involves the delivery of pathogen-specific antibodies (intracellular antibodies) into the host to express antibody fragments inside the cell that can bind with and inactivate a pathogen.

Marker vaccines: A marker vaccine (live or inactivated vaccine) is either based on deletion mutants or on isolated antigenic proteins that enables differentiation between infected and vaccinated animals (DIVA). A DIVA vaccine is used in conjunction with a companion diagnostic test that detects antibodies against a protein that is lacking in the vaccine strain. Originally, the term DIVA was applied to gene-deleted marker vaccines but it can be applied to subunit vaccines, heterologous vaccines or some killed whole pathogen vaccines such as the highly purified FMD vaccine that is used in conjunction with non-structural protein-based serological tests. It can also be used for recombinant-based vaccines.

Virus-vectored vaccines: Many virus species including the vaccinia, fowlpox and canarypox viruses are used as vectors (delivery systems) for exogenous genes to deliver vaccine antigens. These viruses can accommodate large amounts of exogenous genes and infect mammalian cells, resulting in the expression of large quantities of encoded protein. An example of a virus acting both as a vector and a self-vaccine is the recombinant capripox virus expressing a peste des petits ruminants (PPR) virus antigen.

Sterile insect technique (SIT)

The SIT for control of insect pests (in the present context, screwworm and tsetse flies, which cause widespread disease in livestock with enormous economic consequences for livestock keepers and governments) relies on the introduction of sterility in the females of the wild population. The sterility is produced following the mating of females with released males carrying dominant lethal mutations in their sperm that have been induced by ionizing radiation. It is an environment-friendly method of insect control and is usually applied as part of an area-wide integrated pest management (AW-IPM) approach.

3.3.4 Trends

Some clear trends were seen in this Section. Fermentation-based animal biotechnologies were developed prior to the 1950s. From 1950 to 1980, the livestock industry reaped substantial benefits from biotechnologies such as AI and oestrus synchronization. Since the 1980s, DNA-based technologies have played an increasingly important role in making animal production more efficient, economical and sustainable. Tremendous growth in molecular genetics and genomics research has taken place since the 1980s and may revolutionize the way animal genetic resources are managed and used in the future.

A common theme in the brief historical perspective presented here is that the biotechnologies have generally become progressively more complex over time, usually requiring increasingly well-trained and skilled human resources and often greater investment in laboratory infrastructure. Opportunities and risks have both tended to increase over time and approaches for analysing potential costs and benefits are becoming increasingly necessary. An important lesson that can be learned from past trends is that future biotechnologies will require an even higher degree of preparedness if their full potential is to be exploited. Biotechnology will undergo even more dramatic changes in the years to come than in the past.

3.4 CURRENT STATUS OF APPLICATION OF LIVESTOCK BIOTECHNOLOGIES IN DEVELOPING COUNTRIES

Quantitative information on the current status of use of animal biotechnologies in developing countries is lacking, except the use of some assisted reproductive biotechnologies such as AI, ET and molecular markers. The generation of quantitative information on these biotechnologies was possible due to a painstaking and well organized study conducted by FAO in which information on a country's capacity to manage its animal genetic resources for food and agriculture was gathered. Reports were received by FAO from 169 countries between 2002 and 2005 and published in the State of the World's Animal Genetic Resources (FAO, 2007).

3.4.1 Biotechnologies in animal reproduction, genetics and breeding

Artificial insemination

Among this set of biotechnologies, AI is the most widely used both in developing and in developed countries. A large number of AIs are performed globally each year, more than 100 million cattle, 40 million pigs, 3.3 million sheep and 0.5 million goats (FAO, 2006b). In India alone, 34 million inseminations were carried out in 2007 (DADF, 2008). The total number of inseminations in Brazil in 2008 was 8.2 million (ASBIA, 2008). According to FAO (2007), of the 42 African countries that submitted reports, 74 percent reported using AI. This proportion was smaller for Southwest Pacific countries (55 percent) and greater for Asia (86 percent), Latin America and the Caribbean (95 percent) and the Near and Middle East (100 percent). Nearly all countries in Europe and the Caucasus region (97 percent) reported using AI and in North America the figure was 100 percent.

Of the African countries that responded, 17 percent reported using ET and 14 percent molecular genetic technologies. For Asian and Latin American and Caribbean countries the numbers were considerably greater, with 47 percent and 50 percent respectively using ET, and 86 percent and 73 percent using molecular genetic technologies. The relative use of these biotechnologies was: AI followed by ET and then molecular genetic technologies. The gap in the application of these technologies between developed and developing countries was greatest for molecular genetic technologies, followed by ET and then AI. A large number of countries in developing regions did not apply these biotechnologies routinely, and their use in small-scale or low-input systems is very limited.

In respect of Africa, Asia and Latin America and the Caribbean, the following conclusions can be drawn about AI (FAO, 2007):

- It is mostly used for cattle production systems, especially in the dairy sector. In Africa and Asia its use is concentrated in peri-urban areas. Other species for which AI is used in all three regions are sheep, goats, horses and pigs, with use more common for sheep and pigs than goats and horses. In addition to these species, AI is used in Asia for chickens, camels, buffaloes and ducks, and in Latin America and Caribbean regions for rabbits, buffaloes, donkeys, alpacas and turkeys.
- Semen for AI is mostly from exotic breeds and used in the expectation of increasing the production of local livestock populations. Semen from local breeds is also used for this purpose, but to a lesser extent. In Côte d'Ivoire, semen from trypanotolerant cattle has been used and exotic semen has also been used for crossbreeding with naturally trypanotolerant cattle.
- Most AI services are provided by the public sector but the contribution of the private sector, breeding organizations and NGOs is also substantial (Table 1).

TABLE 1

NUMBER OF PUBLIC AND PRIVATE SECTOR ORGANIZATIONS IN AFRICA, ASIA AND LATIN AMERICA AND THE CARIBBEAN PROVIDING ARTIFICIAL INSEMINATION SERVICES

	Africa	Asia	Latin America and the Caribbean
Public sector	26	17	11
Private sector	12	6	9
Breeding organizations	2	5	5
NGOs	8	4	not reported
Universities	2	1	not reported

Source: adapted from FAO (2007)

Countries providing information on AI service providers: Africa, 26; Asia, 17; Latin America and Caribbean, 17.

- Concerns have been raised regarding the loss of biodiversity due to inappropriate and poorly planned use of AI to inseminate locally adapted cattle with imported semen for increased production.
- Most developing countries in Africa and Latin America do not have a clear breeding policy in place.

The country reports also indicate that nations such as Bhutan, the Democratic Republic of the Congo, the Gambia, Guinea and Laos wish to initiate AI activities but need to build the necessary infrastructure and capability required for initiating sustainable programmes. Cape Verde, Chad, the Cook Islands, Ghana and the Sudan all reported having started AI in the past but having stopped due to financial constraints. The AI infrastructure has subsequently deteriorated in these countries (FAO, 2006b). The availability of economically priced liquid nitrogen for the cryopreservation of semen is a particular constraint.

Progesterone measurement

Radioimmunoassay for measuring the hormone progesterone provides information both on the problems in breeding management by farmers and on the deficiencies in the AI services provided to them by government, cooperatives or private organizations. FAO cooperates with the International Atomic Agency (IAEA) in assisting countries to use nuclear techniques and related biotechnologies for developing improved strategies for sustainable agriculture through the activities of the Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture, based in Austria. Progesterone radioimmunoassay based on ^{125}I has been one of the cornerstones of the support provided by the Joint FAO/IAEA Division for improving the productivity of livestock in many developing countries, and the capacity to use this technique at the field level has been built in more than 30 Asian, African and Latin American countries through several regional networks and national programmes[1].

Oestrus synchronization

The use of oestrus synchronization in developing countries is generally limited either to intensively managed farms that are under the supervision of government livestock development departments, or to smaller farms with links to farmers' associations and cooperatives where AI is routinely used. Protocols for oestrus synchronization often include the administration of oestradiol which has been banned in the EU since 2006. This ban has implications for developing countries exporting, or aspiring to export, meat into the EU. Alternative options for synchronization do exist and these have been reviewed by Lane, Austin and Crowe (2008). However, amongst the various options available, oestrogenic compounds seem to be the most efficient and cost effective. Since the benefits of using oestrus synchronization will vary depending upon the production system, the potential benefits have to be weighed against the cost before specific recommendations can be made regarding its use.

Embryo transfer

An evaluation of country reports (FAO, 2007) shows that only five of the African countries providing information (Côte d'Ivoire, Kenya, Madagascar, Zambia and Zimbabwe) use ET technology, all on a very limited scale. The use of ET has also been independently reported in South Africa (Greyling *et al.*, 2002). Eight out of the 17 Asian countries that provided information on the issue reported some use of ET technology, but this was largely confined to research stations. However, the demand for establishing this technology was highlighted by many countries. The animal species in which the technology has been applied are cattle, buffaloes, horses and goats. In the Latin America and the Caribbean region, ET is increasingly being used by commercial livestock producers. Twelve out of the 14 Latin America and the Caribbean countries that provided information mention the use of this technology. All reported its use with cattle, two with goats, three with horses, two with sheep, one with llamas, one with alpacas and one with donkeys. Exotic embryos were used for cattle and the dairy sector was the main beneficiary. Private sector organizations are involved in providing ET in Brazil and Chile (FAO, 2007).

Each year, the Data Retrieval Committee of the International Embryo Transfer Society provides a summary of worldwide statistics of ET in farm animals. Table 2 summarizes these figures for cattle in 2007 (Thibier, 2008), and shows that about 820 000 embryos were transferred, of which 70 percent were produced *in vivo* and 30 percent *in vitro*.

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[1] www-naweb.iaea.org/nafa/aph/index.html

TABLE 2

NUMBER OF *IN VITRO* PRODUCED AND *IN VIVO* PRODUCED BOVINE EMBRYOS TRANSFERRED IN 2007

Region	*in vitro*	*in vivo*	Total
Africa	no data	7 416	7 416
Asia	32 462	95 733	128 195
North America	9 252	301 982	311 234
South America	195 920	66 908	262 828
Europe	5 832	97 967	103 799
Oceania	1 791	7 871	9 662
Total	245 257	577 877	823 134

Source: Thibier (2008)

About 1 percent of the total was from Africa, mostly from South Africa. About 32 percent were from South America, dominated by Brazil which was responsible for almost 30 percent of all embryo transfers worldwide in 2007. Among developing countries, a large number of embryos were also transferred in China and Argentina. While the majority of embryo transfers carried out worldwide are in cattle, Thibier (2008) also reported on ET use in other species, showing that South Africa is an important player for ET in small ruminants and that the three main countries involved in equine ET are Argentina, Brazil and the United States.

Alarcon and Galina (2009) reported that government organizations in Mexico have initiated programmes to popularize ET, particularly in small-scale enterprises not bigger than 50 cows per unit. However, based on their analysis which considered the costs of preparing the donor and recipient, embryo recovery and the resulting gestation, ET is not profitable enough for farmers to sustain such programmes on their own. These programmes had a high degree of acceptability only when the organizations provided substantial subsidies since once the subsidized programmes stopped, ET was no longer sustainable.

Semen and embryo sexing

Although these biotechnologies do not dramatically increase the rate of genetic gain, they can increase production efficiency. At a research level, they are being developed and refined in a number of research institutions in developing countries. The involvement of private companies providing these services is likely to increase their accessibility in developing countries where AI is already established. With few exceptions, they are not widely used by breeders or farmers in developing countries (FAO, 2007). Sexed sperm is commercially available in several developing countries, including Argentina, Brazil and China (Garner, 2006; Rath, 2008).

Cryopreservation

A large number of livestock breeds (>20 percent) are at risk of extinction (FAO, 2007). Semen and embryo cryopreservation have been used for conserving rare livestock breeds (Long, 2008). An evaluation of country reports indicates that over one third of countries use *in vitro* conservation (FAO, 2007). For example, the figure is 50 percent in Asian countries, although the state of *in vitro* conservation at the national level is very variable. Well established genebanks exist in Japan and India, and genebanks are under establishment in China, the Republic of Korea and Vietnam. Semen is preserved from all the main species, and embryos from cattle, sheep and goats are also stored. In a few countries, tissue DNA is collected from all the main species. Governments undertake these *in vitro* activities in collaboration with industry. In some other countries there is limited storage of semen at AI stations, while elsewhere, particularly in the western part of the region, no *in vitro* activities exist (FAO, 2007).

Cryopreservation of gametes, embryos, DNA or cells (for example skin fibroplasts) is a cost-effective approach for the conservation of endangered species, although using DNA or non-germ cells to regenerate an extinct breed is still problematic with available technologies. It has been suggested (Hodges, 2005) that cryopreserved cells of each breed should be stored long-term in secure locations and accessed if and when the need arises in the future, either to sequence their DNA to understand genetic differences among breeds or to use the cells in cloning to regenerate extinct breeds. Conservation of indigenous genetic resources is one of the top priorities of developing countries and several country reports noted the potential use of AI and ET for cryoconservation purposes (FAO, 2007). Due to changes induced by global warming, it is plausible that the need in developed countries for the indigenous genetic resources in developing countries will increase. This highlights the need for North-South cooperation in this area and for greater financial contributions and technical support from developed countries.

Cloning

Since the birth of Dolly in 1996, cloning has been achieved for various species. Up to 2004, about 1 500 calves had been produced through somatic cell nuclear transfer (SCNT), mainly in Europe, North America, Japan and New Zealand, but also in South America and Asia (Heyman, 2005). China produced the first cloned buffalo in 2004 and India followed suit in February 2009. At present the production of cloned animals is at the experimental stage in most developing countries. From a research standpoint, cloning makes possible the efficient evaluation of genotype x environment interactions. At the farm level, it has the advantage of increasing the rate of dissemination of tested superior genotypes in commercial populations and possibly also of increasing the uniformity of a given livestock product for market. A chapter in the World Organisation for Animal Health (OIE) Terrestrial Animal Health Code is dedicated to SCNT in production livestock and horses, aiming to provide a scientific basis and recommendations on animal health and welfare risks to animals involved in SCNT cloning compared with other assisted reproductive technologies[2].

Transgenesis

Although at present no transgenic livestock have been commercialized for food production, a number of transgenic animals producing therapeutic proteins in milk are at different stages of commercial development. These proteins include lactoferrin, fibrinogen and a malaria vaccine (see Table 2 in Niemann and Kues, 2007). In 2006, the European Medicines Agency approved the commercialization of the first recombinant protein (antithrombin III, ATryn) produced in milk of transgenic animals (goats). The United States Food and Drug Administration (FDA) approved ATryn in 2009. It is being used for the prophylactic treatment of patients with congenital antithrombin deficiency. A number of other transgenic farm animals have been produced but not yet commercialized, including: 1) phytase transgenic pigs which enable the better use of phytate-phosphorus and decrease manure-based environmental pollution; 2) cows that express a lysostaphin gene construct in the mammary gland to increase resistance to mastitis; and 3) pigs containing a desaturase gene derived from spinach that makes pork better for human consumption by increasing the ratio of polyunsaturated to saturated fatty acids in muscle (Karatzas, 2003; Nieman and Kues, 2007). The first approvals for transgenic animals have been for biomedical applications but it is likely that food and/or environmental applications will increase over time.

According to a survey conducted by the OIE in 2005 (MacKenzie, 2005) in which 91 countries participated (60 percent from developing countries), 4 percent of the respondents in Africa and 23 percent of the respondents is Asia reported having cloning capabilities. For transgenesis, the corresponding numbers were 8 percent and 23 percent. No Near Eastern country claimed cloning or transgenesis capability at the time of the report, but in the intervening period camels have been successfully cloned in Dubai and sheep and goats in Iran. In Europe, 18 percent and 26 percent of countries claimed cloning and transgenesis capability respectively. Asian countries lag only slightly behind Europe in their capability to produce transgenic animals.

Molecular markers

According to FAO (2007), four countries in Africa (Cameroon, Chad, Nigeria, and Togo) reported using molecular markers to characterize genetic resources. In addition, molecular characterization of livestock has been undertaken in South Africa and in other countries

2 www.oie.int/eng/normes/mcode/en_sommaire.htm

through international collaboration. In Asia, out of eight countries using molecular markers, six use them for genetic characterization and for the evaluation of diversity and two for MAS. The species involved are cattle, sheep, goats, pigs, buffaloes, horses, camel, deer, chicken, ducks, quails and guinea fowl. In Latin America and the Caribbean, 11 countries use molecular markers, largely for the molecular characterization of breeds: cattle, sheep, pigs, chickens, horses, goats, buffaloes and camelid species including llamas and alpacas.

Molecular marker information has not yet been widely integrated into breeding programmes in developing countries. MAS can accelerate the rate of genetic progress by enhancing the accuracy of selection and by reducing the time to gather the data needed for selection. The benefit is greatest for traits with low heritability and which are unavailable before sexual maturity or without sacrificing the animal. However, in the low-input systems existing in many developing countries it may be more difficult to realize the full value of marker information because the phenotypic and pedigree information necessary to determine associations between traits and markers is often not available.

Much of the work in developing countries using molecular markers for characterization involves international collaboration. FAO activities in the area of animal genetic resources are being complemented by programmes on molecular marker-based characterization of genetic resources in Asia and Africa by the Joint FAO/IAEA Division and the International Livestock Research Institute (ILRI). Bangladesh, China, Indonesia, Iran, Pakistan, Sri Lanka and Vietnam are participating and the focus is on building capacity to genetically characterize their breeds of small ruminants[3]. ILRI's programmes focus on the characterization of local poultry in Cambodia, Laos, Vietnam, Egypt, Ethiopia, Kenya and Uganda and on small ruminants from seven countries. At ILRI, work is also underway on marker identification for trypanotolerance. The identification and subsequent use of markers for trypanotolerance and helminth resistance would enhance future prospects of breeding for such traits in developing countries. The International Bovine HapMap project (Gibbs *et al.,* 2009) included two African breeds considered to be resistant to trypanosomosis. Opportunities to increase disease resistance seem particularly promising but uptake in developing countries is likely to be achieved only in the medium to long term rather than in the near future.

Marker/gene-assisted selection has been applied in the Awassi and Assaf dairy breeds in Israel for the introgression of the Booroola gene (FecB gene) for enhancing prolificacy (Gootwine *et al*., 2003), and in India it has also been used to introgress the Booroola gene in the Deccani breed of sheep, a meat-producing breed (see Case Study 3.6.1 later). In developing countries, genotype information is expected to be initially more useful in marker/gene-assisted introgression rather than in selection within breeds (Perera and Makkar, 2005).

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3 www-naweb.iaea.org/nafa/aph/crp/aph-livestock-phase1.html

The recent development of DNA chips that can simultaneously type tens of thousands of SNPs has opened up the possibilities of “genomic selection” (Meuwissen, Hayes and Goddard, 2001). This approach is already being used for commercial species in developed countries and may potentially be a useful option in some developing countries. However, because few genetic analysis programmes currently exist in developing countries to provide the data needed to underpin any type of MAS, the capability for genomic analyses for the short to intermediate term will remain centred in developed countries.

3.4.2 Biotechnologies in animal nutrition and production

Nutrients and feed additives

Of the biotechnologies available to improve animal nutrition, the use of feed additives such as amino acids and enzymes appears to be most prominent and widespread in developing countries. The use of these technologies has already realized substantial economic and environmental gains. In developing countries the greatest use is in pig and poultry production, where over the last decade intensification has increased, further accelerating the demand for feed additives.

Amino acids

The amino acids in feed, L-lysine, L-threonine, L-tryptophan and DL-methionine constitute the largest share (56 percent) of the total amino acid market, which amounted to around US$4.5 billion in 2004. Amino acids are mostly produced by microbial fermentation and in the world market for fermentation products, after ethanol and antibiotics, amino acids are the most important category and demand for them is increasing rapidly (Leuchtenberger, Huthmacher and Drauz, 2005). Most grain-based livestock feeds are deficient in essential amino acids such as lysine, methionine and tryptophan and for high producing monogastric animals (pigs and poultry) these amino acids are added to diets to increase productivity. Balancing of diets using amino acids also decreases excretion of nitrogen from the animals into the environment. Lysine is the first limiting amino acid for pigs and, after methionine, it is the second limiting amino acid for poultry. In 2005, the estimated demand for lysine as lysineHCl was 850 000 tons while for L-threonine (the second limiting amino acid for pigs) and L-tryptophan (third limiting amino acid for pigs) it was 70 000 tons and 3 000 tons respectively. Whereas fermentation methods for producing lysine, threonine and tryptophan are well established, cost-effective production of L-methionine has not yet been successful (Leuchtenberger, Huthmacher and Drauz, 2005). The production of methionine has been through a synthetic process or through the use of enzymes obtained from microbes. L-cysteine, generally needed for feeding to wool-producing animals, is also produced by enzymatic processes. Rumen-protected methionine and its analogues and amino acid chelates (for increasing mineral absorption) are also used in developed countries and to a very limited extent in intensive livestock production systems in some developing countries.

Enzymes

The use of phytase in pig and poultry feeds in intensive production systems in developing countries is significant. Phytase addition can reduce phosphorus excretion by up to 50 percent, contributing significantly to environmental protection. It also increases profitability (phosphorus resources are limited and expensive) by decreasing the amount of phosphorus added to the diet and increasing productivity by improving the availability of minerals, trace elements and nutrients for the animal. In 2007, animal feed enzymes had a market of US$280 million worldwide, with phytase making the largest contribution. The animal feed enzyme sector grew at a rate of 4 percent per year between 2004 and 2009 and it is expected to grow annually by 6 percent from 2007 to 2012 (Thakore, 2008). The phytase market in China amounts to 5 500 tons per year.

At present, there are over 100 companies producing feed enzymes in China (Yu, Wang and Zhang, 2008). According to the China Fermentation Industry Association, feed enzyme production was 10 000 tons in 2001, forming 3 percent of China's enzyme production and 4 percent of its feed additive production (Deng, Chen and Deng, 2008). In India, the use of phytase in monogastric diets is approximately 500 tons/year (CLFMA, 2007). Other exogenous enzymes such as xylanases, glucanases, proteases and amylases and their mixtures are also added to the diets of monogastric animals in commercial farms in some developing countries. In India, 625 tons of these enzymes were used in monogastric diets in 2007 (CLFMA, 2007). Their use in developed countries is widespread. They improve digestion, remove antinutritional factors and improve productivity. The use of cellulases and xylanases has the added advantages of increasing digestibility, thereby reducing the amount of manure and possibly methane emissions from ruminants. However, the response to the addition of enzymes in ruminants appears to be variable (Rode *et al.*, 2001). The reasons for this variability are not yet fully understood. Due to a ban on the use of growth promoters in animal diets in the EU since 2006 and increasing pressure for a ban in North America, new agents for promoting growth are being investigated. The potential use of enzymes such as cellulases, xylanases and other fibre-degrading enzymes in ruminant diets is likely to increase both in developing and developed countries provided a consistent and large response is achieved and their cost is low.

Ionophores

The use of monensin is banned in the EU, although it is used in some industrialized countries. In China, monensin can only be used as an anti-coccidian for chicken and as a growth promoting additive for beef cattle, whereas it is prohibited for use during lactation in dairy cows and laying chickens (MOA, 2001).

Single cell protein

From the 1970s to the 1990s extensive research was conducted on single cell proteins. With the exception of some algae, however, they are not being incorporated in livestock diets in either developing or developed countries. Algae such as azolla and lemna are used to a limited extent as feed for pigs by small-scale farmers in Vietnam and Colombia.

Solid-state fermentation

The degradation of wheat and rice straws and other lignocellulosic materials using white rot fungi that degrade lignin was also extensively researched from the 1970s to the 1990s. In general, however, the nutrient availability from the treated material is decreased due to the consumption of carbohydrates present in the lignocellulosic materials by the fungi for their growth and metabolism. The nitrogen content of the treated material is higher but a large proportion of this nitrogen is contributed by nucleotides which do not increase productivity. Probably for these reasons, this technology has never got off the ground but solid-state fermentation for producing enzymes, especially phytase for animal feeding is being employed commercially (Vats and Banerjee, 2004).

Probiotics and prebiotics

Although probiotic and prebiotic products have been claimed to elicit several beneficial effects in both monogastric and ruminant animals, the results have been variable (Krehbiel *et al*., 2003; Patterson, 2005). Much remains to be established about the diet, the environment, husbandry condition and dose-dependence of their effects. Despite the inconsistent results, probiotics are in use in a number of developing countries, with their use being greater for monogastrics. For example, in China there are currently more than 400 companies producing feed microbe additives, some engaged in large-scale production. Fifteen microbes have been approved for use as feed additives in China. In India, 2 000 tons of probiotics have been used in monogastric diets and the total market value of probiotics and enzymes in India is around $US1 million (CLFMA, 2007). In Indonesia, a number of undefined probiotics for animal feeding are available on the market (H.P.S. Makkar, personal communication), but information is lacking about the number of viable microbes per unit weight or volume, their stability through processing and digestion, shelf-life and efficacy. Live microbes such as *Aspergillus oryzae* and *Saccharomyces cerevisiae* are being used increasingly in ruminant diets to improve rumen efficiency, especially in intensive production systems. A number of commercial products are available. Their use in the reduction of methane output from ruminants is also being investigated.

A success story in the use of live microbes for ruminants is the introduction of a bacterium *Synergistes jonesii* into the rumen. It prevents mimosine toxicity and enables the safe use of *Leucaena leucocephala* as a protein-rich feed in many developing countries. Manipulation of probiotics and rumen microbes through transgenic processes to obtain microbes capable of degrading toxins holds promise (an example being genetically modified [GM] *Butyrivibrio fibrisolvens* capable of degrading a toxin, fluoroacetate); but may face obstacles for regulatory approval and adoption because of their possible adverse ecological effects.

Prebiotics are commonly fed to weanling pigs in Japan and are increasingly being used in Europe (Ficklinger, van Loo and Fahey Jr., 2003), while their use in North America is just beginning. Due to lack of information about their efficacy, the commercial use of prebiotics is not as widespread as of probiotics, and in both developed and developing countries use is limited to some research stations. Novel products in the form of synbiotics, a mix of pre- and pro-biotics are expected to be available, once more is known.

Silage additives

The use of bacteria such as *Lactobacillus plantarum*, *L. buchneri, L. acidophilus, Streptococcus bovis*, *Pediococcus pentosaceus*, *P. acidilacti*, and *Enterococcus faecium* and yeasts such as *Saccharomyces cerevisiae* alone or their mixtures, and the use of enzymes (cellulases, hemicellulase, amylase etc.) alone or as a mix with microbial inoculants in silage production is restricted to few intensively managed commercial dairy and beef production farms in developing countries. However, the extent of their use in developed countries is higher.

Recombinant metabolic modifiers

The beneficial effects of recombinant somatotropin in most farm animals are well established. Recombinant somatotropin technology is considered to be very effective for pigs, less so for ruminants and mostly ineffective for chickens. Recombinant bovine somatotropin (rBST) increases feed conversion efficiency and milk yield and decreases milk fat. The increase in milk yield has been reported to be about 10–15 percent, both in developed and developing countries (Chauvet and Ochoa, 1996; Forge, 1999). Administration of rBST to lactating Holstein cows also improved milk yield during heat stress without compromising fertility (Jousan *et al*., 2007). The commercial use of rBST is common in approximately 20 countries, including developing countries, for example Brazil, Colombia, Costa Rica, Egypt, Honduras, Jamaica, Kenya, Mexico, Namibia, Peru, South Africa, Turkey and Zimbabwe (Forge, 1999; Cowan and Becker, 2006). It is banned in the EU and most other industrialized countries with the exception of the United States, mainly because of animal welfare concerns. Recombinant porcine somatotropin is permitted for use in approximately 14 countries. It increases muscle growth, reduces body fat and improves carcass composition, which gives higher market value to the product.

A prerequisite to realizing the benefits of recombinant somatotropin is feeding a good quality diet. In most developing countries, animals, particularly those raised by smallholder farmers, do not have access to such diets. In addition, the genetic potential of these animals for production is usually low compared with animals in developed countries, giving lower "absolute" response to the administration of somatotropin, and thus decreasing the benefit to cost ratio. Therefore, the use of recombinant somatotropin in developing countries could be expected to be commercially viable only in intensive livestock production systems. However, before adopting this technology, an economic analysis of the production unit should be available. Regular administration of recombinant somatotropin could also become a constraint under some production conditions. The risks of increasing mastitis or latent viral or other pathogenic infections (the elimination of xenobiotics is slower in animals receiving rBST) and the negative effects of rBST on fecundity and fertility when administered before breeding must also be taken into consideration before introducing this technology (Chilliard *et al*., 2001).

Genetically improved feed

While crops are covered separately in Chapter 1, it should also be mentioned that the genetic enhancement of feed crops represents another important pathway towards the improvement of animal nutrition. A range of conventional strategies and biotechnology tools have been used for this purpose. For example, in the 1960s, scientists discovered that maize with the opaque-2 gene had higher levels of lysine and tryptophan which are essential amino acids for monogastric animals. This led to the release of "quality protein maize" (QPM) varieties developed through conventional or marker-assisted selection. Over 1.2 million ha have been planted to QPM varieties and hybrids in developing countries which are used for direct human consumption or as animal feed (Vivek *et al.*, 2008). Although no GM crops specifically developed for animal nutrition purposes have yet been commercially released, they are in the pipeline. For example, it is estimated that GM maize containing the gene encoding the phytase enzyme may be commercialized in China in 2010 (Stein and Rodríguez-Cerezo, 2009). Further details on applications of crop biotechnologies in developing countries are given in Chapter 1.

Molecular gut microbiology and rumen microbe genomics

Although at the research stage, these approaches have high potential for increasing livestock productivity by providing a better insight into the digestive physiology of livestock. Since the development of the Hungate tube in 1950, understanding has increased about the role of strict anaerobic rumen micro-organisms in the digestion of feed, the microbiological transformations that occur in the rumen, and the physiological importance of the products released from feed as a result of microbial digestion. The molecular era in the field of rumen microbiology started with the building of gene libraries, cloning and manipulation. By the early 1990s there were over 100 cellulase genes sequenced from rumen bacteria. Cellulolytic bacteria were found to contain multiple copies of genes from a variety of cellulase gene families, and in some cases the cellulases were assembled into cellulolytic complexes called cellulosomes. From the complexity of the genetic system required to degrade cellulose it became obvious that it would be very difficult in the short term to make a significant impact on cellulose hydrolysis using genetic manipulation. At present, another technical challenge is to introduce and maintain recombinant strains in the mixed rumen population, and survival of new strains is not well understood.

Stahl *et al*. (1988) described the use of 16S rRNA gene sequences to classify and identify rumen microbes based on DNA sequence. This study and the development of PCR revolutionized the study of diversity and complexity of ruminal microbial communities without the need to culture them. The ongoing "omics" phase in rumen microbiology is giving functional dimension to the changes in microbial ecology of the rumen and is likely to provide opportunities for manipulation of rumen microbes for enhancing the efficiency of fibre utilization, decreasing methane production and increasing the utilization of feeds containing toxins and antinutritional factors.

So far, the direct benefit of these advances to developing countries has been by providing a means to track the establishment of a bacterium, *Synergestis jonesii* (which degrades mimosine, a toxic component) in the rumen by using a PCR-based technique, enabling better utilization of *Leucaena luecocephala* leaves as livestock feed. PCR-based tracking techniques would also be useful in developing effective probiotics for monogastric and ruminant animals. In developing countries, PCR-based detection methodologies are better developed for animal health applications. A strategic collaboration between the health and production scientists within developing countries would certainly make animal nutritionists better able to address challenges in economic animal nutrition. The Joint FAO/IAEA Division has helped to build capabilities in Brazil, China, Colombia, Cuba, Ethiopia, India, Thailand and Turkey to evaluate microbial diversity, quantify microbes without culturing them, and study changes in commensal microbes as affected by additives and feeding strategies[4]. These PCR-based methodologies will complement conventional feed evaluation methodologies to develop rational feeding strategies in developing countries.

3.4.3 Biotechnologies in animal health

In vast areas of the world, animal diseases cause severe losses in livestock systems, wildlife and, in the case of zoonotic diseases, humans. Often the devastation of acute diseases which kill a high percentage of animals or the long-term effect of chronic diseases, has a massive effect on economies and hence on the overall conditions for human existence. Recent

4 www-naweb.iaea.org/nafa/aph/crp/aph-molecular-techniques.html

incidences of emerging and re-emerging transboundary animal diseases have resulted in huge economic losses. Since 2005, the OIE has reported the occurrence of FMD in Africa, Asia and South America; classical swine fever (CSF) in Africa, Asia and Europe; and highly pathogenic avian influenza (HPAI) in Africa, Asia and Europe. The Secretariat of the Global Framework for the Progressive Control of Transboundary Animal Diseases (GF-TADs), a joint FAO/OIE initiative, carried out regional consultations to identify priority diseases and the best ways for their administration, prevention and control. From this, it was noted that FMD was the first global priority (Domenech *et al*., 2006). Rift Valley fever and HPAI were ranked as major zoonotic diseases. PPR, contagious bovine pleuropneumonia. African swine fever and CSF were also regionally recognized as top priorities (Domenech *et al.,* 2006). The specific detection of agents causing such diseases and establishment of early warning systems are major tasks since timely action could prevent their spread to large animal populations and many countries.

The widespread occurrence of animal diseases in developing countries is one of the major factors responsible for decreasing livestock productivity in these countries. Generally, these diseases mostly affect resource-poor livestock farmers and hence their effective control is essential for poverty alleviation. Vaccination and molecular-based diagnostics are increasingly being used to improve control strategies. The application of inactivated or live attenuated vaccines offers a cost-effective measure to control or even eradicate an infectious disease as exemplified by the near-eradication of rinderpest. During the last two decades these vaccines have played a more prominent role in enhancing livestock production in developing countries. In 2003, the estimated market value of animal diagnostics was around US$0.5 billion while that of animal therapeutics such as vaccines, pharmaceuticals and feed additives was US$15.1 billion (Elder, 2004). The number of licenced animal products is 105, most of them biological, including veterinary vaccines and diagnostic kits. The animal health industry invests over US$400 million annually in research and development (R&D) and the value of animal health biotechnology-based products is US$2.8 billion (Belák and Gay, 2007), while the contribution of veterinary vaccines to this global market is approximately 23 percent (Meeusen *et al*., 2007).

Diagnostics

Molecular-based serological techniques, for example those using monoclonal antibodies and recombinant antigens in ELISA, as well as PCR-based diagnostics, are widely used in developing countries. Information on their application for specific diseases, as well as detailed descriptions of the methods involved, are provided by the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (OIE, 2008), whose objective is to provide internationally agreed diagnostic laboratory methods and requirements for the production and control of vaccines and other biological products. It covers standards for diagnostic tests and vaccines for the large number of diseases listed in the OIE Terrestrial Animal Health Code.

Methods based on ELISA and PCR are in wide use globally. In Africa, ILRI and the ARC-Onderstepoort Veterinary Institute, South Africa, are leaders in this area. Currently, ELISA forms the large majority of prescribed tests for the OIE-notifiable animal diseases, with many kits available in developing countries. Nevertheless, despite a great deal of technology transfer many countries still lack the capacity to exploit the full potential of this type of assay to develop tests, and their level of training needs to be improved. The OIE has developed a twinning programme between OIE Reference Laboratories and candidate laboratories for scientific capacity building and the improvement of expertise within developing countries (OIE, 2006). National laboratories such as the Laboratoire National de l'Élevage et de Recherches Vétérinaires in Senegal, the National Veterinary Institute in Ethiopia and the Central Veterinary Laboratory in Niamey, the Niger are examples of institutions that possess good diagnostic capability. In South Africa, efforts are being made to develop molecular diagnostic kits for tick-borne diseases. In Asia and Latin America, public sector production of diagnostic kits for animal diseases can be found in China, India, Thailand, Brazil, Mexico, and Chile. Research capabilities for the development, standardization and validation of diagnostic methods are also well advanced in these countries.

PCR-based diagnostics are increasingly used in developing countries for the early diagnosis of disease. However, their use is largely restricted to laboratories of research institutions and universities and to the central and regional diagnostic laboratories run by governments. Their use in field laboratories belonging to veterinary health authorities is basically non-existent. The participation of the private sector in animal disease diagnostics is restricted to the development and commercialization of kits, and that too in few developing countries such as India, China, Thailand, Brazil, Chile and South Africa.

Molecular epidemiology is one of the most powerful applications of gene-based technologies in animal health. PCR-based techniques are used in molecular epidemiology in some developing countries (for example, Brazil, China, India, Mexico, South Africa) to compare sequence data on PCR products to determine the genetic relationship of the disease-causing agents, thereby facilitating the determination of their source, monitoring their spread, and providing new information about their biology and pathogenicity. The information obtained from such investigations helps develop appropriate strategies for the diagnosis and control of diseases and to monitor the impact of disease control programmes. Molecular genetic analysis studies of rinderpest viruses have contributed substantially to the Global Rinderpest Eradication Programme (GREP). Similar studies on virus serotypes associated with FMD were useful for vaccination and control programmes in Asia (Madan, 2005).

Increased use of molecular-based diagnostics in developing countries has been possible due to the availability of reliable and affordable laboratory equipment and the increased support of international organizations such as FAO, IAEA and OIE, in providing training and post-training support services, regular proficiency testing, and giving increased emphasis on validation, standardization and quality control of diagnostic techniques.

Lately, the emphasis in training programmes and developmental projects, for example, those sponsored by FAO and IAEA, has been on quantitative or qPCR which requires less hands-on time than conventional PCR, is less labour intensive and more accurate, has a higher rate of throughput, obviates the need to handle post-PCR products, has a higher sensitivity and lower risk of contamination, allows quantitative estimation and uses multiplex diagnostics (multiple primers allowing amplification of multiple templates within a single reaction). The Joint FAO/IAEA Division has technical cooperation projects in 23 countries where qPCR is used as part of diagnostic services, and has held a number of training courses on biotechnology-based disease diagnostics tools for participants from many developing countries. The training has covered the diagnosis of brucellosis, fascioliasis and HPAI.

An EU-funded Consortium, FLUTRAIN, is also active in providing training to East European, Asian and African scientists in diagnostics and disease management tools. In January 2009, it provided training on diagnosis of HPAI to participants from Bangladesh, India, Morocco, Egypt and the Philippines. Currently, the National Veterinary Institute[5], Uppsala, Sweden, an OIE Collaborating Centre, is planning hands-on training focusing on HPAI sequencing, bioinformatics and phylogeny to participants from Bulgaria, Hungary, Iran, Iraq, Macedonia, Namibia, Romania, Syria, Turkey, and Ukraine. WHO and FAO have also trained developing country scientists in molecular diagnostics in zoonotic and transboundary animal diseases.

Through a Joint FAO/IAEA Division Coordinated Research Project on the examination of methods to differentiate infected and vaccinated animals with FMD[6], kits from many sources were examined in a network of laboratories. Thousands of sera were evaluated from many sources in order to validate the practical use of the kits. Such kits are now used routinely and are important in epidemiological decision making concerning whether countries or areas within countries are FMD virus free. This project also highlighted the cooperation between public institutions and commercial companies producing kits using non-structural proteins of FMD as target antigens.

The area of diagnostics is beset with problems of validation. Many competent diagnostic assays that are fit for their intended purpose exist, but to varying degrees may need to be validated and harmonized. International staff providing training on PCR-based

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5 www.sva.se/oie-cc

6 www-naweb.iaea.org/nafa/aph/crp/aph-fmdv.html

methodologies are of the opinion that only 30 to 50 percent of laboratories in developing countries are using the techniques properly (J. Crowther and G.J. Viljoen; personal communication). One-time training is not sufficient and there is a need for after-training support services to most of laboratories. The challenges are most severe in those countries with a low knowledge base in biochemistry and in good laboratory practice and which lack a good laboratory infrastructure. Work to make PCR-based assays robust, to develop isothermal amplification methods (which do not require thermal cycling and result in a colour change that can be seen without the need for equipment), and on-site assays (e.g. pen-side tests, biosensors) (Belák, 2007), is ongoing. For example, efforts are underway to develop isothermal amplification-based assays for HPAI and PPR at the Joint FAO/IAEA Division[7]. Such developments would particularly enhance the possibility of accurate testing and reporting in developing countries where reporting systems and sending of samples are highly problematic. The Institute for Animal Health (IAH) in the United Kingdom has developed a pen-side diagnostic kit for rinderpest which uses eye-swabs and gives results in only five minutes. Field trials have been conducted in India and Africa.

Efforts to enhance human capacities in developing countries and countries in transition to use modern diagnostic methods will improve the capability of surveillance systems and disease control in these countries. International organizations are encouraged therefore to develop mechanisms and provide resources to train scientists to have the necessary skills to perform good research. Such capabilities will equip the scientific community to develop and adapt biotechnologies that meet local conditions and provide solutions to emerging and future problems.

Recombinant vaccines

Immunization can be one of the most effective means of preventing and hence managing animal diseases. In general, vaccines offer considerable benefits at a comparatively low cost, which is a primary consideration for developing countries. Molecular techniques can be used to produce a variety of different constructs of pathogenic agents and offer several advantages over more conventional vaccines such as: the deletion of the gene(s) responsible for causing disease and thus greater safety; increased stability (which is an advantage for their effective use in developing countries); the possibility of developing vaccines against protozoan and helminth parasites; and differentiating between infected and vaccinated animals through detecting antibodies either against the peculiar proteins elicited by the vaccine or failing to detect antibodies against the deleted gene/protein (DIVA vaccines). However, few recombinant vaccines are being commercially produced (Table 3), and so far their use in developing countries is negligible.

[7] www-naweb.iaea.org/nafa/aph/stories/2009-avian-influenza.html

TABLE 3

SOME COMMERCIALIZED RECOMBINANT VACCINES

Target pathogen	Target animal	Brand name	Distributor	Characteristics
Viral vaccines				
Porcine circovirus type 2 (PCV2)	Pigs	Porcilis-PCV2	Intervet	Inactivated baculovirus expressed PCV2 ORF2 protein; adjuvanted
PCV2	Pigs	Suvaxyn PCV2	Fort Dodge	Inactivated PCV1-2 chimera; adjuvanted
Pseudorabies virus	Pigs	Suvaxyn Aujeszky	Fort Dodge	gE- and thymidine kinase-deleted marker vaccine
Classical swine fever virus	Pigs	Porcilis Pesti	Intervet	Baculovirus recombinant E2 protein without emulsion
Classical swine fever virus	Pigs	Bayovac CSF E2	Bayer Leverkusen	Baculovirus recombinant E2 protein without emulsion
Bovine herpesvirus type 1 (BHV-1)	Cattle	Bovilis IBR Marker	Intervet	Live or inactivated gE-deleted marker vaccine
Marek's disease virus (HTV) and infectious bursal disease virus	Poultry	Vaxxitek HVT+IBD	Merial	Live recombinant chimera virus expressing VP2 gene of IBD on HTV virus
Newcastle disease virus (NDV)	Poultry	Not applicable	Dow AgroSciences	HN recombinant produced in plant cell lines (registered but not on market)
Newcastle disease virus	Poultry	Vectormune FP-ND	Biomune	Fowlpox virus vectored
Avian influenza virus (H5N1) and NDV	Poultry	Not applicable	Intervet	Chimera virus on NDV backbone; field trials in 2007
Avian influenza virus	Poultry	Poulvac FluFend I AI H5N3 RG	Fort Dodge	Chimera H5N3 virus, inactivated in oil-based adjuvant
Avian influenza virus	Poultry	Trovac AI H5	Merial	Fowlpox virus-vectored H5
Bacterial vaccines				
Actinobacillus pleuropneumoniae	Pigs	PleuroStar APP	Novartis Animal Health	Recombinant ApxII, TbpB, CysL, OmlA(1), and OmlA(2) proteins
Actinobacillus pleuropneumoniae	Pigs	Porcilis APP	Intervet	Extracted ApxI, ApxII, ApxIII, and outer membrane proteins
Salmonella	Chickens, Hens	Megan Vac1 MeganEgg	Lohmann Animal Health International	Double gene-deleted *S. enterica* serovar *Typhimurium* strain
Brucella abortus	Cattle	RB-51	Colorado Serum Company CZ Veterinaria	Spontaneous rifampin-resistant rough mutant

Source: Meeusen *et al.* (2007)

Commercial tick vaccines: TickGUARD and Gavac vaccines against Boophilus microplus (Egerton, 2005)

The successful application of a recombinant DNA vaccine for the elimination of foot-rot disease in Nepal and Bhutan has been described, but was done on an experimental basis only (Egerton, 2005). In 1994, recombinant vaccines against *Boophilus microplus* were produced in Australia (TickGUARD vaccine) and Cuba (Gavac vaccine). Both vaccines have been commercialized and tested in the field, e.g. in Argentina, Australia, Brazil, Cuba, Egypt and Mexico, and have been shown to be efficacious, although with some degree of variation (Willadsen, 2005). A killed subunit vaccine has been developed in Israel against coccidiosis in poultry. However, it is expensive to produce (Meeusen *et al*., 2007). The University of California, Davis, United States, has developed a recombinant DNA vaccine against rinderpest and tested it in restricted conditions in Ethiopia. DNA sequencing and other molecular tools are in use at the University of Ibadan, Nigeria, in an effort to develop a vaccine for the prevention of infectious bursal disease, also known as Gumboro disease, which causes poultry deaths worldwide (Juma and Serageldin, 2007). Also in Africa, ILRI and the ARC-Onderstepoort Veterinary Institute, South Africa, are leading the way in the development of new vaccines.

According to an OIE survey (MacKenzie, 2005), 17 percent and 50 percent of African and Asian countries respectively produce or use animal vaccines that are biotechnologically derived (Table 4). Most of these countries are using vaccines produced in other countries rather than producing their own. In Africa, only one country reported using DIVA vaccine.

A recombinant capripox-rinderpest virus vaccine has been developed by the IAH and field trials are running in Kenya. Using the genome data of African swine fever virus, efforts to design, develop and test new vaccines are also underway at this institute[8].

TABLE 4

APPLICATION OF BIOTECHNOLOGY-DERIVED ANIMAL VACCINES IN DIFFERENT PARTS OF THE WORLD

	Global	Africa	Asia	Middle East
Number of countries producing or using biotechnology-derived vaccines in animals	40 (44)*	4 (17)	7 (50)	1 (50)
Number of countries using viral-vectored vaccines which include antigen(s) from unrelated organisms	26	2	4	0
Number of countries using bacterial-vectored vaccines which include antigen(s) from unrelated organisms	16	1	5	0
Number of countries using vaccines which have deleted antigen(s) to differentiate infected from vaccinated animals (DIVA)	22	1	3	1
Number of countries using vaccines that include recombinant proteins	26	0	6	0
Number of countries using DNA vaccines	6	0	2	0
Number of countries using other products (undefined)	1	0	1	0

Source: adapted from MacKenzie (2005)

* Values in parentheses are the percentage of countries that responded

8 www.iah.bbsrc.ac.uk/

The DIVA technology has been applied successfully to HPAI and pseudorabies (Aujeszky's disease) eradication campaigns, and has been proposed for use in the eradication of CSF and FMD (Pasick, 2004). The DIVA-based vaccines for infectious bovine rhinotracheitis (IBR) and pseudorabies have been available commercially since the 1980s (Meeusen *et al*., 2007). Work to develop marker vaccines against PPR and rinderpest is also in progress (Mahapatra *et al*., 2006; Parida *et al*., 2007; Diallo *et al*., 2007). For CSF, the first DIVA-based vaccines were based on baculovirus-expressed E2 glycoprotein of CSF virus and have been marketed since 1993. However, these have the disadvantage of inducing a delayed immune response and are therefore not as effective as the conventional live attenuated vaccine. Various possibilities for the development of effective DIVA-based vaccines for CSF are discussed by Beer *et al*. (2007).

The first plant-based vaccine (recombinant viral hemagglutinin neuraminidase (HN) protein generated in plant cell lines via *Agrobacterium* transformation) for Newcastle disease virus in poultry could successfully protect chickens from viral challenge, but no product is yet on the market (Meeusen *et al*., 2007). Recombinant vaccines have been developed that are highly effective in preventing infection with tapeworms: *Taenia ovis* in sheep, *Taenia saginata* in cattle, *Taenia solium* in pigs and *Echinococcus granulosus* in livestock (Lightowlers, 2006; Eddi *et al*., 2006). Since farmers must destroy meat from animals infested with tapeworm, the new vaccines could save farmers from huge economic losses.

In addition to validated, robust, specific and sensitive diagnostic tools and safe and effective vaccines, control and eradication of animal diseases requires a complete package of good veterinary infrastructure, reporting systems, laboratories with skilled staff, epidemiological units able to execute surveys, and a carefully designed plan with clear objectives. Regional and intergovernmental cooperation is also vital since many of animal diseases are transboundary.

Sterile insect technique

The SIT depends on the integration of biological and engineering techniques to produce on an industrial scale and release, usually by air, adequate numbers of reproductively sterilized insects of the target pest in areas where it severely threatens the environment, agriculture or livestock production. Virgin female individuals in the target insect pest population that are mated and inseminated by released sterile male insects do not produce any offspring. Repeated inundative releases of mass-produced sterile insects can be integrated with suppression, eradication, containment or prevention strategies against key insect pests.

Trypanosomosis is a disease caused by blood parasites of the genus *Trypanosoma* and is transmitted in Africa by tsetse flies (*Glossina* spp). More than 30 tsetse fly species and subspecies infest an area of 8.7 million square km (approximately a third of Africa's total land area) and affect animals and humans in 35 sub-Saharan countries. The infection threatens approximately 45–50 million head of cattle and WHO estimates that in the year 2000 some 50–60 million people in Africa were exposed to the bite of tsetse flies, which can result in sleeping sickness. There are situations where the SIT may be a necessary component of an AW-IPM approach for freeing areas under agricultural development from the trypanosomosis disease burden.

The SIT played a vital role in the eradication of the tsetse population of *Glossina austeni* from Unguja Island (Zanzibar) using an AW-IPM approach. The fly population was initially suppressed using insecticide-based control strategies such as stationary targets and pour-on insecticides for livestock. This was followed by the sequential aerial release of sterile males which drove the population to extinction, i.e. the last wild tsetse fly was trapped in 1996. Using data from 1999 as a baseline, an increase in average income per annum of farming households by 30 percent was recorded in 2002. Overall the quality of people's life improved substantially due to increased livestock and crop productivity, animal availability for transport and traction etc. In addition, the removal of the tsetse population from the Jozani forest reserve facilitated preserving this endangered habitat and removed a major threat to adjacent livestock and agricultural systems. Efficient wildlife management practices have also resulted in an increase in the numbers of some rare and protected wildlife species, such as the Zanzibar red colobus monkey, *Pilicolobus kirkii*.

The African Union's Pan-African Tsetse and Trypanosomiasis Eradication Campaign (AU-PATTEC) is coordinating various national programmes that aim to integrate the SIT for creating selected trypanosomosis- and tsetse-free zones in Ethiopia, Kenya, Senegal, Uganda, Tanzania and in a transboundary area in Mozambique, South Africa and Swaziland, (Feldmann *et al*., 2005). The Joint FAO/IAEA Division supports this programme, providing in addition technical advice in Burkina Faso, Chad, Mali and Zimbabwe to assess whether the SIT can be used in these countries as part of AW-IPM campaigns[9].

The SIT was also used to suppress, locally eradicate or prevent the (re-)invasion of two other livestock pest insects, namely the New World screwworm (NWS) fly, *Cochliomyia hominivorax*, and the Old World screwworm (OWS) fly, *Chrysomya bezziana*, which cause myiasis in warm-blooded vertebrates (humans, livestock and wildlife). The SIT has been used to eradicate NWS in North and Central America and Libya, as well as containing it along the Panama-Colombia border. Most of the South American continent, except Chile, is infested with NWS. Vargas-Terán, Hofmann and Tweddle (2005) have described the various steps needed for making this continent free of NWS. OWS is widely distributed on the Indian subcontinent, in sub-Saharan Africa, and in Southeast Asia, as far north as Taiwan Province of China and to

[9] www-naweb.iaea.org/nafa/ipc/field-projects-ipc.html

Papua New Guinea in the southeast. The SIT has been successfully tested against this species in Papua New Guinea and Malaysia. In late 2007, an outbreak of OWS flies was observed in Yemen that is threatening the livelihoods of people, either directly or through their livestock.

Biotechnological tools such as molecular markers are being used to study the degree of gene flow between various pest insect populations and provide indications on their relationship and potential isolation. This useful information about particular pest populations can lead to better planning of AW-IPM campaigns that may integrate a SIT component. At present, there are many uncertainties surrounding the production and use of transgenic insects due to instability of the insertion and expression of the transgene. In addition, it requires addressing public concerns and putting in place a regulatory mechanism to properly conduct a risk assessment (Robinson, 2005).

Bioinformatics

Bioinformatics is the comprehensive application of statistics, biology and a core set of problem-solving methods for helping to understand the code and evolution of life as well as their implications. It deals with the use of information technology in biotechnology for data storage and warehousing and DNA sequence analysis. Bioinformatics has overarching implications in the areas of animal health, reproduction and nutrition.

The design of diagnostic tools, drugs and vaccines will rely increasingly on bioinformatic data through sequence analysis. Gene prediction and functional annotations play an essential role in this process. Developing countries can benefit hugely through such studies because much sequence information and many bioinformatic tools are publicly available and freely accessible. Furthermore, molecular immunoinformatic tools also have the potential to help scientists in developing countries to produce epitope-driven multigene synthetic vaccines. However, developing-country scientists are not skilled in this rapidly expanding area of biology, with the exception of very few countries. In India, web-accessible databanks such as the Animal Virus Information System, and tools to store and analyse information generated by molecular and genomic projects in livestock research are available. Strong linkages exist between information technology and the biotechnology sector. The Biotechnology Information System Network, a division of the Department of Biotechnology of India, has covered the entire country by connecting to more than 50 key research centres. India also has programmes to upgrade the skills of agricultural scientists from other Southeast Asian countries. The contribution of bioinformatics research is of growing importance in the study of life sciences in China and Brazil, while in Africa, ILRI is building capacity in this field through various training programmes. In addition to training, access to improved search engines, data mining programs and other tools to improve access through the Internet to a vast body of biomedical literature and sequence data is required in developing countries.

Although bioinformatics is discussed here in the context of biotechnologies for animal health, it is certain to play a major role in other sectors of livestock production. The cattle genome sequence has recently been completed (Elsik *et al.,* 2009) and the sequences of chicken, pig and sheep genomes are either already available or nearing completion. Bioinformatics has played an important role in these achievements. As stated elsewhere in this Chapter, genome sequence information can be exploited to enhance animal production and health in several ways. In the "post-genomic" era, it has innumerable applications in the areas of comparative, functional and structural genomics.

3.5 REASONS FOR SUCCESSES AND FAILURES IN LIVESTOCK BIOTECHNOLOGIES IN DEVELOPING COUNTRIES OVER THE LAST 20 YEARS

Some important factors affecting success or failure in the applications of biotechnologies in developing countries are listed in Tables 5, 6 and 7 for animal reproduction, genetics and breeding; animal nutrition and production; and animal health respectively. For the purposes here, it is not relevant to list specific technical factors for each of the animal biotechnologies that prevent their wider applicability because many papers are available in the literature providing this information. It is evident from the Tables that, with the exception of molecular diagnosis, the most advanced biotechnologies based on molecular biology are hardly used in developing countries, mainly because they are cost prohibitive, complex and require highly skilled personnel. The high cost of registering products such as new vaccines, probiotics and enzymes is another factor that limits their production in developing countries. The adoption of cloning and transgenesis is also affected by ethical, religious and animal welfare concerns. In addition, these two technologies and recombinant vaccine technology also need to be improved in terms of cost and efficacy in order to be of practical value.

The adoption of less advanced biotechnologies (e.g. progesterone measurement, oestrus synchronization, IVF and ET, cryopreservation, and semen and embryo sexing) has been low. This has largely been due to a combination of inadequate technical skills and infrastructure and inadequate profits for users. For example, liquid nitrogen is necessary for AI with deep-frozen semen and cryoconservation of genetic resources, but it is often costly when purchased commercially and requires a significant capital investment for on-site production. Factors such as slow speed of sorting, low sperm viability and low fertility rates (12 to 25 percent of that with conventional semen) together with the high cost of semen also limit the successful application of sperm sexing technology. Meanwhile, complicated IVF, ET and embryo freezing procedures and the low rates of success and high costs involved in producing embryos also constrain their wider adoption. The use of monensin and rBST is also affected by low public acceptance and by the lack of adequate or good quality feed in developing countries. Although the production and use of prebiotics, probiotics and silage enzymes are relatively simple, technical constraints, especially insufficient knowledge about how to create the conditions that result in consistent positive responses are the limiting factors for their wide application, even in intensive production systems. Quality control systems and regulatory oversight of the products are non-existent. Silage making is common in developed countries, but has not been popular in developing countries due to a variety of factors including insufficient technical skills of farmers, extension activities and infrastructure and tools; also, in many countries the timing of silage making conflicts with other farm activities that are rated as more important. Silage additives will not be used in developing countries if silage preparation is not practised.

Although technologies such as single cell protein production and solid-state fermentation of lignocellulosic materials can be categorized as low-tech, they have practically not been used at all. The main reason for the failure in adoption of single cell technology is the high cost of production. The amount of biomass produced is small and the liquid volume in which it is produced large; the equipment required for removing water is expensive and the methods are time-consuming; and the energy needed for drying the isolated biomass also increases the cost. Furthermore, the biomass produced has a high nucleic acid content which limits its use in the diets of monogastric animals. The presence of high levels of nucleic acids in single cell protein also makes it a poor protein supplement for ruminants. The reasons for the failure of solid state fermentation of lignocellulosic materials such as straw are also the high cost involved in transport and processing of the straw before inoculation with white rot fungi, considerable loss in energy from lignocellulosic material during fermentation and difficulty in upscaling the process. The quality of the feed obtained after fermentation is not commensurate with the efforts and money spent. In short, the technology does not seem to be profitable.

Among the animal biotechnologies, modest success has been achieved only in the application of AI, molecular diagnostics and conventional vaccines, feed additives and the SIT.

Artificial insemination

AI has played an important role in enhancing animal productivity, especially milk yields, in developing countries that have a well defined breeding strategy and a sound technical base to absorb and adapt the technology to meet their needs. Such countries also have: 1) an effective technology transfer mechanism for AI; 2) effectively integrated international assistance into their national germplasm improvement programmes; 3) built and maintained the infrastructure required; 4) complemented AI with improvements in animal nutrition and veterinary services; and 5) provided adequate economic incentives to their farmers by giving them access to markets and making sure that they get the right price for their products. Many other developing countries lack one or more of these requirements.

Molecular diagnostics and conventional vaccines

In the area of disease diagnosis and control, most national governments have provided reasonably good policy and financial support, driven largely by the zoonotic nature of most of the diseases concerned. The availability of government support facilitated the development of the technical capabilities and physical infrastructure required. The international assistance obtained by developing countries in this field has been well integrated into their national programmes, leading to the realization of better adoption and higher impact. Furthermore, the impact of using these biotechnologies is easy to estimate economically based on projections of the number of animals prevented from dying or becoming diseased. This makes it easier for national and international agencies to quantify the impact of specific technologies and justify their programmes properly. This helps countries to raise more funds nationally and from donors, which in turn gives further impetus to the programmes.

The assistance of international organizations such as FAO, IAEA, OIE and WHO has contributed substantially to the success of biotechnologies such as AI, molecular diagnostics and conventional vaccines. They have facilitated training programmes to improve technical, analytical, and technology transfer skills, and provided financial assistance for building infrastructure, including state-of-the art laboratories. There is a strong positive correlation between the research capabilities of national biotechnological scientists and the scale of application of technologies in the field.

Feed additives

The addition of nutrients and feed additives such as amino acids, enzymes and probiotics to the diets of monogastric animals is driven mainly by the increased benefit to cost ratio of these interventions, leading to greater profit of commercial livestock enterprises. The companies producing additives usually have skilled workers to advise farmers in preparing diets, as well as access to software for balancing protein requirements through the addition of amino acids. These factors have also been important for the success of these technologies. Another reason is that the production of additives is based on fermentation technology which has a long history of use in developing countries and is a low-cost intervention. The technologies have the added advantage of making the farms more environmentally sustainable by reducing pollution. In the near future, regulations on the release of nutrients such as nitrogen and phosphorus into water channels will increasingly be enforced in developing countries, which will further increase the adoption of the technology.

Sterile insect technique

This technology is being applied along with a number of conventional approaches in a concerted manner. The reasons for its success in some places and failure in others have been critically examined (Vreysen, Gerardo-Abaya and Cayol, 2005; Alphey *et al*., 2010). The SIT projects supported by the Joint FAO/IAEA Division in Zanzibar and Libya were highly successful, as were many SIT projects in the area of crop pest control. On the other hand, the NWS programme in Jamaica showed that success cannot be taken for granted and that several prerequisites need to be in place. On the technical side, particularly important success ingredients are: the accurate and adequate collection of baseline data through the involvement of experts; the timely analysis of data; the development of sound operational plans and strategies; the delivery of extensive training to improve local expertise; the use of sterile males that are capable of competing with wild males for mating with wild females, and the availability of backup strains in case of loss of competitiveness in the field; the use of sound monitoring methods to evaluate the competitiveness of sterile insects; the availability of sound monitoring methodologies and their consistent use (use of different methods at the time of baseline data collection and during the SIT execution and monitoring phase could lead to wrong decisions being made). Equally important are meeting sound managerial and operational requirements which include: the presence of a flexible and independent management structure; the consistent availability of funds and trained staff; the presence of adequate expertise in the biology of the target insects and in the management of integrated projects; the strong commitment of all stakeholders, including though public awareness and education initiatives; an independent peer review system; consistency and continuity in the implementation of various components. Many of these are also critical to the success of applying other biotechnologies.

TABLE 5

CURRENT STATUS OF ANIMAL BIOTECHNOLOGIES AND FACTORS INFLUENCING THEIR APPLICABILITY IN DEVELOPING COUNTRIES: ANIMAL REPRODUCTION, GENETICS AND BREEDING

Biotechnology	Extent of use	Public and government acceptance	Current technical capability for using it	Current technical capability for adapting or developing it	Infrastructure and materials and tools available for its use	Relative cost	Skills required for application	Potential for generating impact (time frame < 10 years)
AI	Moderate	High	Moderate	Low	Moderate	Moderate	Moderate	High
Progesterone measurement	Low	High	Low	Low	Low	Moderate	Moderate	Moderate
Oestrus synchronization	Low	High	Low	Low	Low	Moderate	Moderate	Moderate
IVF and ET	Low	High	Low	Low	Low	High	High	Moderate
Molecular markers	Low	High	Low	Low	Low	Moderate	High	Low
Cryopreservation	Low	High	Moderate	Low	Low	Moderate	High	High
Semen and embryo sexing	Low	High	Low	Low	Low	High	Moderate	High
Cloning	Low	Low	Low	Low	Low	High	High	Low
Transgenesis	None	Low	Low	Low	Low	High	High	Low

TABLE 6

CURRENT STATUS OF ANIMAL BIOTECHNOLOGIES AND FACTORS INFLUENCING THEIR APPLICABILITY IN DEVELOPING COUNTRIES: ANIMAL NUTRITION AND PRODUCTION

Biotechnology	Extent of use	Public and government acceptance	Current technical capability for using it	Current technical capability for adapting or developing it	Infrastructure and materials and tools available for using it	Relative cost	Skills required for application	Potential for generating impact (time frame < 10 years)
Feed additives: amino acids, enzymes & probiotics	Moderate in intensively managed commercial monogastric farms; low in ruminant production systems	High	Moderate	Moderate	Moderate	Moderate	Moderate	High
Prebiotics	Low	High	Low	Low	Low	Moderate	Moderate	Moderate
Silage additives	Low	High	Low	Low	Low	Moderate	Moderate	Low
Monensin	Low	Moderate	Moderate	Moderate	Low	Moderate	Moderate	Moderate
Single cell protein	Low	High	Moderate	Moderate	Moderate	Moderate	Moderate	Low
Solid state fermentation of lignocellulosics	None	High	Moderate	Moderate	Moderate	Moderate	Moderate	Low
Recombinant somatotropin	Low	Moderate	Low	Low	Low	Moderate	Moderate	Moderate
Molecular gut microbiology	Low	High	Low	Low	Low	Moderate	High	Moderate

TABLE 7

CURRENT STATUS OF ANIMAL BIOTECHNOLOGIES AND FACTORS INFLUENCING THEIR APPLICABILITY IN DEVELOPING COUNTRIES: ANIMAL HEALTH

Biotechnology	Extent of use	Public and government acceptance	Current technical capability for using it	Current technical capability for adapting or developing it	Infrastructure and materials and tools available for using it	Relative cost	Skills required for application	Potential for generating impact (time frame < 10 years)
Molecular diagnostics	Moderate	High	Moderate	Low	Moderate	Moderate	High	High
Recombinant vaccines	None	Moderate	Moderate	Low	Low	High	High	High
Conventional vaccines	Moderate	High	Moderate	Low	Moderate	Moderate	Moderate	High
SIT	Moderate	High	Moderate	Low	Moderate	Moderate	High	High
Bioinformatics*	Low	High	Low	Low	Low	Moderate	High	High

* This field is also relevant to animal reproduction, genetics, breeding, nutrition and production

3.6 CASE STUDIES OF THE USE OF BIOTECHNOLOGIES IN DEVELOPING COUNTRIES

3.6.1 Sustainable intensification of sheep rearing on the Deccan plateau in India[10]

Deccani sheep are reared traditionally in flocks of 20–200 ewes on the Deccan plateau in southwestern India by the Dhangar community in Maharashtra State as well as in the States of Karnataka and Andhra Pradesh. Sheep rearing is well integrated in the agricultural production system. Sheep graze on crop residues and grass along roadsides, farm bunds and canal verges. Sheep manure is sold to farmers at a remunerative price and is in great demand for cash crops such as sugarcane and orchards. Often sheep are penned overnight in farmers' fields. Sheep rearing communities earn a good livelihood but are socially disadvantaged with poor access to civic amenities and education. They rear sheep mainly to earn an income from selling lambs. The sale price of the coarse wool produced is usually not enough to cover the cost of shearing. Breeding rams are always with the ewe flock and mating is unplanned. Deccani ewes exhibit oestrus throughout the year with the possible exception of the winter months of January–February and the hot summer months of April to early May. Deccani ewes have only single offspring and lamb about every ten–twelve months. Flock owners sell the lambs in nearby markets on specified weekly market days when the lambs have reached about 3.5 months of age and 12–15 kg of weight. Lambs are sold on a per head basis and the price per kg live weight works out at 80–100 rupees (US$1.6–2). The price of sheep meat has increased by 10–20 percent every year for the past several years.

Seventy percent of smallholder shepherds migrate during the dry season to areas with higher rainfall to find grazing and water for their sheep. The duration of migration varies from 3-8 months and the migration distance varies from 20–200 km. Grazing flocks are always shepherded and supervised closely, and the sheep are penned near the owner's house at night. It is common to cross-foster lambs to ewes or goat does that produce more milk than the dam. Lambs are valuable and even very young orphan lambs fetch a price. The profitability of sheep production is thus sensitive to the reproductive rate and even a modest increase would increase the owner's income substantially. Grazing land available for sheep is being lost steadily over the years due to erosion and other forms of degradation, increasing urbanization, industrialization and the expansion of irrigation and crop agriculture into marginal lands. Demand for sheep meat, however, is also increasing constantly. The sustainable intensification of sheep rearing to improve sheep productivity and efficiency could therefore be viable.

[10] Contributed by Chanda Nimbkar, Animal Husbandry Division, Nimbkar Agricultural Research Institute, Phaltan, Maharashtra, India - April 2009; Nimbkar et al., 2009.

The *FecB* or Booroola mutation in sheep is an autosomal mutation in the bone morphogenetic protein receptor, type 1B, gene (BMPR1B) that has a large additive effect on the ovulation rate and is partially dominant for litter size. *FecB*^{B} is the allele at this locus promoting higher fecundity while *FecB*$^{+}$ is the wild type allele. For ten years from 1998, the Nimbkar Agricultural Research Institute (NARI), an NGO, ran a series of projects funded by the Australian Centre for International Agricultural Research (ACIAR) to investigate ways of improving the performance of the local Deccani breed. The University of New England, Australia, the National Chemical Laboratory (NCL), Pune, India, and the University of Melbourne, Australia were major collaborators in the projects. One of the initiatives was the introduction of the *FecB*^{B} mutation from the small, prolific Garole sheep (adult ewe weight 12–15 kg) of Sunderban in West Bengal State into the Lonand strain of the Deccani breed (adult ewe weight 28 kg) followed by backcrossing based on the *FecB* genotype in order to improve prolificacy while retaining the larger size, local adaptation and meat producing ability of the Deccani breed. A composite strain of Deccani, Israeli Dairy Awassi and Bannur was also produced with the *FecB*^{B} mutation introduced from the Garole to benefit from the larger size and superior milking ability of the Awassi and the meaty conformation of the Bannur. Crossbred *FecB*^{B} carrier ewes and rams were disseminated into local shepherds' flocks. However, after the first introduction of ewes, further dissemination was only through rams due to adaptation problems associated with the ewes. Additionally, 40 *FecB*^{B} carrier rams were purchased for breeding by individual sheep owners, NGOs and State governments from Maharashtra and five other states.

One copy of *FecB*^{B} led to an increase in the ovulation rate from 1.0 egg to 2.0 eggs and an increase in live litter size at birth from 1.0 to 1.6 in the NARI flock and from 1.0 to 1.4 in smallholder flocks. Litter size of homozygous ewes was similar. Thus, only about 40 percent of the *FecB* carrier ewes in smallholder flocks had twins and less than 5 percent of the litters of carrier ewes were triplets. The increased litter size was found to be moderate and manageable under the existing production system of smallholders. The small changes in management with increased twinning in smallholder flocks included keeping young lambs behind in the pens when ewes were grazing and providing lambs with a small amount of supplementary feed. Compared with 0.9 lambs of three months of age weaned by non-carrier ewes, *FecB*^{B} ewes weaned 1.3 and 1.2 lambs in the NARI and smallholder flocks respectively. This was a 33 percent increase in productivity and income for a negligible amount of extra expenditure on feed and some extra care. A higher gain in productivity and income is expected from the progeny of the more recent batches of *FecB*^{B} carrier rams sent to smallholder flocks as they are the products of more generations of backcrossing, leading to a smaller Garole proportion, a larger size and more of the phenotypic features desired by smallholders. Smallholders were given free veterinary care and sheep insurance for the first four years. Training in ewe and lamb management and health care has been an integral part of the projects since the beginning.

The phenotype of *FecB^B^* carriers (increased number of ovulations and lambs) cannot be measured in males nor in females before the age of puberty, and is not completely associated with genotype in females (a female with two lambs is more likely to carry the *FecB^B^* mutation but often will not be a carrier and carrier ewes do not have twins at every lambing). The DNA test for *FecB^B^* detection was therefore established under the project at NCL.

There are now 13 homozygous and 240 heterozygous adult ewes in 16 smallholder flocks which were born in these flocks. Some shepherds have retained heterozygous rams born in their flocks for further breeding. NARI will continue disseminating *FecB^B^* carrier rams in these and other flocks under a newly funded project from the Indian Government's Ministry of Science and Technology. Under the new project, the DNA test for *FecB^B^* detection will be set up at NARI and cost-effective management techniques for ewes and lambs will be investigated under smallholder flock conditions.

Twinning was thus introduced successfully into non-prolific Deccani sheep from the Garole breed by introgressing the *FecB^B^* mutation with the help of the direct DNA test for detecting the animal's genotype at the FecB locus. NARI is the agency maintaining the nucleus flock and carrying out the genotyping and extension in smallholder shepherds' flocks. Genetic improvement is permanent and is therefore the best technology to improve the productivity of smallholder flocks in remote areas. For additional discussion of this case study, see Nimbkar (2009b).

3.6.2 The Global Rinderpest Eradication Campaign[11]

Rinderpest (cattle plague) is an infectious viral disease of cattle, buffalo, yak and numerous wildlife species that has caused devastating effects throughout history. In the 1890s, rinderpest destroyed nearly 90 percent of all cattle in sub-Saharan Africa and millions of wild animals. Major rinderpest outbreaks last approximately five years and have an average of 30 percent mortalities in a population. This poses a massive risk to millions of small-scale farmers and pastoralists. Major outbreaks of rinderpest could destroy more than 70 million (or 14 million per year) of the 220 million cattle in Africa. With an estimated value per head of US$120, the cost of such an outbreak would be more than US$1 billion per year and a total of US$5 billion, based on an average outbreak lasting five years.

Today, the world is nearly free from rinderpest. Eliminating rinderpest could be viewed as producing a net annual economic benefit to the African region of at least US$1 billion.

[11] Sources: www-naweb.iaea.org/nafa/aph/stories/2005-iaea-rinderpest.html and John Crowther, Joint FAO/IAEA Division; April 2009

The only evidence of the disease surviving refers to a small focus in the Somali pastoral ecosystem that encompasses north eastern Kenya, southern Somalia, and some areas of Ethiopia. The goal of achieving complete freedom from rinderpest from the world is within reach. Its elimination would mark only the second time in history a disease has been eradicated worldwide, the first being smallpox.

The progress towards eradication through large-scale vaccination and surveillance campaigns has been a remarkable triumph for veterinary science. It serves as a powerful example of what can be achieved when the international community and individual national veterinary services and farming communities cooperate to develop and implement results-based policies and strategies. The key local coordinating institutions in the battle against rinderpest have been the Pan African Rinderpest Campaign (PARC) and later the programme for Pan-African Control of Epizootics (PACE), overseen by the African Union. FAO has provided support by serving as the Secretariat of the GREP, while the Joint FAO/IAEA Division provided technical expertise to projects funded by the Technical Cooperation Department of the IAEA.

The initial live vaccine developed by Walter Plowright and colleagues in Kenya with support from the United Kingdom, was based on a virus that was attenuated by successive passages in tissue culture, and he was awarded the World Food Prize in 1999 for this work. Although this freeze-dried live vaccine is highly effective and safe, the preparation loses some of its effectiveness when exposed to heat. Further research was directed at developing a more thermostable vaccine for use in remote areas and success was achieved through research in Ethiopia by Jeffery Mariner supported by the United States Agency for International Development (USAID). One of the striking features of the planning for the latest campaign was the total lack of foresight into the need and use of diagnostics. Although the vaccine side was well catered for (supply), the estimation as to whether vaccines worked (whether antibodies were produced so estimating whether cattle had actually been vaccinated) and whether cattle were immune (the level and relevance of antibodies produced) were not initially addressed in scientific or financial terms.

The task of rescuing this situation fell on the IAEA and certain national institutions such as the IAH and the Institut d'Elevage et de Médecine Vétérinaire Tropicale in France. Basically, serological assays involving ELISA were developed to provide kits for the estimation of anti-rinderpest antibodies in cattle, and to determine also whether animals had antibodies against PPR, the equivalent of rinderpest in sheep and goats. The latter was necessary to sort out the complicated epidemiology of PPR and rinderpest in all species. Then the science of the epidemiology was necessary to allow an accurate assessment of the campaign's success. Later developments involved producing molecular-based methods for the identification and differentiation of rinderpest and PPR. This work allowed the unequivocal determination of

PPR, or ruling out rinderpest, in cases where clinical signs were compatible with presence of either disease. Along with ELISA for antibody detection there were developments of pen-side tests for detecting rinderpest and PPR antigens from eye swabs.

The combined technologies of serology and PCR produced a battery of tests able to specifically assess vaccine efficacy and to differentiate true rinderpest from PPR. Sampling frames were also important as they provided the statistical framework on which success was measured, and these were developed by FAO and IAEA with support from the Swedish International Development Cooperation Agency (SIDA). Along with the supply of tests came quality assurance methods (charting) to allow continuous assessment and external validation of methods (both vital in the long term for laboratory assurance). Such an armoury has permitted many countries to obtain official recognition of freedom from rinderpest according to the provisions of the OIE's international standards. Rinderpest disease is now no longer observed in the world. This status is assured through serosurveillance and other monitoring and by well trained personnel using methods which are of the correct diagnostic sensitivity and specificity to allow the results to be assessed statistically.

Although the cost of vaccination, blood sampling and testing have been high for both developing and developed nations, their effectiveness is demonstrated by the fact that there is only one small focus of virus with the potential to generate disease outbreaks left in the world. By contrast, in 1987, the disease was present in 14 African countries as well as in western Asia and the Near East. The economic impact of these efforts is already clear. Although the costs and benefits have varied considerably from country to country, the figures for Africa mentioned above illustrate the cost-effectiveness of the control measures implemented.

3.6.3 Oestrus synchronization and artificial insemination in buffaloes in Punjab, India[12]

The buffalo is an important component of Indian livestock and contributes around 50 million tons of milk and 1.5 million tons of meat annually, in addition to high valued hides, bones and draught power for agricultural operations. Compared with cattle, however, the buffalo is a slow breeder owing to its delayed puberty (around 36 months), and has a high incidence of suboestrus (20-80 percent) and prolonged postpartum anoestrus (>60 days), resulting in prolonged calving intervals. Interventions to improve fertility and production that are commonly used in dairy cattle have remained ineffective due either to species differences (suboptimal response to various endocrine treatments in buffalo) or to the impracticality of the smallholder farming systems prevalent in India (1–5 animals owned by each farmer).

Total AIs performed in Punjab rose from 1.9 million to 2.8 million between 1998 and 2005 (DADF, 2006). Although buffaloes in Punjab outnumber cattle (six million compared with two million), only 5 percent of buffaloes are bred using AI compared with 45 percent of

[12] Contributed by P.S. Brar and A.S. Nanda, Guru Angad Dev Veterinary and Animal Sciences University, Ludhiana, Punjab, India; April 2009

cows. Poor expression of oestrus, especially during summer (ambient temperature 35–45 °C and a severe lack of green fodder), and poor conception rates following AI have been the major deterrents. The synchronization of oestrus with progesterone and/or prostaglandins followed by fixed-timed AI (FTAI), commonly practised for dairy cows, failed to give the expected results in dairy buffalo, probably due to induced ovulations being inconsistent with too long a time spread. Therefore, there was a need to shorten the "ovulation window" following synchronization to improve fertility in dairy buffalo.

In Punjab, most buffaloes are bred through natural service by using any available bull, very few of which are progeny-tested or evaluated in any way. The genetic potential of buffaloes has therefore seen no discernible increase over the years. An effective protocol that would induce precision in ovulations, increase conception rates and improve progeny through the use of higher potential germplasm could substantially enhance the reproductive efficiency of buffalo. With these objectives, an "ovusynch" protocol was developed for buffalo to improve their fertility following AI. Ovusynch refers to the use of a set of hormones to synchronize oestrus and ovulation followed by FTAI. Extensive studies involving ultrasonographic, endocrinological and clinical observations on cycling buffalo were initiated in 2003. An effective ovusynch protocol was established in 2005 on the basis of the most probable time of ovulation and the best fixed time for AI that would yield acceptable conception rates.

The protocol consists of intramuscular injection of 20 µg of buserelin on the first day of the treatment, 500 µg cloprostenol on day seven and 10 µg buserelin on day nine (~60 hours after an injection of cloprostenol). Postpartum (>60 days) suboestrous buffaloes which remain unbred due to various reasons are selected. They are inseminated at 16 and 40 hours after the second buserelin injection irrespective of the expression of oestrus. Semen from proven and pedigreed bulls of known fertility and genetic superiority is used. Following this treatment, approximately 67 percent of buffalo conceive in winter and 30 percent in summer. If they are supplemented with monensin (200 mg/buffalo/day for 30 days) before the start of the ovusynch application, the conception rate in summer is increased to 60 percent.

Multiple outreach activities are being undertaken to extend the technology for the genetic improvement of farmer-owned buffalo:

- *Pilot Projects:* Twelve pilot farms, involving 700 buffalo have been established in rural Punjab. Up to 70 percent of the enrolled buffalo conceived with semen from progeny tested bulls.
- *Training of Trainers:* Under the auspices of the Centre for Advanced Studies in Veterinary Gynaecology and Reproduction of the Indian Council of Agricultural Research, New Delhi, around 25 scientists from nine Indian states, 75 veterinary staff from the Punjab State Animal Husbandry Department and two international fellows from Mongolia and Myanmar have been trained on the application of ovusynch.

- *Linkages with NGO:* The Dr A.S. Cheema Foundation Trust, Chandigarh, India, is actively involved in the promotion of livestock production in rural areas in north India. The Trust is also bringing the technology to a large number of farmers in various districts of Punjab and the adjoining States of Haryana and Himachal Pradesh through its well established outreach activities.
- *Extension services of the Guru Angad Dev Veterinary and Animal Sciences University, Ludhiana, India:* The extension services of the University are disseminating this technology through the "Lab-to-Land Programme", which consists of field services, field days and other animal health programmes. A conservative estimate would suggest that around 1 000 farmers and 5 000 buffalo have benefited from this programme to date. Of these, 60–75 percent of the buffaloes would have remained unbred for a variable period of 6–12 months in the absence of these efforts. A close follow-up of about 100 heifers produced through this programme at some of the pilot farms revealed that the female buffaloes produced under this study attain puberty at <28 months, compared with an average of >36 months for the state. The intervention led to an increase in milk production and provided additional calves of improved genetic potential to farmers by decreasing the calving interval and the age of first calving in heifers.

Ongoing wider adoption of this technology would contribute substantially to improving dairy buffalo production and benefit the economic situation of the farmers in India and in other buffalo-rearing countries.

3.6.4 Community-based artificial insemination, veterinary and milk marketing services in Bangladesh[13]

Bangladesh has the largest population density in the world and most of its population is rural, with a per capita income among the lowest in the world. This population is continually growing, increasing the demand for food including animal products. Agriculture has evolved in an attempt to meet this demand. The purpose of rearing cattle has been shifting from their utilization as traction to milk and meat producing animals. AI was introduced in 1969 to help contribute to increase productivity but growth rates in production have lagged behind increases in consumption.

At the beginning of the 1990s, the Government of Bangladesh began a programme for small-scale dairy farming which led to a growth rate of 5.6 percent in the industry by 1995. The programme included the use of AI and crossbreeding for introducing germplasm from higher-producing exotic breeds. Farmers initially procured a large number of crossbred

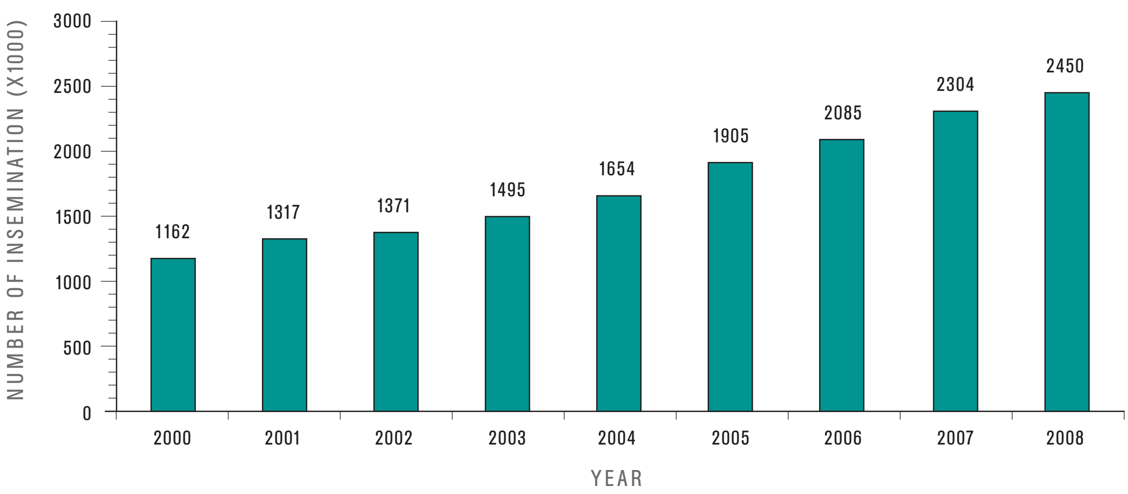
[13] Contributed by Mohammed Shamsuddin, Bangladesh Agricultural University, Mymensingh, Bangladesh; July 2009

cows through the popular AI services. However, the initial programmes were not all sustainable and the growth rate dropped sharply to 2.6 percent in 1997. Poor or non-existent opportunities for milk marketing and a lack of veterinary services to help manage the potential for increased productivity were the major causes for the lack of sustainability. The programme fared better in peri-urban areas with easier access to inputs and services and in areas where cooperatives such as the Bangladesh Milk Producers' Cooperative Union Limited operated milk collection and service delivery activities. It was concluded that AI and crossbreeding could contribute to improving dairy productivity and the incomes and livelihoods of farmers, but had to be complemented with other services to maintain the health and fertility of high-producing cows and to provide a good market for the increased volume of product.

Complementing AI with other services has helped increase its adoption, contributing to a doubling of the number of inseminations over the last nine years (Figure 1). About three million crossbred cattle are now in Bangladesh, representing 13 percent of the population. Two major players operate AI field services with semen produced from their own bull stations: the Department of Livestock Services, a public organization, and the AI Programme of the NGO Building Resources Across Communities (BRAC). AI in buffalo has also been introduced recently through an IAEA Technical Cooperation project.

FIGURE 1

NUMBER OF INSEMINATIONS IN BANGLADESH FROM 2000 TO 2008



Crossbred animals generally perform well, assuming that veterinary services are included in the AI programme and milk marketing opportunities are made available. Veterinary services are required because the crossbred cattle tend to suffer more from health and reproductive problems than local animals. Crossbred cows also require more inputs in feed and health care, so an available market is necessary to allow the farmer to obtain the revenue to cover these increased costs.

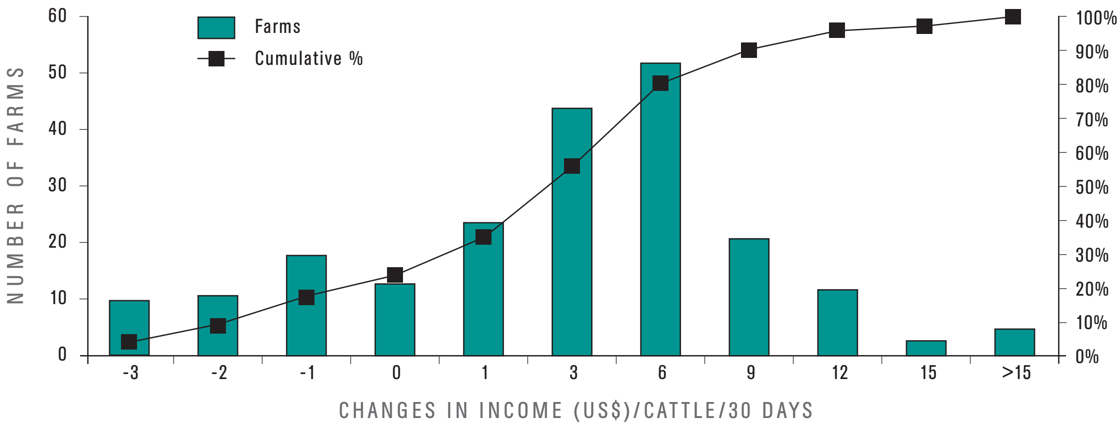
The impacts of such comprehensive AI programmes were evaluated in two districts of Bangladesh, Satkhira and Chittagong. In Satkhira, farmers were offered the opportunity to crossbreed their local cows with semen from a local AI programme. At the same time, a community-based dairy veterinary service (CDVS) was offered. Finally, a milk processor, BRAC Dairy and Food Projects, installed milk chilling tanks in the community. The CDVS is delivered through farmers' groups and associations which have laid the foundation towards operating the programme as self-financed. Three such associations collect about 7 000 litres milk per day and transport it to five BRAC milk chilling centres. BRAC also pays 1.65 Bangladeshi taka (approximately US$0.024) for each litre of milk to the CDVS in addition to the milk price paid to producers, yielding a yearly income of approximately US$62 000 – enough to pay the salary of three veterinarians, one field assistant, rents for three veterinary offices and the cost of vaccines and anthelmintics for all animals of the farm community. In addition, 69 men are employed to collect the milk and transport it to the BRAC chilling centres. Each man works two to three hours a day and earns at least US$20 a month. The programme generates a large amount of off-farm employment, which is very important in a country like Bangladesh where unemployment is high.

A typical pattern observed is for farmers to use crossbreeding and improved veterinary services initially to increase the milk yield per cow. Over time, this allows farmers to accumulate funds and increase the number of cows. This has led to increases on single farms ranging from 35 to 90 times in total milk production and allowed farmers to become solvent members in the community. According to a recent economic analysis, the CDVS has tended to increase net income as well (Figure 2). More than 75 percent of farm families benefited from an increase in net income by using the services of the CDVS, with increases ranging from US$1.0–US$19.2 per cow per month.

A similar programme was established in Chittagong in 2002. At the beginning, there were 70 farmers producing about 1 500 litres of milk per day. Currently, the programme involves 210 farm families that collectively produce about 6 000 litres per day. In addition, the CDVS developed a farmers association that negotiates the milk price with the dairy sweetmeat industries. Prior to this, farmers used to be exploited by middlemen and sweetmeat producers. Now that productivity veterinary services and AI are available and the associations guarantee a reasonable price for milk, both the number of dairy farmers and milk production per farm have increased.

FIGURE 2

EFFECTS OF PRODUCTIVITY VETERINARY SERVICES ON FARMERS' NET INCOME IN SATKHIRA



minimum and maximum differences were US$-8.0 and 19.2 (number of farms = 213)

For sustainable continuation of the programme, the Bangladesh Agricultural University has created the Community-based Dairy Veterinary Foundation. The Foundation, in collaboration with farmers' associations and dairy processors, will run the programme without financial support from the university. The keys to the success of the programme are the inclusion of a dairy processor to ensure the marketing of the milk produced by the farm community and the availability of AI services.

3.6.5 Assisted reproductive biotechnologies for cattle in Brazil[14]

During the last 40 years, the application of reproductive biotechnologies in the livestock sector of Brazil has experienced several phases of development in which methods were adapted, improved, substituted or added. Specifically in regard to the cattle industry, the major livestock sector in Brazil with around 200 million head, the 1970s were marked by the consolidation of AI use on a commercial scale. The use of frozen semen through AI programmes allowed the massive introduction of selected bulls of high genetic potential into different agro-ecological zones in the country, leading to an overall increase of production.

However, this success was limited in some cases by the fact that different *Bos taurus* breeds were introduced into tropical or semi-arid regions without proper monitoring of their capability to tolerate heat and resist parasitic infestation, resulting in unsustainable production systems. At that time, the recognition of zebu (*Bos indicus*) as ideal breeds for Brazilian tropical environments (they were originally imported from India in the 1920s and

[14] Contributed by José Fernando Garcia, Animal Production and Health Department, São Paulo State University, UNESP, Araçatuba, Brazil

1930s and then again in the 1960s), led to the establishment of several AI centres dedicated to the collection and distribution of semen from better adapted breeds, especially Nellore and Guzerat for beef production and Gir for dairying. In parallel, breeding programmes through breeders' associations and agribusiness groups were established, which played a pivotal role in the dissemination and monitoring of germplasm.

In the 1980s, when AI was increasingly being used, a second phase started, namely the use of multiple ovulation and embryo transfer (MOET) methods. Since then, Brazil has become one of the major users of this biotechnology (Garcia, 2001).

Recent data from the International Embryo Transfer Society indicate Brazil's leading position in South America in the use of embryo technology (Thibier, 2008; Table 2 earlier). In the 1990s, *in vitro* embryo production (IVEP) was taken from the laboratory to the field and emerged as one of the advanced technologies to solve specific bottlenecks in the use of bovine embryos for breeding purposes, namely, the lower response of zebu cows to ovarian stimulation with hormones and the rapid increase in market demand for high quality animals. This method can exploit the best of both male and female genetic potential and produce large numbers of descendents from the same specific artificial mating. One superior cow can have both ovaries submitted to monthly transvaginal ultrasound follicle aspiration, generating a large number of oocytes and producing on average more than 50 descendents per year. Of the approximately 820 000 bovine embryos transferred in the world in 2007, almost 30 percent were from Brazil, with about 46 000 being produced through MOET and 200 000 through IVEP. More than 90 percent of these were from zebu beef breeds. The use of IVEP was non-existent in Brazil until only ten years ago, but the current production represents about 95 percent of the total transferrable embryos produced *in vitro* in South America and about 50 percent in the world (Thibier, 2008).

Another recent development has been the increased application of FTAI, which has allowed large-scale application of AI in the beef sector. During the last decade, Brazilian scientists and pharmaceutical industries working in close partnership, developed a method consisting of the treatment of beef heifers or cows with specific hormone combinations to synchronize ovulation, allowing their insemination at one time. This revolutionized the use of AI even in areas where the infrastructure is not well developed and there is a dearth of highly skilled technicians because AI can be performed on a large number of animals in a single day by a qualified technician without oestrus detection (Baruselli *et al*., 2004). The cost of the entire procedure is low (between US$7–10 per treated cow). According to data from the Brazilian Association of Artificial Insemination, around eight million doses of semen were sold in 2007, with consistent growth during the last five years as FTAI has spread year after year and largely replaced conventional AI.

The combined use of AI, MOET, IVEP and FTAI in Brazil coupled with infrastructural development and overall nutrition, health and sanitary improvement has allowed fast distribution of animals having superior genetic attributes and opened new avenues for putting in place well structured production chains which now benefit the country's economy. This integrated approach has created the basis for cattle population growth and contributed to elevating the productivity of both the beef and dairy sectors, stabilizing meat and milk prices, increasing food consumption per capita and positioning Brazil as a top meat exporter and a self-sufficient producer of milk (Table 8).

Unfortunately, the neglect of grassland management and the increase of deforestation have constantly been associated with the development of the cattle sector in Brazil, particularly with regard to beef production. The mitigation of the negative environmental effects of cattle production is becoming mandatory for the continuation of this sector. This requirement is forcing major changes in the organization of the cattle production chain to comply with the strict new environmental protection legislation. Cattle in Brazil occupy about 200 million ha of agricultural land and the major challenge now for the livestock sector in the country is to increase productivity while simultaneously releasing 100 million ha for other forms of agriculture production in order to prevent deforestation. According to recent data, in 2009 deforestation in Brazil reached its lowest level for the last 20 years, indicating the effectiveness of the measures adopted.

In conclusion: Brazil has experienced dramatic developments in the cattle industry in which the excellence of zebu breeds for tropical production systems has been exploited using assisted reproductive technologies. These biotechnologies have accelerated the spread of improved germplasm and played an important role in the economic development of the country. Brazil's research and technology in this area now equals that of developed countries. As a result of combining well-adapted germplasm to the environment, the prevailing technical competence and recent advances in genomic research, it is expected that zebu breeds and hybrids (especially the Nellore, Gir, Guzerat, Brahman and Girolando breeds) will emerge as promising options for cattle development in tropical countries, making Brazil an important player on the international cattle genetics market.

TABLE 8

CATTLE MEAT AND MILK PRODUCTION RECORDS AND FACTS FROM BRAZIL (1970-2007)

	Meat production (ton)*/**	Consumption (kg/person/yr)*	Meat Price (US$/ton)*	Meat Exports (US$Mio)**	Milk Production (ton)*	Milk Price (US$/ton)*
Year	1970	1970	1994	1994	1970	1994
	1 845 182	17	1 800	573	7 353 143	254.97
Year	2007	2003	2006	2008	2004	2006
	9 296 700	33	1 550	5 500	24 202 409	221.81
Change (percent)	+500	+94	−20	+960	+350	−10

Sources: *FAOSTAT (http://faostat.fao.org/) and the **Brazilian Institute of Geography and Statistics (IBGE, www.ibge.gov.br/home/)

B. LOOKING FORWARD: PREPARING FOR THE FUTURE

3.7 KEY UNSOLVED PROBLEMS IN THE LIVESTOCK SECTOR WHERE BIOTECHNOLOGIES COULD BE FUNDAMENTAL TO THEIR SOLUTION

Continued population growth and urbanization, global warming, globalization of trade and the ongoing intensification of livestock production systems and value chains, in addition to providing opportunities for development, have given rise to a number of new challenges in animal production and these trends and new challenges will continue in the future. The challenges include the occurrence of new diseases, such as HPAI caused by virus of the H5N1 sub-type and, more recently, influenza A/H1N1, the re-occurrence of many old transboundary animal diseases, the release of pollutants such as methane, nitrogen and phosphorus into the environment, water scarcity, land degradation, the erosion of animal biodiversity and the scarcity of feed (due to the need to feed a growing population or because of diversion to other uses, such as biofuels). Animal biotechnologies provide opportunities for addressing new challenges and solving upcoming problems.

Control of new and (re-)emerging diseases

The emergence of vector-borne diseases such as African swine fever, bluetongue, Rift Valley fever and African horse sickness in new areas which is linked to global warming, is an increasing threat worldwide. The breaking down of borders between many countries, increasing international trade in live animals, animal products and feeds, and increasing wildlife-human interactions promoted by global climate changes are also contributing to new high-risk situations. For African swine fever there is no effective vaccine available and new variants of the virus have emerged in Africa, while in Sardinia it is present in endemic form. The infectious agents could appear in unexpected and unknown areas which may lead to improper or delayed diagnosis and result in the uncontrolled spread of the agent to large areas. These situations require sustained surveillance over the spread of diseases throughout the world. For example, the emergence of the West Nile virus in Europe and the United States requires continuous surveillance and a control programme for the presence of the virus in birds, horses and humans (Hayes and Gubler, 2006). New diseases such as Hendra virus, Nipah virus and severe acute respiratory syndrome coronavirus (SARS) demand continuous surveillance of wildlife for potential disease risks. Given that many of the emerging diseases worldwide are zoonotic, the risk to humans and animals and animal productivity could be better managed through the application of recent biotechnology-based diagnostics such as qPCR methods, microarrays, nucleic acid fingerprinting, DNA sequencing, biosensors, isothermal amplification methods and pen-side tests. These are powerful techniques that enable the rapid, accurate and sensitive detection and identification of variants of the pathogens. The availability of effective DIVA-based vaccines is likely to increase in the future. This would also facilitate the control and eradication of transboundary animal diseases, including zoonotics.

Lately, PPR became a much more prominent disease because, apart from causing disease in small ruminants, it also impacted on the diagnostic and vaccination work for preventing rinderpest in large ruminants. The PPR virus can produce subclinical infection in large ruminants and the antibodies thus produced cross-react with the rinderpest virus and cause confusion in the diagnosis, with important implications for the campaign to eliminate rinderpest. Additionally, in areas declared free of rinderpest, the rinderpest virus strain cannot be used to vaccinate against rinderpest or PPR. The problem can be solved using molecular techniques such as DNA sequencing and through the development of a PPR marker vaccine.

Poultry and wildfowl have been considered as the major carriers of the HPAI H5N1 virus, and thus of the disease. However, recent data have demonstrated that both wild and domestic cats can carry the HPAI virus and may present a source of disease for humans (Kuiken *et al.*, 2004). Pigs are susceptible to both human and avian influenza viruses and it is speculated that co-infection of pigs with HPAI virus and human influenza virus may create viral reassortant strains with the ability for human-to-human transmission (Cyranoski, 2005). PCR-based and DNA sequencing methodologies have been central for genetically characterizing strains of H5N1 viruses. Similarly, for the ongoing outbreak of influenza A/H1N1, these techniques have been invaluable for characterizing the influenza virus and establishing that the virus circulating in the United States and Canada is the same as that in Mexico. Furthermore, using molecular techniques this virus has now been completely sequenced, which will help to pinpoint its origin, spread and change over time, and explain the differential and severity of disease between Mexico and the rest of North America.

The danger of bioterrorism is also looming. The emerging challenges cannot be met effectively without the use of molecular tools. Molecular diagnostics and molecular epidemiology have played and will keep on playing an essential role in detecting pathogens and preventing natural and bioterrorism-induced pandemics. The role of DNA marker vaccines will also be vital in providing a secure and productive environment for animal agriculture to flourish. The ongoing genomic studies for gaining insight into host-pathogen interactions are likely to produce novel and more effective approaches for diagnosis and control of diseases.

Efficient utilization of forages, global warming and land degradation

Climate change is currently an issue of critical importance on the global stage. Livestock production has been implicated as substantially contributing to climate change as well as other types of environmental degradation (FAO, 2006a). Biotechnologies could play a role in alleviating the impact of livestock on the environment. In the area of animal nutrition, the ongoing efforts to sequence the genomes of predominant rumen bacteria and assign functions to genes provide the opportunity to extend our understanding of gastrointestinal microbiomes beyond the degradative and metabolic characteristics relevant to both host animal health and nutrition. This facilitates acquiring the knowledge of a bacterium's competitiveness and colonization potential in the rumen and of the nutrient requirements of microbes, underpinning the roles of microbes in the process of feed digestion, and understanding better the mechanism of fibre degradation in the rumen. This knowledge may provide new opportunities for using roughages and crop residues more effectively and for developing strategies to achieve sustainable decreases in methane production through new means, one of which could be through the establishment of acetogens in the rumen. Better utilization of tree leaves and agro-industrial by-products through identification of antinutritional factor(s) degrading microbes and their establishment in the rumen may also be possible. Similarly, the genomic information of cattle and other ruminants could assist in identifying animals that are low methane emitters and have better feed conversion efficiency (Hegarty *et al*., 2007). Potential applications of studies on farm animal genomes, including rumen microbial genomes, are innumerable.

The plant kingdom in the tropics is full of diversity. Tropical plants contain a large number of bioactive phytochemicals, the activity and diversity of which in tropical regions is considered greater than in temperate regions (Makkar, Francis and Becker, 2007). Local knowledge of using herbal products is also rich in many developing countries. With the ban on antibiotic growth promoters in the EU and increasing pressure on North American countries to follow suit, efforts are underway to identify natural plant growth promoters. The PCR and oligonucleotide probing methods for studying gut microbial ecology are affordable and within the capacity of molecular biology laboratories in developing countries. The application of these tools along with conventional tools could give an edge to developing countries over developed countries by identifying compounds from their rich and diverse flora that could be useful for the manipulation of rumen fermentation. They might, for example, be used to decrease methane emissions and increase the uptake of nitrogen and carbon by rumen microbes, and thus improve gut health while conserving the environment. The demand for natural products that enhance livestock productivity and animal welfare and make animal agriculture environmentally friendly will increase substantially in the future. The potential exists for developing countries to capture a large segment of the business in this area.

The use of enzymes and other additives in feeds, the development and use of genetically improved crops for animal feeds – including forages having higher water use efficiency, salt and drought tolerance, high quality, and low lignin; the development of animals with high feed conversion efficiency through biotechnological means (e.g. MAS or cloning) and their widespread use would help mitigate problems linked both to global warming and land degradation. In addition, the biotechnologies discussed in this Chapter that improve animal health, fertility, productivity and efficiency would decrease greenhouse gas emissions by decreasing the number of animals needed to yield a given quantity of product. These are some examples, among many others, of the potential applications of biotechnologies in addressing the environmental impact of livestock production. It may be noted that strategies for mitigating greenhouse gases often also contribute to the adaptation of the livestock sector to climate change (FAO, 2009b).

Sustainable management of animal genetic resources

The genetic diversity of livestock is in a state of decline globally. According to FAO (2007), 20 percent of the world's livestock breeds are at risk of extinction and the risk status of a further 36 percent cannot be determined owing to the absence of information. As mentioned previously, demand for increased production has led many countries to import exotic germplasm. Many livestock farmers have moved to cities to seek alternative livelihoods and left their livestock behind. Improved management of animal genetic resources is high on the agenda of most nations, and FAO is contributing enormously to this cause. Some developing countries, often in collaboration with international partners, are characterizing animal genetic resources using genetic markers and other conventional tools with the aim of gathering the information necessary to propose plans to conserve and utilize their resources more effectively. Molecular technologies may be a useful tool in determining the genetic basis for the adaptation of local breeds to their environment, including their ability to resist endemic diseases. Molecular genetics in concert with conventional breeding approaches can be used in the development of genetic improvement programmes for indigenous breeds, making them more competitive with exotic breeds and helping to ensure their *in situ* conservation while improving the livelihoods of their keepers. In some cases, breeds may risk extinction before utilization plans can be enacted and *in vitro* conservation will be a short-term solution. The development of new approaches for collecting and preserving germplasm, including improved cryopreservation methods, can contribute to achieving this objective. Advances in animal cloning technologies would be invaluable to increase the efficiency and decrease the costs of regenerating extinct populations from somatic cells and DNA which are relatively cheap to collect and store.

3.8 IDENTIFYING OPTIONS FOR DEVELOPING COUNTRIES

With reference to the stock-taking exercise that has been central to this Chapter, a number of specific options can be identified that should assist developing countries make informed decisions regarding the adoption of appropriate biotechnologies in the livestock sector in the future.

Biotechnologies should build upon existing conventional technologies

Solving new problems will require novel ideas and may involve new technologies. However, substantial impact of new biotechnologies can only be realized at the ground level in developing countries if the capabilities and infrastructure to effectively use conventional technologies are in place. For example, molecular diagnostics and recombinant vaccines will not improve the health or well-being of animals if an effective animal health infrastructure does not exist. Semen sexing and ET have no relevance in places where less advanced reproductive technologies such as AI are not well established and systems for the distribution of improved germplasm are not in place. The same is true for the application of MAS where animal identification and recording systems for relevant traits (e.g. milk yield, resistance to diseases, growth rate) are not in place. Efficient animal identification systems, e.g. based on ear tags, animal passports and computer recording, are needed in order to take full advantage of molecular markers, DNA sequencing and other advanced biotechnologies for animal genetics, nutrition and health. Similarly, biotechnology-based nutritional strategies will not work if farmers do not have access to adequate feed resources or to the knowledge of how to prepare balanced diets. An exception to this rule could be the use of simple "turn-key" approaches such as on-site "dip-stick tests" for disease diagnosis, provided these are low-cost and simple to use and interpret. This situation could be analogous to the use of mobile phones which has revolutionized communication in developing countries. "Dip-stick tests" have the potential to make a significant contribution to enhancing food security through the rapid diagnosis of diseases in remote areas. This would certainly make disease control and eradication programmes more effective and efficient.

In short, although biotechnologies have many advantages, they should not be considered as replacements of conventional (non-biotechnology) approaches just because of a desire to follow a scientific fashion. The introduction of a biotechnology should be done after assessing the field situation critically, considering the various options available and the comparative advantages and disadvantages of each in solving a specific problem, and the final decision should be made in a scientific and unbiased manner, remembering that technology *per se* is not a solution in itself.

Biotechnologies should be integrated with other relevant components in any livestock development programme

Not all biotechnologies can be applied successfully in all situations at all times. Each biotechnology has relevance to a specific situation and in most cases it has to complement conventional technologies and other components of the livestock production and marketing system to elicit the desired impact for the farmer. An example is the integrated programme involving farmer organizations, extension workers, researchers and policy-makers that reversed the decline of a locally-adapted dairy sheep breed in Tunisia (Djemali *et al*., 2009). This initiative was backed up by sound R&D involving biotechnologies such as AI and oestrus synchronization. These technologies were minor components but played a vital role in the success of the entire programme. They would not, however, have brought about the desired results had the other components not been in place. In other words, the focus should be on the reasons for the low food security and poor livelihoods of farmers rather than the solutions of applying a particular biotechnology. The importance of integrating biotechnologies as components rather than being the primary focus of a livestock development programme was illustrated clearly in Case Study 3.6.4, where AI was implemented as part of a wider programme to improve dairy production in Bangladesh.

The increasing importance of environmental issues also means that these should also be considered in any livestock development programme. For example, plans for the application of biotechnologies for nutrition (e.g. prebiotics and probiotics, enzymes and silage additives) should consider both the effects on animal productivity and the potential impacts (positive or negative) of the technology on the production system and the environment.

Application of biotechnologies should be supported within the framework of a national livestock development programme

Developing countries must ensure that animal biotechnologies are deployed within the framework of national development programmes for the benefit of producers and consumers and not as stand-alone programmes. The models of biotechnology interventions in developing countries differ distinctly from those in developed countries. The biotechnologies that are simple and cost-effective are more likely to be successful in developing countries. To ensure the successful application of a biotechnology in the complex and diverse animal agriculture scenarios present in developing countries, not only does the mitigation of technical challenges need to be addressed but also, and probably more importantly, issues like management, logistics, technology transfer, human capacity, regulation and intellectual property. This is particularly the case when a technology is well developed in developed countries and yet relevant to the needs of developing countries.

Policy-makers in developing countries should be aware that there will be practical, financial and legal obstacles that will preclude the full-scale adoption of many livestock biotechnologies. In such instances, strategies for adoption and use must be based on realistic expectations. Many biotechnologies are biased with respect to scale, so that their application is only economically feasible in large enterprises. The building of infrastructure (laboratories, equipment etc.) will not be possible in every country, so that North-South, South-South and public-private partnerships will be required, meaning that countries may have to accept the loss of some autonomy in exchange for access to certain biotechnologies. In such cases, capacity building in developing countries should be directed at understanding the technology and financial investments involved and should emphasize adapting and using the technology to meet livestock development goals unique to the country, rather than replicating an entire system at the local level.

With the SIT, for example, there is a strong positive correlation between the research capabilities of in-country biotechnologists and the scale of its application in the field. The translation of research into commercial enterprises requires solid science, long-term resource commitments and extensive steps of validation to reach the thresholds of reproducibility and profitability. Therefore, strong scientific drive, vision and entrepreneurial skills are needed for contributing to progress in animal biotechnologies. The capacity to conduct research in biotechnology and develop products cannot just be "turned on". It requires prior nurturing over many years with an adequate and uninterrupted provision of funds, which is possible only through strong commitment from science and policy managers in developing countries.

Access to biotechnological products by end users should be ensured

An appropriate model for scaling up and packaging the technology should be integrated into the development and application of biotechnologies and biotechnological products, particularly for vaccines, diagnostics, probiotics, prebiotics and enzymes so that the products are not cost-prohibitive. It has to be borne in mind that the target end users of these biotechnologies in developing countries are normally resource-poor farmers with limited purchasing power. Without this scaled-up business approach/model, even good science and quality biotechnological products might not deliver desired impacts at the field level. In the business model, it is also imperative to consider the intellectual property issues which impinge on several aspects of biotechnology. For example, for manufacturing a recombinant vaccine, developing countries might find that the use of antigens, delivery mechanisms, adjuvants and the process are already patented and subject to intellectual property conditions. Equally important in the business model is the cost of registration of a product such as a vaccine, which could be very high or prohibitive. To illustrate this, registration of the TickGUARD vaccine against *B. microplus* required several vaccination trials on approximately 18 000 cattle. This took a long time to complete and consumed huge resources (Willadsen, 2005).

The fostering of private-public partnerships – particularly in the areas of AI and associated reproductive biotechnologies, the production of biotechnological products such as amino acids, feed additives, vaccines and molecular diagnostics, and bioinformatics – is expected to enhance the pace of development in the animal agriculture sector and help contribute to meeting the UN Millennium Development Goals.

3.9 IDENTIFYING PRIORITIES FOR ACTION FOR THE INTERNATIONAL COMMUNITY

The international community (FAO, other UN organizations, NGOs, development and donor agencies) can play a key role in international cooperation and in supporting developing countries to implement appropriate biotechnologies for their needs in the future. Below is a set of Priorities for Action for the international community to enable it to play this role.

- International support should be provided to developing countries for completing surveys and characterizing livestock diversity, within which molecular evaluation of genetic diversity is an important component.
- International institutions should provide assistance to developing countries in framing animal breeding policies that consider both indigenous and exotic animal genetic resources, and help them strengthen their AI infrastructure and capabilities. Policies should be based upon existing national action plans for animal genetics resources.
- Assistance provided in the adoption of biotechnologies to increase the genetic merit for livestock productivity in developing countries should be complemented by the creation and maintenance of markets for the end products.
- In order to enhance the impact of assisted reproductive biotechnologies such as AI, semen sexing, IVF, ET and germplasm cryopreservation, national and international public-private research and technology transfer partnerships must be built and strengthened.
- Through the support of international organizations, national and multinational cryobanks for storing animal genetic resources should be established. The legal framework for regulating the use of animal genetic resources and operation of cryobanks needs to be formulated.
- The establishment of public-private partnerships for the development and production of animal nutrition products of biotechnology should be considered at both national and international levels to increase the uptake of the technologies.
- Diagnostic approaches involve both serological and newer molecular techniques. Provision of training in diagnostics, potentially including international training courses, should

be supported by both international organizations and the nations concerned and they should ensure that internationally recognized standards such as those published in the OIE Animal Health Code are implemented.

- Training programmes for establishing quality assurance methods such as those published by OIE allow continuous assessment of the assays used, and network programmes for validation of diagnostic methods should be organized by international funding agencies as the area of disease diagnostics is beset with problems of validation.
- Reference laboratories for conventional and newer technologies including biotechnologies provide useful services in the diagnostic and vaccine control areas and should work in collaboration with national veterinary services. The proper establishment of reference laboratories to implement international standards (e.g. standards approved by OIE or the International Organization for Standardization [ISO]) should be supported by international organizations through training, advice and political negotiations to secure sustainable funding. The exact role of any reference laboratory has to be defined from the beginning. National and regional acceptance and support is vital to sustaining them.
- The early and accurate detection and efficient monitoring and control of transboundary animal diseases, particularly zoonoses, are of great international interest. Therefore, international cooperation in the development, uptake and adaptation for use of the associated biotechnologies is essential.
- The international community should help developing countries to integrate animal biotechnologies within the context of national livestock development programmes and overall developmental needs. Furthermore, the formulation of programmes should be based on solving specific problems rather than imposing specific solutions to these problems. Initiatives that aim to reconstruct (or tailor) animal biotechnologies to specific needs and localities as part of a comprehensive and holistic solution to a given problem are important and need encouragement as well as tangible support.
- International and national institutions alike should identify ways of improving cooperation to address issues pertaining to animal biotechnology. Firm and committed North-South and South-South collaborative programmes and partnerships should be developed and fostered through the consistent and long-term provision of sufficient funds.
- Short-sighted worldwide research policies have neglected animal research in recent years. The amount spent by developing nations on animal research should be increased. The international donor agencies should also designate increased funds for R&D in the area of animal science in developing countries.
- International funding agencies should support the training of people to perform quality research. Research competence is a prerequisite for harnessing the benefits of animal biotechnologies. The training programmes should be directed at young scientists and

complemented with incentives (e.g. subsequent employment, research funding and networking opportunities) to encourage graduates to apply their training to addressing livestock production issues in their home countries.

- Support for capacity building must extend beyond training for the adoption of a specific biotechnology to include investment in improvement of higher education in general. Academic and professional institutions in developing countries must be strengthened so that they may provide an intellectual base on which to build an understanding of the problems that confront livestock production and determine which solutions (including biotechnologies) are best to address the problems.
- Public awareness of advanced animal biotechnologies such as animal cloning and genetic modification should be encouraged and enhanced by international organizations based on sound scientific evidence of the technologies' efficacy, safety, and costs and benefits in the context of a developing country.

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CHAPTER **4**

CURRENT STATUS AND OPTIONS FOR BIOTECHNOLOGIES IN AQUACULTURE AND FISHERIES IN DEVELOPING COUNTRIES

SUMMARY

The rapid growth of aquaculture has significantly benefited from both conventional technologies and biotechnologies and it is expected that advanced biotechnologies will further help the sector in meeting the global demand for aquatic food in the coming decades. While biotechnologies are being applied in fisheries management, their use is very limited compared with aquaculture. The four main areas where biotechnologies have been used in aquaculture and fisheries include genetic improvement and control of reproduction; biosecurity and disease control; environmental management and bioremediation; and biodiversity conservation and fisheries management.

One of the main reasons for the success of aquaculture is the diversity of species currently in culture (over 230) and the genetic diversity that can be exploited through captive breeding and domestication. However, the rearing of many newly cultured species is to a large extent based on juveniles and/or broodstock obtained from the wild. In order to establish practical breeding programmes to produce seed in hatcheries, it is necessary to have a detailed understanding of the complete production cycle. Such knowledge is also required to disseminate breeding improvements to the production sector. Improvements that allow the wider application of appropriate genetic and reproduction biotechnologies will undoubtedly increase aquaculture production, thus contributing to global food production. These biotechnologies include polyploidy, gynogenesis and androgenesis, the development of monosex populations and cryopreservation.

Disease outbreaks are a serious constraint to aquaculture development. Disease control and health management in aquaculture are different from the terrestrial livestock sector, particularly due to the fluid environment. Disease occurs in all systems, from extensive

to intensive, and losses are possible in all types of production systems. There is a need for better management of intensive systems, and biotechnologies are being used for this purpose. Immunoassay and DNA-based diagnostic methods are currently used to screen and/or confirm the diagnosis of many significant pathogens in aquaculture in developing countries. Also, one of the most important factors leading to reduced antibiotic use by the aquaculture sector is the availability of good prophylactic measures for diseases causing severe mortalities in cultured fish and shellfish. The use of vaccines provides good immunoprophylaxis for some of most important infectious diseases of finfish. As molecular-based vaccine production procedures rely heavily on biotechnological tools, vaccines are being produced mainly in developed countries.

Reducing the environmental impacts of aquaculture is a significant task. Aquaculture is often accused of being unsustainable and not environmentally friendly. Reducing the impacts of effluent discharge, improving water quality and responsible use of water are key areas to be considered in aquaculture development. Some biotechnologies are being used to address these areas, including bioremediation for the degradation of hazardous wastes and use of DNA-based methodologies for the early detection of toxin-producing algae.

In capture fisheries, the sustainable management and conservation of fisheries is a priority. Better understanding of the population structure of the fishery is therefore of paramount importance. Some biotechnologies have already been applied but there is ample scope for the greater use of biotechnologies in fisheries management worldwide. The use of molecular markers and the principles of population genetics have proved very effective for assessing the actual levels of genetic variability within single populations and for measuring the extent of differentiation between populations.

4.1 INTRODUCTION

Capture fisheries and aquaculture supplied the world with over 113 million tonnes of food fish in 2007, providing an apparent per capita supply of 17.1 kg (live weight equivalent), which is among the highest on record. Global production of fish from aquaculture has grown rapidly during the past four decades, contributing significant quantities to the world's supply of fish for human consumption. Aquaculture currently accounts for nearly half (44.3 percent) of the world's food fish (Figure 1). With its continued growth, it is expected that aquaculture will in the near future produce more fish for direct human consumption than capture fisheries (FAO, 2009).

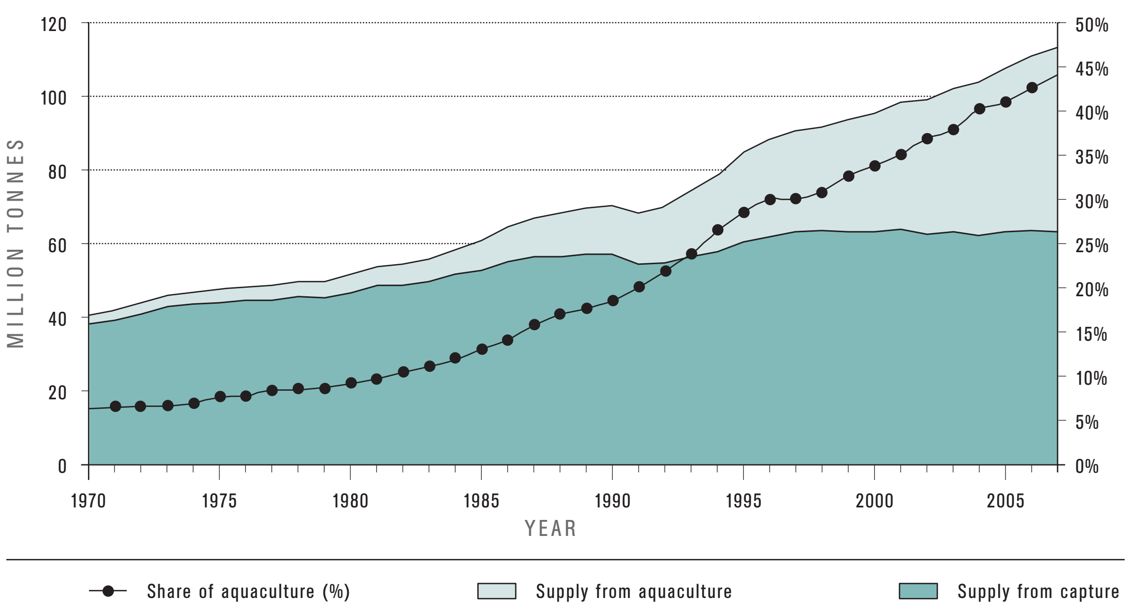
Started as primarily an Asian freshwater food production system, aquaculture has now spread to all continents, encompassing all aquatic environments and utilizing a range of aquatic species. From an activity that was principally small-scale, non-commercial and family-based, aquaculture now includes large-scale commercial or industrial production of high value species that are traded at national, regional and international levels. Although production remains predominantly Asian and is still largely based on small-scale operations, there is a wide consensus that aquaculture has the potential to meet the growing global demand for nutritious food fish and to contribute to the growth of national economies, while supporting sustainable livelihoods in many communities (Subasinghe, Soto and Jia, 2009).

In 2006, fish provided more than 2.9 billion people with at least 15 percent of their average per capita animal protein intake. The contribution of fish to the total world animal protein supplies grew from 14.9 percent in 1992 to a peak of 16.0 percent in 1996 before declining to about 15.3 percent in 2005. Notwithstanding the relatively low fish consumption in low income food deficit countries of 13.8 kg per capita in 2005, the contribution of fish to total animal protein intake was significant – at 18.5 percent – and is probably higher than indicated by official statistics in view of the under-recorded contribution of small-scale and subsistence fisheries and aquaculture (FAO, 2009).

Aquaculture is the farming of aquatic organisms including fish, molluscs, crustaceans and aquatic plants. Farming implies modifications and intervention in the production cycle such as regular stocking, sorting, feeding and protection from predators in order to enhance production.

FIGURE 1

CONTRIBUTION OF FOOD FISH SUPPLY FROM CAPTURE FISHERIES AND AQUACULTURE



Source: FAO FishStat and FAO (2009)

It is important to note that aquaculture has a long tradition in the developing countries of the Asia-Pacific region, supplying most of the world's aquaculture production (over 90 percent), and making important contributions to the livelihoods and subsistence of small-scale farmers and coastal populations in many countries in the region. In Latin America, small-scale aquaculture has yet to be widely developed; however, there are several examples of newly established industries based on intensive aquaculture practices, especially using exotic species. Salmon farming in Chile is one of the best examples, but there are also expanding aquaculture industries for shrimp and tilapia culture in Ecuador, Costa Rica and Honduras. While Europe and North America import significant quantities of farmed aquatic animals, they also produce fish and shellfish both from freshwater and marine environments. Africa's contribution to global aquaculture is still small; however, the region is moving forward and increasing production.

Aquaculture covers a wide range of species and methods. It is practised from the cold waters of the far north and south, where fish like salmon, Arctic char and sturgeon are grown in ponds, flowing raceways and cages in the sea, and through the latitudes as far as the tropics, where carp and tilapia flourish in freshwater and shrimp and sea bass are farmed along the coasts. It ranges from the production of fish in naturally occurring ponds in rural areas to the intensive culture of ornamental fish in plastic tanks in the middle of a city. It is practised by the poorest farmers in developing countries as a livelihood and supply of much needed protein for their families, and by urban sports shop owners in Europe and North America producing baitfish for weekend anglers.

Aquaculture systems can range from an intensive indoor system monitored with high tech equipment through to the simple release of fry and fingerlings to the sea, but the aim remains the same: to improve production. Some of the simplest production systems are the small family ponds in tropical countries where carp are reared for domestic consumption. At the other end of the scale are high technology systems such as the intensive indoor closed units used in North America for the rearing of striped bass or the sea cages used in Chile and Europe for growing salmon and bream.

All products and systems are geared to produce animals for market and are much governed by market demand at all levels. Regardless of whether it is a high value commodity like shrimp, salmon or grouper, or a low-value commodity such as carp and Tra catfish, all products are destined for markets, be they local, regional or international. All production systems contribute to food security and human development although small-scale rural production systems provide more support to improving or maintaining livelihoods and generating employment and income for many around the world.

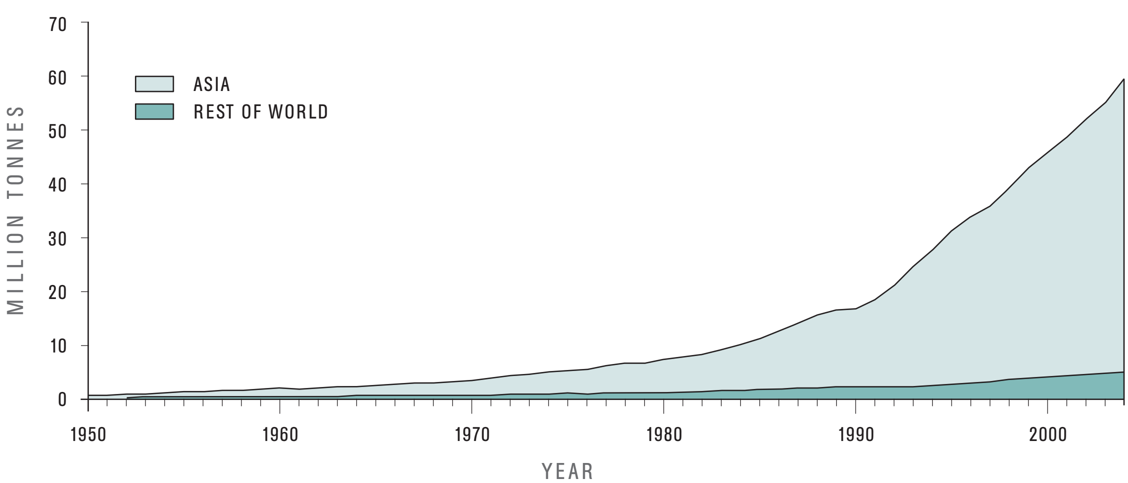
It is important to note that most of these small-scale aquaculture activities occur in developing countries, especially in regions or rural areas where food supply is at risk. For example, tilapia has become a globally important aquatic species that is produced in nearly 100 developing countries worldwide. According to FAO, about 80 percent of the world's farmed tilapia comes from small-holders in developing countries, and this species is particularly prominent in production systems in the Asia-Pacific, the region that provides most of the world's aquaculture supply (FAO, 2004a).

Another good example of extensive aquaculture is the production of major carps in India. In this case, the majority of the production takes place in rural areas with relatively few impacts on the environment, particularly by using multitrophic culture of species such as catla (*Catla catla*), rohu (*Labeo rohita*) and mrigal (*Cirrhinus mrigala*). It is true that some instances of uncontrolled aquaculture development have caused significant negative environmental and social impacts. However, except for a very few species, there are few negative environmental impacts associated with current production systems and practices. Moreover, most traditional and extensive systems produce fish with little or no negative environmental or social impact.

There has been a steady increase in the growth of aquaculture in developing countries, the rate of growth being twice that of developed nations. The most recent figures for global aquaculture production show that more than 90 percent of total fish production comes from developing countries, particularly China which contributes about 70 percent of the total global fish and shellfish production (Subasinghe, Soto and Jia, 2009). Aquaculture is thus often one of the most important food production sectors in developing countries, and in many cases it is one of the most important sources of both food and income for rural populations (Figure 2).

FIGURE 2

GLOBAL AQUACULTURE PRODUCTION



Source: FAO FishStat and FAO (2009)

Aquaculture practice is an example of a strong continuum of production systems. From the simplest production system with absolutely no inputs and with minimal interventions, aquaculture ranges up to highly sophisticated, fully automated, industrial production systems comprising submerged offshore cages producing large quantities of fish from a single unit. Intensive or extensive aquaculture requires good quality seed for farming. Seed quality is not only dependent on good hatchery technology, but also on good broodstock with improved genetic quality. The genetic quality of the broodstock and seed used in aquaculture can be improved using biotechnological tools and procedures. There have been some interventions, and good results have been reported.

Modern aquaculture, through the intensification of culture systems and the diversification of both the species cultured and the culture methods employed, often creates an ideal environment for disease-causing organisms (pathogens) to flourish. The expanded and occasionally irresponsible global movement of live aquatic animals has been the cause of transboundary spread of many pathogens, which have sometimes resulted in serious damage to aquatic food productivity. Some of these pathogens have become endemic in culture systems and in the natural aquatic environment, thus making them difficult to eradicate. Since they have become endemic, recurrent pathogen incursions and disease outbreaks occur in farms making it difficult for the farmers to effectively manage farm health. Instead of implementing effective health management strategies and practices, many farmers opt to use antimicrobials as treatments. There is therefore a need to develop alternate methodologies and tools for maintaining aquatic animal health in aquaculture systems. Such tools and methodologies are generally the result of biotechnological research and several success stories exist. Similarly, biotechnological research has also helped in the improvement of feeds, feeding and nutrition as well as of water quality and the environmental impacts of aquaculture.

This paper is divided into two main Sections: “Stocktaking: Learning from the Past” and “Looking Forward: Preparing for the Future”. For the first one, Part 4.2 provides a brief overview of the main areas where biotechnologies are currently been applied; Part 4.3 documents the current status of application of biotechnologies in developing countries; and Part 4.4 presents two relevant case studies. For the second Section, Part 4.5 examines a couple of key issues for the future where biotechnologies could be useful; Part 4.6 identifies a number of specific options for developing countries to help them make informed decisions regarding adoption of biotechnologies; and Part 4.7 proposes a set of priorities for action for the international community (FAO, UN organizations, NGOs, donors and development agencies).

A. STOCKTAKING: LEARNING FROM THE PAST

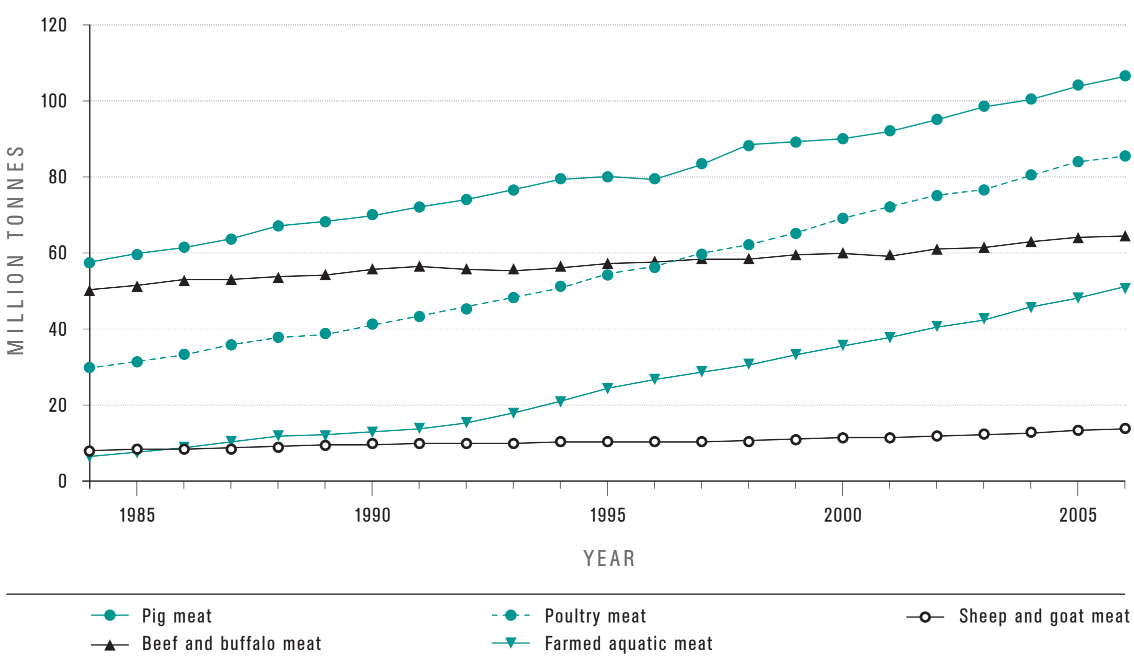
4.2 OVERVIEW OF MAIN AREAS WHERE BIOTECHNOLOGIES ARE BEING APPLIED IN AQUACULTURE AND FISHERIES IN DEVELOPING COUNTRIES

4.2.1 Genetic improvement and control of reproduction

Aquaculture is still the fastest growing food producing sector, compared with other food commodities (FAO, 2009) (Figure 3). One of the reasons for this is the diversity of species in culture at present (over 230), and the genetic diversity that can be exploited through captive breeding and domestication, enabling the development of improved culture methods for a diverse array of species to expand commercial aquaculture (Subasinghe, 2009). A lack of knowledge of the biology of many of these species and the cost of technology development are constraints that explain in part why biotechnologies are only now emerging as useful tools for increasing the productivity and sustainability of this sector. Aquaculture is a sector that is likely to benefit greatly from the application of appropriate genetic and reproduction biotechnologies to increase food production.

FIGURE 3

GROWTH IN PRODUCTION OF DIFFERENT FOOD COMMODITIES: 1984–2006



Source: data calculated from FAOSTAT Database (2008)

Despite the current trend towards the intensification of production systems, aquaculture has not made full use of conventional technologies such as genetic selection and breeding improvement programmes to increase production as have other food production sectors. The rearing of many newly cultured species is to a large extent based on juveniles and/or broodstock obtained from the wild. In order to establish practical breeding programmes to produce seed in hatcheries it is necessary to have a detailed understanding of the complete production cycle. Such knowledge is also required in order to disseminate breeding improvements to the production sector.

One of the best examples is the inability to fully domesticate *Penaeus monodon*, the black tiger prawn which is arguably the most valuable species produced globally. Although specific pathogen-free (SPF) hatchery stocks bred for improved growth have become available recently, production still depends on broodstock collected from the wild. As a result, production of this species has been replaced over the last few years by that from the white shrimp, *L. vannamei*. Improved SPF *L. vannamei* have been readily available for some time and now supply essentially all farmed white shrimp and more than 60 percent of all farmed penaeid shrimp world wide. The shrimp aquaculture sector therefore illustrates the benefits of genetic improvement for increasing production and the competitiveness of aquaculture industries.

The *P. monodon* example illustrates how a lack of knowledge concerning some phases of the life cycle such as reproduction or metamorphosis may be a limiting factor in developing domesticated stocks. Certain species of tuna, a marine resource that is being harvested under a quota system, are now produced in considerable quantities in captivity or culture. The aquaculture production of this valuable species will undoubtedly increase once the life cycle is closed and the hatchery production of tuna fry becomes a reality. This scenario is also applicable to the hatchery production of mollusc species. There is a huge demand for spats (fertilized shellfish larvae) but most spats are still coming from the wild.

The use of hormones for the control of reproduction has been primarily developed for inducing the final phase of ova production, i.e. for synchronizing ovulation and for enabling broodstock to produce fish in the first part of the season or when environmental conditions suppress the spawning timing of females. These procedures began with the pioneering work of Houssay (1930), who demonstrated that extracts of the hypophysis (pituitary gland) can have an effect on sexual maturation of fish and reptiles (Zohar and Mylonas, 2001). These results allowed the development of a relatively simple procedure consisting of injecting hypophyseal extracts purified by chromatography that contain products such as inductive hormones related to sexual maturation. Human chorionic gonadotrophin and the gonadotrophin-releasing hormone (GnRH) were also used to control the maturation of many fish species without limitations due to species-specific effects (Zohar and Mylonas, 2001). GnRHa, an analogous GnRH developed chemically, is more efficient in inducing maturation and is relatively inexpensive. It can be injected or administered by means of pellet implants which facilitate its practical use. The use of hormones such as GnRHa has allowed advancement of the date of egg-laying in several species of fish, mainly salmonids, although for relatively short periods of time (Valdebenito, 2008). Several other molecules are currently under development for use in molluscs (e.g. scallops, oysters and mussels), where synchronous reproduction is required for the hatchery rearing of larvae for aquaculture production in developing countries instead of using seed obtained from natural banks.

4.2.2 Biosecurity and disease control

Disease outbreaks are a serious constraint to the development of intensive aquaculture systems and can have a major impact on production due to mortality and decreased growth. It has been recognized that disease is the most significant factor impacting the intensive production of shrimp, salmon, carp and tilapia, with losses of 10-90 percent of total production (Peinado-Guevara and López-Meyer, 2006). Although many aquatic animal pathogens are well studied, unlike in terrestrial animals the spread of pathogens is easy through water and control is difficult due to high density culture in fluid environment. Disease occurs in all systems, from extensive to intensive, although heavy losses are always possible in intensive production systems (Bondad-Reantaso *et al.*, 2005).

Intensive and semi-intensive aquaculture can have important effects on the quality of the aquatic environment in which the animals are reared. Poor water quality resulting from increased waste products, inadequate farm management, increased stocking densities within farms and increased densities of aquaculture units per sector can increase the likelihood of disease outbreaks and other environmental problems such as eutrophication, episodic oxygen shortages, algal blooms etc., all of them potentially resulting in high mortalities. A more "systems-oriented approach" is therefore needed to provide suitable husbandry for effective growth and to control disease outbreaks effectively.

There is a greater need for management intervention in intensive systems. Here biotechnological tools can be a valuable part of management approaches. Their scope of application is broad – they can be used as sensors in the production environment, for waste management (through controlled microbial technologies), and for disease detection and control (molecular methods). Traditionally, disease control is often carried out only after mortality has been observed. In the past, the diagnosis of fish diseases has been achieved primarily using histopathological methods supported by parasitological, bacteriological and viral studies based on necropsy and *in vitro* cell culture. These are well-proven techniques. However, they require a high level of expertise and are often quite time-consuming, not being amenable to automation. For these reasons, although expert training is required, polymerase chain reaction (PCR) technology (described later) has become an important tool for pathogen assessment in developing countries, for example in the shrimp industries of Asia and Latin America.

4.2.3 Environmental management and bioremediation

Aquaculture has often been accused of being unsustainable and not environmentally friendly. Although in some cases, where aquaculture development has failed to live up to the global expectations of sustainable development, these allegations are not entirely unfounded, the majority of aquaculture is practised sustainably and with a high degree of environmental conscientiousness. Reducing the impact of effluent discharge, improving water quality and the responsible use of water are key areas to be considered during aquaculture development. A number of biotechnologies are being used to address these areas: bioremediation for the degradation of hazardous wastes; the use of vaccination and probiotics to reduce antimicrobial use; and the use of DNA-based methodologies for the early detection of toxin-producing algae.

4.2.4 Biodiversity conservation and fisheries management

In fisheries management, conservation is an important concept. Good fisheries management requires effective conservation measures, which require better understanding of the population structure of the fishery. One of the most important population parameters for assessing the fate of a population is the effective population size (N_e), which determines the amount of genetic variation, genetic drift and linkage disequilibrium in populations and can be calculated as half the reciprocal of the rate of inbreeding (e.g. Tenesa *et al.*, 2007). There is much concern in fisheries and aquaculture production about the potential loss of genetic variation that may result from the relatively high rates of inbreeding expected in these populations. This is because many fish and shellfish species produce thousands or even millions of fertile eggs from a single female. Due to differences in the biological and environmental factors affecting the survival of individual families, many species show a relatively large variance in family size, further decreasing the N_e (Falconer and MacKay, 1996). Fisheries resource managers have focused on the actual number of individuals in a population (census numbers) (Grant, 2007), which may be many times higher than the N_e (Hauser *et al.*, 2002; FAO, 2006). Therefore, it is difficult or even impossible in some cases to infer the N_e using the census number. Inadequate procedures for stock enhancement can yield a very small effective population size due to the high prolificacy of fish and shellfish species. Thus, a very small number of breeders could be used for restocking purposes, and bottlenecks can affect the fitness of the population in future generations. A range of biotechnology-based approaches are being used to conserve wild fish populations such as the use of molecular markers: to estimate N_e in wild populations; to study gene flow between farmed and wild fish populations; and to monitor and understand changes in wild fish population sizes (FAO, 2006; Hansen, 2008).

4.3 CURRENT STATUS OF APPLICATION OF BIOTECHNOLOGIES IN DEVELOPING COUNTRIES

In fisheries and aquaculture, although perhaps not as much as in livestock and crop production, some biotechnologies have been used in developing countries. As mentioned earlier, use of biotechnologies in fisheries is very limited whilst in aquaculture biotechnologies are represented in a few fields such as genetic improvement, disease control, feeds and nutrition and environmental improvement.

4.3.1 Genetic improvement and control of reproduction

4.3.1.1 Polyploidy

Many fish and shellfish species are relatively tolerant to chromosomal manipulation in the early stages of their development. The use of genetic manipulation including polyploidy (i.e. increasing the number of sets of chromosomes) to improve aquaculture production has been examined. However, there has been little discussion of the use of these technologies in practical management programmes in developing countries or on how they can be used efficiently within the context of breeding programmes. Furthermore, the potential value of this technology under practical conditions for enhancing the performance of commercial populations in developing countries is not clear.

The induction of polyploidy has been considered by many researchers (Purdom, 1983; Thorgaard, 1986) because of the advantages related to triploid sterility. For example, triploids (with three sets of chromosomes) may be useful for conservation programmes where sterility can prevent introgression of genes from escaped individuals of commercial stocks into natural populations (Galbreath and Thorgaard, 1994), or in commercial operations where sterile fish are desirable to prevent side effects such as deterioration of carcass quality due to maturation or the occurrence of high mortalities in stocks when males mature early or that occur prior to maturation, especially in populations of Pacific salmon (Purdom, 1983; McGeachy, Benfey and Friars, 1995).

Triploidy leads to the production of nearly completely sterile populations, as has been observed in rainbow trout populations with spontaneously occurring triploids (Thorgaard and Gall, 1979). However, the degree of reproductive disruption varies depending on the species and the sex. Gametogenesis is severely disrupted in triploid females of salmon while, in contrast, triploid males usually display secondary sexual dimorphism (i.e. darkened skin colour and modified body conformation), courtship behaviour and develop an endocrine profile similar to that of diploid males. Spermatogenesis, however, appears to be somewhat reduced in comparison with diploid males (Benfey *et al.*, 1986). Although triploid males are to a great extent sterile, fertilization has been reported to occur. In the salmon aquaculture industry, sexual maturity and the associated gonadal development is generally an economic drawback as metabolic energy is diverted from somatic cell growth to reproduction, resulting in the deterioration of flesh quality and appearance. In this situation, the advantages of triploidy occur primarily after the onset of maturation when triploid female fish may show an extension of growth (Thorgaard, 1986) and the inhibition of maturation prevents the normal degradation in carcass quality that is observed during the spawning season (Asknes, Gjerde and Roald, 1986). Furthermore, female salmon triploids show a significantly higher dress-out percentage (Thorgaard and Gall, 1979) and higher pigment (canthaxanthin) retention (Choubert and Blanc, 1989), but concomitantly, there is an increase of fat deposition surrounding the viscera.

In developing countries, the practical implementation of triploidy in fish production has not been very successful. Most of the research on the application of this biotechnology has been experimental, without extensive testing under practical conditions that consider the wide range of environments in which aquaculture takes place. In species such as tilapia and carp, testing of triploidy is a very important issue considering that there is intraspecies variation in the rate of triploidization due to the size and quality of the eggs. For this reason, it is not possible to ensure 100 percent triploidy when applying this technique on a commercial scale. Also, an increased mortality rate at the beginning of the life cycle and the detrimental effect of triploidy on growth and fitness could be significant constraints to the commercial production of triploids in some species (Basant *et al.*, 2004). The lack of knowledge about the effects of competition between triploids and diploids in large extensive conditions in species such as tilapia could also be a disadvantage, since triploids sometimes lack robustness compared with normal diploids, but this expression varies among species (Benfey, 1999). In many cases, the variation in performance between diploid and triploid stocks has not been fully estimated, and thus it may not be possible to accurately predict the relative performance of triploids in commercial conditions, which may be a problem in conventional breeding programmes of many fish and shellfish species (Pechsiri and Yakupitiyage, 2005).

In developing countries, for various reasons, these techniques are not currently used for commercial purposes. Tilapia, for example, cannot be easily reproduced using external fertilization which is a prerequisite for shock treatment. Furthermore, when a very small number of eggs are obtained per spawn, it is not possible to ensure a constant rate of triploidy per spawning. In rainbow trout, it is only profitable to use triploid females since males show some degree of reproductive onset. For developing such female triploid populations, neomales (i.e. morphologically male but genetically female) are required, which in some instances are difficult to stock up to a commercial scale. In Indian carps, sterility aiming at faster growth and thus enhanced production may not be cost-effective since harvesting after one year of age is not profitable (males mature at one year of age and females when approaching two years).

In southern India, precocious maturation is a potential constraint on yields of cultured common carp as both males and females can attain sexual maturity well before reaching a marketable size. However, triploid fish did not show any improvement over diploid individuals except for higher dress-out percentages (Basavaraju *et al.*, 2002).

Despite the plethora of research conducted on triploidization and chromosomal biotechnologies, there remains a gap between research findings and the practical implementation of triploidy. Several reasons explain this fact. The usefulness of applying chromosomal biotechnologies such as triploidy for aquaculture production seems to be very species-specific, and therefore in some cases (such as in salmon, tilapia and carp), the advantages due to delayed maturation or increased growth are unclear. Furthermore, the results of using these techniques to increase growth rate or delay reproduction are not seen as sufficiently beneficial for the technique to be implemented on a large scale (P. Routray, Central Institute for Freshwater Aquaculture, personal communication, 2009).

For the technology to be practical, it should be possible to produce all-triploid populations without the need to test the triploidy status of each batch of embryos produced. Because triploidy induction using thermal shock is not 100 percent effective, this is a serious drawback to the large-scale commercial application of the technique. Crossing between tetraploids (with four sets of chromosomes) and diploids is a way to produce 100 percent triploids; however, in most species tetraploid production is not straightforward. Furthermore, the genetic lag between the tetraploid population and the diploid breeding programme can seriously affect the efficiency of the production system. For all these reasons, this technology has not been used extensively in developing countries for production purposes.

4.3.1.2 Gynogenesis/androgenesis

Gynogenesis is the production of an embryo from an egg after penetration by a spermatozoon that does not contribute genetic material. Androgenesis is the production of an embryo from an egg whose DNA was inactivated and which was fertilized using normal sperm. In both cases, the diploidy is restored using heat/cold shocks. In gynogenesis, if diploidy is restored soon after fertilization, the procedure is called meiotic gynogenesis due to the fact that the second polar body is retained, and this procedure is similar to what is expected under autofertilization in terms of inbreeding. If shocks are applied later or in androgenesis where the ova were DNA-irradiated for DNA inactivation, the same chromosome is duplicated and thus the embryo is a double haploid individual which is completely inbred for every locus.

Several papers have discussed the usefulness of this type of reproduction for genetic analysis in carp, tilapia and rainbow trout breeding programmes. In some cases, the use of gynogenetic individuals has been suggested for capitalizing on non-additive genetic effects to increase additive genetic variance and for product uniformity (Bijma, van Arendonk and Bovenhuis, 1997). However, the production of gynogenetic lines is not without problems. After a first round of gynogenesis from an outbred population, deleterious and/or lethal effects can be fully expressed in the double haploid progeny, which may be a problem when implementing a breeding programme from this source. Furthermore, phenotypes cannot actually be a direct reflection of the same trait measured on normal progeny due to developmental instability. Therefore, the utility of this type of reproduction for practical use in breeding programmes is seen as risky in most cases. Nonetheless, they can be used effectively for developing powerful quantitative trait locus (QTL) mapping experiments using the surviving clonal lines of this sort obtained from an outbred population, but this requires having available the gynogenetic lines that are needed for further assessment (FAO, 2007a).

4.3.1.3 Controlling time of reproduction in fish and shellfish

So far, the application of hormonal treatment has been quite successful especially for controlling reproduction in broodstock. This is particularly the case in salmon and trout farming in Chile where either implants or injection of the hormonal compound are used extensively in salmon farming for synchronizing reproduction. Since hormone application is not done in the commercial fish, but rather in the broodstock which are discarded for human consumption, these procedures are not subjected to a negative consumer preference. In carp breeding, the use of hormones has made it possible to artificially manipulate the number of times and the timing of spawning of major Indian carps and African catfish (Routray *et al.*, 2007).

4.3.1.4 Development of monosex populations

One of the major constraints in practical programmes in developing countries is the fact that mixed sexed populations can behave poorly in production conditions (FAO, 2003). This is primarily due to the negative side-effects of early reproductive onset that decrease the growth rate through a series of physiological mechanisms. The faster growth rate of the other sex is probably caused by its later maturation. The negative relationship between growth rate and gonadal development has been found in many species. One explanation of this finding is the appearance and accumulation of sex hormones that act as growth inhibitory agents (Hulata, Wohlfarth and Moav, 1985).

The advantages of monosex culture depend on the species involved (FAO, 1995). This is because one sex may be superior in growth or have a more desirable meat quality, or to prevent reproduction during grow-out or the appearance of sexual/territorial behaviour (aggressiveness) that occurs when a mixed sexed group triggers the reproductive season. For example, female sturgeon are more valuable than males because they produce caviar; female salmon are more valuable because sexually precocious males die before they can be harvested, and salmon roe has an economic value; and male tilapia are more desirable than females because they grow twice as fast and because reproduction is not significant in males during grow-out.

The sex of fish can easily be manipulated using hormonal treatments. In many fish and shellfish species, sex is not permanently defined genetically and can be altered by a number of factors including hormonal treatment during the early stages of development. Gonadal development starts from primordial germ cells, with females starting differentiation prior to males (Phelps, 2001). The point in time when differentiation occurs depends on the species involved. In tilapia and trout, this mechanism is triggered early in life, while in grass carp and paddlefish it is the opposite (Phelps, 2001). Considering this pattern of development, treatment with the steroid methyl testosterone can be used to develop all-male tilapia populations (Mair, 1999) and androgens (male sex hormones) can be used in trout and carp monosex culture.

There has been concern about the use of hormones in animal production including in aquaculture systems, arising from the risk of presence of residues in final products. Although there is little evidence regarding hormonal residues in fish whose sex has been reversed early in life, consumer acceptance may be compromised as a result of the perception of hormonal treatment itself (FAO, 2003). For this reason, it appears that other biotechnologies have had more use in those developing countries whose production goes mainly to export markets.

A variation on this scheme is to produce all-male progeny in one more generation. This requires feeding young fish with estrogens (female sex hormones), resulting in a population of all-female fish (Fitzsimmons, 2001). These morphologically female but genetically male fish (neofemales) are then raised to maturity when they are mated to normal male fish. After maturation, the all-male fry produced are tested in order to identify the "super males" (YY), which are then crossed to normal females (XX), thus generating all true male (XY) progeny. The importance of this method is that male fry for commercial production can be produced that have never been treated with hormones. However, one of the disadvantages is that this technique requires more than a single generation to obtain the all-male fry, i.e. this procedure cannot be used without extensive progeny testing to determine which "female" fish will produce all-male progeny, thus requiring a reasonable time span for developing the neomales.

Although tilapia breeding programmes using YY super males are possible, this procedure is not necessarily required because the application of direct hormonal treatment of undifferentiated fry to produce monosex populations is still a major breakthrough.

However, the great expansion of tilapia aquaculture in Asia has been due to mixed-sex tilapia culture which addresses the high demand for relatively small fish (i.e. fish less than 300 g) that can be obtained by rearing the highly selected genetically improved farmed tilapia and other strains.

4.3.1.5 Cryopreservation

The aim of the cryopreservation of gametes is related to:

- disseminating semen from males obtained from selection programmes showing significant response;
- "refreshing" commercial populations in order to avoid the negative impact of bottlenecks;
- directly assessing the rates of genetic gain in ongoing breeding programmes;
- making semen available across the reproduction window when asynchrony of reproduction exists between males and females (usually males mature earlier than females).

Sperm cryopreservation has been successfully implemented for a number of cultured finfish and shellfish species, and modest success has been achieved in the cryopreservation of shellfish embryos and early larvae. Cryopreservation of finfish ova and embryos has not been successful, which is a major difference with respect to terrestrial animals. This is mainly due to the size of the ova which are usually large and have thick chorionic membranes that do not facilitate the inclusion of cryoprotectors.

The use of cryopreserved gametes for commercial purposes is still very limited in developing countries. One explanation is that this biotechnology may require specialized labour and automated procedures to decrease variability in success rates among batches of sperm. Furthermore, it is still uncertain whether this method is economically advantageous compared with disseminating improved broodstock using larval material. In spite of this, the technology has been used for disseminating improved "Jayanti" rohu in India and for the dissemination of improved semen in Sri Lanka (P. Routray, personal communication). In rainbow trout, cryopreservation has been used for storing semen from neomales, but the problem of highly variable fertilization success remains.

4.3.1.6 Genomics

Genomics is the study of the genomes of organisms. It includes the intensive efforts to determine the entire DNA sequence of organisms via fine-scale genetic mapping.

Genome sequencing

One of the major constraints in the rearing of many different aquaculture species is the lack of adequate genomic information. This is because sequencing all the species currently used in aquaculture would be costly. Productive species currently being sequenced are the tilapia and the Atlantic salmon (*Salmo salar*). A multinational initiative for Atlantic salmon aims to sequence the genome using the Sanger method to obtain a coverage of more than six-fold. The project is a partnership between Canada, Norway and Chile, countries that are interested in applying this sequence data for studies related to enhancing conservation and production. The project's output will be delivered to the public domain and provide the required genomic resources for developing single nucleotide polymorphism (SNP) chips that will help implement marker-assisted selection (MAS) programmes in Chilean salmon aquaculture.

Functional genomics

The recent availability of massive amounts of information from functional genomics such as microarrays that are used to assess gene expression or sequence polymorphisms has contributed significantly to the genomic biotechnology in aquaculture. Two colour microarrays have been developed for salmonid species that are publicly available and are currently used to assess disease resistance traits in salmon and for candidate gene discovery. In shrimp, several platforms have been devised in China, Australia, Taiwan Province of China, Singapore and also the United States (Wilson and de la Vega, 2005).

The main use of this resource has been to study differential expression of the transcriptome after viral or bacterial acute infection, but also as bioindicators for assessing chronic disease response. Microarrays are being applied to the fields of ecotoxicology and nutrigenomics. For example, gene expression analysis has been used for assessing the effect of pre-challenging white spot syndrome virus (WSSV) on different genes in order to investigate the immunological mechanisms behind the genetic resistance and to assess potential genes explaining disease resistance at the experimental level in the culture of Pacific whiteleg shrimp (*Litopenaeus vannamei*) in Colombia. In Chile, the salmon microarray available for the consortium for genomics research on all salmon project (cGRASP[1]) in Canada has been used in collaboration with the University of Victoria for assessing disease resistance of piscirickettsia and infectious pancreatic necrosis virus (IPNV) in Atlantic salmon.

4.3.1.7 Genetic modification

A genetically modified organism (GMO) is one whose genetic material has been altered through genetic engineering techniques with DNA molecules from different sources that are combined into one molecule to create a new set of genes. Typically, it involves introduction of a single gene from an unrelated species. After about two decades of very intensive research, the

1 http://web.uvic.ca/grasp/

technology has reached the stage where it is possible to produce GM carp, tilapia and salmon. However, no aquatic GMOs have yet been approved for commercial release for food and agriculture purposes in any country. There are potential concerns about the environmental impact of raising such fish (e.g. effects of possible interbreeding with native populations) and the greater amount of feed required for sustaining the increased growth rates, as well as problems with consumer acceptance, which may be one of the most important reasons that transgenic technology has not developed beyond the experimental phase. Many developing countries have yet to develop a clear policy on the use of transgenic fish.

4.3.1.8 Molecular markers

Marker systems

Molecular markers are identifiable DNA sequences found at specific locations of the genome, transmitted by standard Mendelian laws of inheritance from one generation to the next. They rely on a DNA assay and a range of different kinds of molecular marker systems exist, such as restriction fragment length polymorphisms (RFLPs), random amplified polymorphic DNAs (RAPDs), amplified fragment length polymorphisms (AFLPs) and microsatellites. The technology has improved in the past decade and faster, cheaper systems like SNPs are increasingly being used. The different marker systems may vary in aspects such as their technical requirements, the amount of time, money and labour needed and the number of genetic markers that can be detected throughout the genome (reviewed in detail in FAO, 2007b). RAPDs and AFLPs have been used extensively in aquaculture due to their relatively easy development, i.e. they do not require construction of genomic libraries. Microsatellite markers are used increasingly in aquaculture species (see the review by Liu and Cordes, 2004), due to their higher polymorphic information content, codominant mode of expression, Mendelian inheritance, abundance and broad distribution throughout the genome (Wright and Bentzen, 1994).

Molecular markers are being applied in developing countries in both aquaculture and fisheries management. Here, an overview is provided on their use for parentage analysis and genetic selection in aquaculture and for fisheries management and stock enhancement.

Parentage analysis

Molecular markers can be used successfully to trace alleles inherited by progeny from a group of candidate parents, thus providing a means of parentage analysis. In many fish and shellfish species, reproduction cannot be fully controlled and thus natural mating is the only way to produce offspring for the next generation of a breeding programme. For example, tilapia and carp breeding typically involves mass spawning where males and females are stocked in large "hapas" suspended in ponds, where a relatively large number of parents spawn simultaneously. Since constrained rates of inbreeding are required for sustained rates of genetic gain, in uncontrolled mating schemes it is not always possible to control the genetic contributions of broodstock or, therefore, the rates of inbreeding in a breeding programme using pedigree information. Small sample sizes together with sperm competition (Withler and Beacham, 1994), mating preference (as in Artemia) and other biological factors after fertilization can increase the variance of family size, thereby decreasing the N_e to unsustainable levels (Brown, Woolliams and McAndrew, 2005).

When it is possible to control matings, one of the most important constraints still facing effective breeding programmes of species such as salmon, carp and trout is that newborn individuals are too small to be tagged individually using the traditional marking systems for livestock. The application of sustainable breeding programmes requires tagging a constant number of individuals from each family with passive integrated transponders (PIT tags) when they become sufficiently large after a period of individual family rearing, in order to manage the rates of inbreeding. However, this system of early management creates common environmental effects for full-sib families (Martinez, Neira and Gall, 1999). To address these issues, mixtures of equal-aged progeny from different families can be reared communally to preclude the development of such family-specific environmental effects, and genetic markers can be used subsequently to assign individuals to families after evaluation of individual performance (Doyle and Herbinger, 1994). Thus, the impact of early common environmental effects is considerably reduced if markers are used for parentage analysis when selecting individuals for early growth rate traits (Herbinger *et al.*, 1999; Norris, Bradley and Cunningham, 2000). Several multinational salmon companies are using this system of tagging but there is still no information regarding its economic value compared with conventional tagging systems such as PIT tags. This may be important in species such as carp and tilapia where the costs of genotyping can greatly outperform the use of tanks and individual tagging systems. Furthermore, it is expected that rates of genetic gain for economic traits will not be significantly affected when common environmental effects are present.

Even though there is a plethora of information in the scientific literature on the use of markers for parentage analysis in fish and shellfish, this procedure has not been fully used in species such as tilapia in developing countries where basic conventional breeding programmes have proved very successful (Ponzoni, Nguyen and Khaw, 2006). The sample size (i.e. the numbers of individuals and markers required for accurately reconstructing the pedigree of a population) is a practical issue since not all individuals in a population can be genotyped for all markers available. The issue of sample size may also arise in species where physical tagging is not possible or not economically sound (e.g. shrimp or marine species), or when disease challenges (e.g. with infectious pancreatic necrosis) are carried out very early stages in the life cycle.

For most breeding programmes, physical tagging will prove efficient both in economic and biological terms to achieve acceptable rates of genetic gain while minimizing rates of inbreeding. Genetic marker technology can still be costly in developing countries for routine assignment of parentage, although these costs can be reduced using multiplex PCR technology in which more than one marker can be genotyped simultaneously in a single gel lane or capillary (Paterson, Piertney and Knox, 2004). This is especially the case when only DNA markers are used without physical tagging, since individuals must be re-typed when records for multiple traits are included in the selection criteria (Gjerde, Villanueva and Bentsen, 2002). When it is possible to isolate families, multistage selection offers the possibility of first selecting individuals on a within-family basis directly from tanks or hapas (for traits influenced by common environmental effects) and then selecting at a second stage for traits measured at harvest. This alternative would maintain the rates of gain while decreasing the costs associated with tagging, or even increase rates of gain, when recording traits such as body weight from tanks (within families) that can be carried out relatively inexpensively (Martinez *et al.*, 2006).

Marker-assisted selection

Molecular markers can also be used in genetic improvement through MAS, where markers physically located beside (or even within) genes of interest (such as those affecting growth rates in salmon) are used to select favourable variants of the genes (FAO, 2007b). MAS is made possible by the development of molecular marker maps, where many markers of known location are interspersed at relatively short intervals throughout the genome and the subsequent testing for statistical associations between marker variants and the traits of interest. In this way, genes (called QTLs) thought to control quantitative traits (traits of agronomic importance controlled by many genes and many non-genetic factors, such as growth rate in fish) can be detected.

MAS can enhance rates of genetic gain compared with conventional breeding for traits that are difficult or expensive to measure or when the heritability is relatively low. So far, many QTLs have been identified in different experiments involving trout, salmon, carp and tilapia, but the main problem with the actual use in MAS is to have enough replications or powerful experiments to validate that the QTLs detected in a given experiment are actually real, and are segregating across populations or crosses. Furthermore, many of the QTLs detected were discovered using dominant markers such as RAPDs which are very difficult to replicate in different laboratories, basically due to the use of insufficient sample sizes and failure to account for the presence of false positives. This outcome is explained by the fact that there is a lack of complete genome sequences for many of the species currently used in aquaculture in developing countries such as tilapia, carp and shrimp. This is an important practical issue, because without information from physical maps it may be difficult to characterize the actual genes explaining the genetic variation explained by the QTLs. This situation reflects the relatively high level of financial resources needed both to carry out a genome sequence project for many species used in aquaculture and to actually implement a MAS programme. This is a very important issue in developing countries where smallholders are less likely to have the financial revenue to allow breeding programmes that incorporate the use of molecular information. Although MAS is potentially useful for many cultured species, conventional breeding programmes may be more profitable in the short to medium term in developing countries in low-input environments.

The development of molecular markers and linkage maps can greatly help scientists to understand the different factors that influence the expression of quantitative traits. A number of genetic linkage maps have been published in aquaculture, some of the most comprehensive being for rainbow trout (Young *et al.*, 1998; Sakamoto *et al.*, 2000; Nichols *et al.*, 2003), channel catfish (Waldbieser *et al.*, 2001), tilapias (Kocher *et al.*, 1998; Lee *et al.*, 2005), Japanese flounder (Coimbra *et al.*, 2003) and mussels (Lallias *et al.*, 2007). In shrimp, recent mapping has demonstrated the nature of sex control in shrimp as WZ/ZZ like chickens and unknown until now. Still, in important species such as Indian major carps and Chinese carps, they have not been developed. There are a number of ways in which this information can be used, the difference between them being the level of resolution with which these factors can be mapped. For example, QTLs with major effects on quantitative traits are mapped using markers to track the inheritance of chromosomal regions in families or in inbred line crosses using the extent of linkage disequilibrium generated in the population.

In practice, the identification of genes influencing specific traits is achieved using a combination of genetic mapping (linkage and fine mapping) to localize the QTL to a small region on the chromosome under analysis, and candidate gene or positional cloning approaches are used to identify the genes within the QTL region. According to the literature survey, it appears that very little information has come from developing countries on such research issues.

In some cases, it is possible to use sufficient biochemical or physiological information to investigate the association between the quantitative genetic variation and the level of marker polymorphisms within specific genes. Nevertheless, this approach requires a great amount of detailed information in order to choose which gene explains the greatest effect and to have sufficient power to detect the association. This information is starting to appear in the aquaculture literature from multinational projects such as cGRASP, but it is still scarce for other fish species of interest in developing countries.

So far, QTL mapping in aquaculture using commercial populations has been carried out mainly in developed countries, mostly with single-marker analysis (microsatellites and AFLPs) and using relatively sparse linkage maps when interval mapping is used. In tilapia, the F_2 design and a four-way cross between different species of *Oreochromis* have been used for detecting QTLs affecting cold tolerance and body weight (Cnaani *et al.*, 2003). In outbred populations of salmonids, QTLs that influence body weight have been mapped (Reid *et al.*, 2005).

Studies seeking linkage of markers to traits amenable to MAS, such as disease resistance, have begun to appear in the literature over the past few years. For example, QTLs for resistance have been mapped for IPNV in salmonids (Ozaki *et al.*, 2001; Houston *et al.*, 2008), infectious salmonid anaemia (Moen *et al*., 2007), infectious haematopoietic necrosis virus (Rodriguez *et al.*, 2004; Khoo *et al.*, 2004) and stress and immune response (Cnaani *et al.*, 2004) and cold tolerance in tilapia (Moen *et al.*, 2003). Also, Somorjai, Danzmann and Ferguson (2003) reported evidence of QTLs for upper thermal tolerance in salmonids, with differing effects in different species and genetic backgrounds. To date, there are no examples of the application of these QTLs in practical fish and shellfish breeding programmes in developed or developing countries.

4.3.2 Biosecurity and disease control

Like other farming systems, the aquaculture industry has been overwhelmed by a fair share of transboundary aquatic animal diseases caused by viruses, bacteria, fungi, parasites and other undiagnosed and emerging pathogens. Disease has thus become a primary constraint to the culture of many aquatic species, impeding both economic and social development in many countries. As a result, there will be increasing demand for improved aquatic animal biosecurity, particularly addressing the emerging health problems based on risk analysis. Epidemiological studies generate the data required for risk analysis; biosecurity measures require good information for accurate assessment and this leads to appropriate risk management. Thus, biosecurity, risk analysis and epidemiology are highly interrelated. All are aimed at making good use of scientific research for disease prevention, control and management.

Of equal importance is the need for fundamental information that characterizes diseases in aquaculture. Import risk assessment will of necessity set the risk as "high" when there are little data on modes of transmission, host susceptibility, tolerance to abiotic factors (e.g. temperature, salinity) and immune response elicited, for a particular pathogen under consideration. The clear, unambiguous and rapid detection and identification of potential pathogens using morphological and molecular diagnostic tools are of paramount importance prior to making decisions on the disease status of any aquaculture zone.

Although conventional disease control strategies focus largely on diagnosis and therapy, the prevention of disease through vaccination, immunostimulation, the use of probiotics and bioremediation in culture environments, nutritional improvements etc., has also been practised. Significant advances in these areas have been achieved using biotechnological approaches.

Given the taxonomic diversity of aquaculture species, there is also a need to develop better information on the response of these species to disease in order to develop management strategies for them. Biotechnology approaches are sometimes the only means by which tools for this can be developed.

4.3.2.1 Pathogen screening and disease diagnostics

The control of disease outbreaks relies heavily on having rapid and accurate diagnostic tools available in order to detect and identify the pathogen causing mortality. DNA and RNA methods have been used extensively for detecting a number of viral and bacterial pathogens in aquaculture worldwide. The techniques rely upon the fact that each pathogen species carries a unique DNA or RNA sequence that can be used for identification. The techniques offer high sensitivity and specificity, and the commercial development of PCR primers and diagnostic kits allows rapid screening for a number of serious viral and bacterial infections and has direct application. Molecular-based techniques such as PCR also have applications in situations where the animal shows no antibody response after infection. For example, as molluscs do not produce antibodies, antibody-based diagnostic tests have limited application to pathogen detection in these species.

Considering the difficulties that developing countries may face in using advanced molecular diagnostics, and the importance of gradually improving national diagnostic capacities in developing countries, FAO recommended a three-level diagnostic process (FAO/NACA, 2000). This involves: field observations and necropsy (Level I); laboratory observations, bacteriology and histopathology (Level II); and electron microscopy, molecular biology and immunology (Level III). In countries where Level II and Level III diagnostic capabilities are not found, initial disease screening is carried out using Level I gross clinical examination. Accompanied by histopathology, this has been the traditional method of detecting pathogens in both developed and developing countries. There is a clear need to improve national diagnostic capacities to reach Level II and Level III diagnostic procedures, including molecular diagnostics.

These tools include both immunoassay- and DNA-based diagnostic methods, e.g. fluorescent antibody tests, enzyme-linked immunosorbent assays (ELISA), radioimmunoassay (RIA), *in situ* hybridization (ISH), dot blot hybridization and PCR amplification techniques. They are currently used to screen and/or confirm the diagnosis of many significant pathogens of cultured finfish such as channel catfish virus, infectious haematopoietic necrosis virus, IPNV, viral haemorrhagic septicaemia virus, viral nervous necrosis virus and bacterial kidney disease, as well as shrimp diseases such as WSSV, yellow head virus (YHV), infectious hypodermal and haematopoietic necrosis virus (IHHNV) and Taura syndrome virus (TSV) (FAO, 2000). Similar tools are under development for molluscan pathogens (*Haplosporidium* sp., *Bonamia ostreae*, *Marteilia refringens* and Herpes virus). Immunoassays and nucleic acid assays provide quick results with high sensitivity and specificity at relatively low cost, and are particularly valuable for infections that are difficult to detect (e.g. subclinical infections) using standard histology and tissue culture procedures. Molecular tools are also useful for research into the pathology and immunology of specific infections. They can be used with non-lethal sampling and are valuable for monitoring challenge experiments under controlled laboratory conditions. Further development of these technologies is likely to speed up the detection (field monitoring and laboratory examination) and diagnosis of disease, which is crucial for early and effective control of emergent disease situations.

Antibody-based techniques

A variety of antibody-based tests and molecular tests have been developed to detect mainly bacterial and viral fish pathogens, although tests have also recently been reported for parasites and fungal agents. The antibody-based tests include slide agglutination, co-agglutination/latex agglutination, immunodiffusion, direct and indirect fluorescent antibody tests, immunohistochemistry and ELISA, dot blot/dip-stick and Western blot. The antibody-based test selected for the identification of pathogens depends on a variety of factors since each method has its merits and disadvantages. Although such methods are useful for the detection of pathogens in pure culture or/and in infected fish tissue, their sensitivity thresholds limit their use in environmental samples, especially where pathogen levels are extremely low. DNA detection methods, however, such as PCR and ISH are ideally suited.

DNA-based techniques

Molecular technologies are also widely used for the detection of fish pathogens (Adams and Thompson, 2006 and 2008). They have been successfully utilized for the detection and identification of low levels of aquatic pathogens. Such methods are also particularly useful for micro-organisms that are difficult to culture, may exist in a dormant state, are involved in zoonosis, or in the elucidation of pathogen life cycles. In addition, molecular methods can be used for the identification of pathogens to the species level (Puttinaowarat, Thompson and Adams, 2000) and in epidemiology for the identification of individual strains and differentiating closely related strains (Cowley *et al.*, 1999). Because of the general unavailability of the traditional pathogen isolation methods and immunodiagnostics for molluscs and crustaceans, molecular techniques have increasingly been used (Lightner, 1996; Lightner and Redman, 1998; Berthe, Burreson and Hine, 1999).

DNA-based methods such as PCR are extremely sensitive. However, false positive and false negative results can cause problems due to contamination or inhibition (Morris,

Morris and Adams, 2002). Real-time PCR (closed tube to reduce contamination) and nucleic acid sequence-based amplification are alternatives that reduce these risks and offer high sample throughput (Overturf, LaPatra and Powell, 2001; Starkey *et al.*, 2004). Some of the most common PCR-based technologies used for the detection of pathogens are nested PCR, RAPDs, reverse transcriptase PCR (RT-PCR), reverse cross blot PCR and RT-PCR enzyme hybridization assay (Puttinaowarat, Thompson and Adams, 2000; Wilson and Carson, 2003; Cunningham, 2004). ISH is also widely used in the detection of shrimp viruses (Lightner, 1996; Lightner and Redman, 1998; Tang and Lightner, 1999; Tang *et al.*, 2005) and in the confirmation of mollusc parasites (Stokes and Burreson, 1995; Le Roux *et al.*, 1999; Cochennec *et al.*, 2000; Carnegie *et al.*, 2003). Colony hybridization has also been used successfully for the rapid identification of *Vibrio anguillarum* in fish (Aoki *et al.*, 1989) and has the advantage of detecting both pathogenic and environmental strains (Powell and Loutit, 2004).

In recent years, the use of PCR-related tools has gained wide acceptance in developing countries. The advent of PCR has lead to important advances in the development of routine diagnostic tests, and it has been possible to develop probes aimed at the detection of pathogen genetic material in host tissue, as well as for assessing genetic variability within and between fish and shellfish populations. Both DNA- and RNA-based methods have been devised to detect pathogen genetic material. Depending on the pathogen, conventional PCR can be replaced by the more sensitive nested PCR method, in which primers within the region amplified in a first step are used for further amplification of DNA. RNA quantification can be carried out using RT-PCR of the viral nucleic acids present in sample tissues. As with the immunological methods described earlier, it should be noted that PCR does not demonstrate the presence of disease nor of a viable pathogen, but only that pathogen genetic material was present in the sample being examined. Despite this limitation and other problems related to ease of contamination, false positives, the limited number of primers available etc., when properly applied, PCR offers a relatively rapid and inexpensive way for the routine screening of large numbers of aquatic animals for commercial aquaculture and for testing of imported stocks during quarantine. For example, PCR is very important in the routine screening of massive numbers of penaeid shrimp larvae for serious viral pathogens such as WSSV, TSV etc. in Asian and Latin American countries.

DNA probes and epidemiology

DNA probes have particular value in the fields of epidemiology, routine disease surveillance and monitoring, treatment and eradication programmes in aquaculture and efforts to prevent the spread of pathogens to new geographical areas. These biotechnologies also have important application in risk management for aquatic animal diseases including inspection and certification of production and facilities and consignments for freedom from specific pathogens; achieving recognition of a country as having disease-free status; and implementing disease zoning programmes and effective quarantine measures etc. (Bernoth, 2008).

The Manual of Diagnostic Tests for Aquatic Animals, regularly published by the World Organisation for Animal Health (OIE), validates the use of traditional diagnostic methods such as evaluation of clinical signs, necropsy, histopathology, parasitology, bacteriology, virology, mycology etc., as well as immunological tests such as ELISA for the presumptive and confirmatory identification of OIE-listed diseases. The introduction to the Manual notes that "For the most part, molecular methods for fish diseases are recommended for either direct detection of the pathogen in clinically diseased fish or for the confirmatory identification of a disease agent isolated using the traditional method. With one or two exceptions, molecular techniques are currently not acceptable as screening methods to demonstrate the absence of a specific disease agent in a fish population for the purpose of health certification in connection with international trade of live fish and/or their products. There is a need for more validation of molecular methods for this purpose before they can be recommended in the Aquatic Manual" (OIE, 2009; see also Adams and Thompson, 2008). This highlights the importance of further validating these diagnostic tools for serious and emerging diseases across a range of different laboratories worldwide.

4.3.2.2 Vaccines

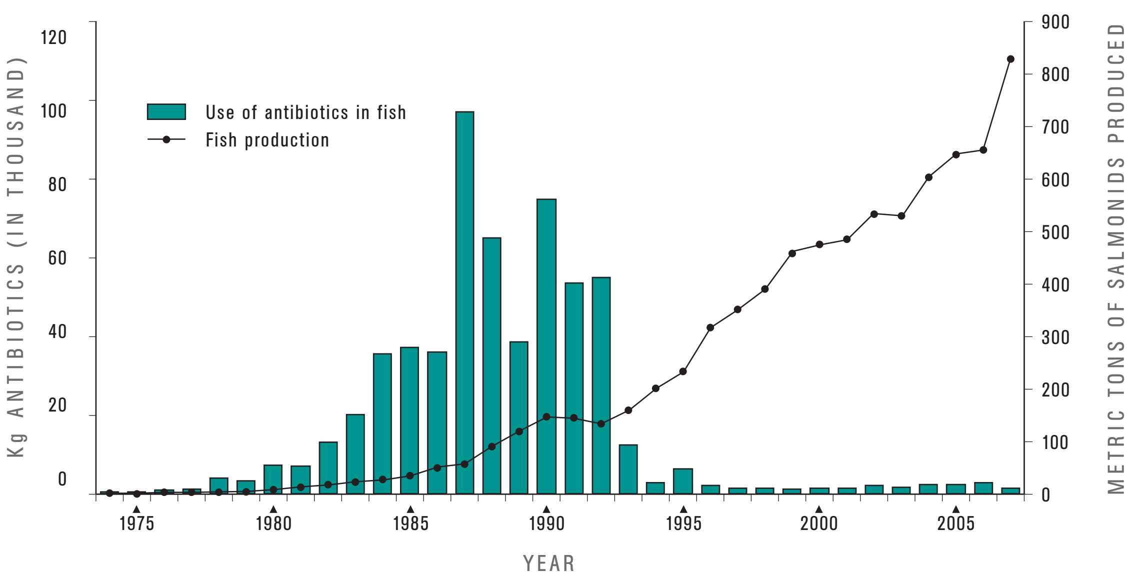
Adams *et al*. (2008) reviewed the vaccine technologies in aquaculture. Vaccination is the action in which a host organism is exposed to organic (biological) molecules that allow the host to mount a specific immune reaction through which it has a better capability to fight subsequent infections of a specific pathogen compared with genetically similar non-vaccinated hosts. It has also been shown to be cost-effective and has led to the reduction in use of antibiotics. In Norway, for example, antibiotic use has decreased from 47 tons to approximately one ton annually (Markestad and Grave, 1997 and Figure 4).

A wide range of commercial vaccines is available against bacterial and viral pathogens and many new vaccines are under development. Most target salmon and trout, and there are expanding opportunities for marine fish (Thompson and Adams, 2004). Traditionally, the organic molecules used for vaccination are directly derived from the pathogen in question. The most straightforward approach is to culture the pathogen after it has been inactivated and presented to the host. So far, vaccines containing more than ten bacterial pathogens and five viral pathogens have been produced based on such inactivated antigens (Sommerset *et al.*, 2005). Alternatively, the pathogen is not inactivated but chemically or genetically weakened so as to survive only for a limited period in the host where it induces a specific immune response without causing disease and mortality. Such vaccines are generally described as “live” vaccines, and there is concern that the attenuated strain may back-mutate and revert to the virulent wild type (Benmansour and de Kinkelin, 1997). Due to environmental and control concerns in most countries, only two live bacterial (*Edwardsiella ictaluri* and *Flexibacter columnarae* for Channel catfish in the United States) and one live viral vaccine (koi herpesvirus for carp in Israel) are commercially available at present.

One of the most important factors leading to reduced antibiotic use by the aquaculture sector is the availability of good prophylactic measures for diseases causing severe mortalities in cultured fish and shellfish. The use of vaccines provides good immunoprophylaxis for some of the most important infectious diseases of finfish. In developed countries, their use has proved very effective at decreasing the unsustainable use of antibiotics. For example, in Norway antibiotic use in salmon farming has become almost negligible, at less than 1 gram per tonne of production, due mainly to the availability of vaccines for furunculosis and cold water vibriosis (Figure 4) (Smith, 2008). At almost similar production levels, Chilean salmon farming shows much more antibiotic use due to the emergence of *Piscirickettsia salmonis*, a pathogen causing severe losses of stock prior to harvest. Thus, there have been recent attempts to develop immunoprophylactic measures.

FIGURE 4

USE OF ANTIBIOTICS VS. PRODUCTION OF FISH IN NORWAY



Source: T. Hastein, personal communication

As molecular-based vaccine production procedures rely heavily on biotechnological tools, vaccines are produced mainly in developed countries. A DNA vaccine is a circular DNA plasmid that contains a gene for a protective antigenic protein from a pathogen of interest (Kurath, 2008). Considerable industrial research has been conducted towards developing DNA vaccines for species such as salmonids against pathogens (generally viruses) for which traditional methods have not been successful. As many strains and varieties of a single pathogen are generally present in the tropics, unlike in temperate pathogens, monovalent vaccines are not practical under tropical conditions. Such difficulties, together with the lack of adequate biotechnological knowledge and financial resources, have led to fewer advances in vaccine development in the tropics, and for tropical species. Commercial vaccines using inactivated bacterial pathogens are available for some species: channel catfish, European seabass and seabream, Japanese amberjack and yellowtail, tilapia, Atlantic cod, salmon and trout (Sommerset *et al.*, 2005). Fewer commercially available viral vaccines have been produced, and no commercially available parasite vaccines exist.

4.3.3 Environmental management and bioremediation

Aquaculture, like any other live production system, produces effluents rich in nutrients. Some aquatic production systems also produce effluents with harmful substances such as residues and metabolites of antibacterials and therapeutics. Developing systems that produce effluents with acceptable standards and improving the quality of the aquatic environment where effluent discharges are unacceptably high is a challenge. Biotechnological interventions such as bioremediation, the use of probiotics, and vaccination offer significant promise for addressing these important issues.

Bioremediation is a promising biotechnological approach for the degradation of hazardous waste to environmentally safe levels using aquatic micro-organisms or other filtering macro-organisms. Although this procedure has been used in various situations such as sewage treatment (e.g. FAO, 2008), application to shrimp and other aquaculture wastes is fairly novel. There are many commercial products on the market, mainly bacterial preparations, but the mode of action and efficacy of many of these have yet to be scientifically measured. In addition to microbes, bivalves, seaweeds, holothurians (sea cucumbers) etc., have been tested to assess their ability to reduce organic loading or reduce the excess nutrients produced during culture production. Various bioremediation preparations have also been developed with a view to removing nitrogenous and other organic waste in water and bottom sludge and thus reduce chemically-induced physiological stress, e.g. in pond-reared shrimp. More products will undoubtedly emerge with continued research in this field, but controlled field trials are urgently needed to determine the effectiveness and cost-benefit of these products under culture conditions.

Probiotics are generally administered as live microbial feed supplements which affect the host animal by improving the intestinal microbial balance to optimize the presence of non-toxic species. A stable gut microflora helps the host resist pathogenic invasions, particularly via the gastro-intestinal tract. Antibiotics reduce specific or broad-spectrum gut microflora and probiotics may have post-antibiotic treatment potential for restoring the microbial balance. Probiotics are widely used in animal husbandry but their use in aquaculture is still relatively new. However, there are increasing reports of potential probiotics for shrimp aquaculture which has been plagued by opportunistic bacteria such as the luminescent *Vibrio harveyi*, and in some cases probiotics have been reported to significantly reduce antibiotic use in shrimp hatcheries. Suppression of proliferation of certain pathogenic bacteria (e.g. *Vibrio* spp.) in shrimp hatcheries has been achieved by introducing (inoculating) non-pathogenic strains or species of bacteria that compete for microbial metabolite resources. This procedure shows promise to be effective and economical. However, further refinement of the administration and concentration loads needed for effective pathogen suppression is required. Effective and economically viable probiotics also require greater research into optimal strains of probiotic micro-organisms and stringent evaluation under field conditions.

As discussed earlier, the control of disease using vaccines is a reputed technology. There are interesting examples of reducing antibacterial use in aquaculture through the use of vaccination particularly in temperate species such as salmon and trout. Reduction of the use of antibacterials not only diminishes the risk of rejection of aquatic products at international trading borders due to the presence/detection of residues above acceptable levels, it also helps in reducing the contamination of natural water bodies with harmful residues and the development of antimicrobial-resistant bacteria.

The proliferation of red tides with the blooming of harmful algae has been increasingly reported in many parts of Latin America, where the toxins represent a threat to food safety as well as a cause of fish and shellfish losses from the associated mortalities. Red tides can produce significant economic losses to fisheries and aquaculture due to bans on the marketing of fish and shellfish from the affected geographical area and to the toxic effects on fish. In Central America and the Caribbean, la “ciguatera” is the most important cause of toxic poisoning, resulting from consumption of tropical fish. In Latin America, blooms of *Alexandrium* spp. are one of the major causes of large economic losses due to the banning of commercial sales of mussels. In Chile, preventive closures cause about US$100 million in annual losses to the artisanal bivalve fishery. Furthermore, these closures have a direct negative impact on local employment in the shellfish production sector, which is labour intensive, thus having a detrimental effect on livelihoods. While it is not known if climate change is increasing the number of episodes of algal blooms, it is recognized that red tide episodes have recently become more common (Jessup *et al.*, 2009). Warm episodic currents also play a key role in causing large economic losses through mass mortalities of fish (Kedong *et al*., 1999).

To date, the detection of toxins due to algal blooms is carried out using mouse bioassays and high performance liquid chromatography, but new methodologies are being developed for detection of *Alexandrium catenella* (Uribe and Espejo, 2003). Expressed sequence tag (EST) libraries are now publicly available (Uribe *et al.*, 2008), so that it may be possible to develop molecular diagnostic techniques. To improve the prevention of impacts on aquaculture, PCR techniques and EST libraries can be used also to assist the early detection of toxin-producing algae in vast marine areas.

4.3.4 Biodiversity conservation and fisheries management

Restocking procedures are common in many developing countries, but the potential of restocking and stock enhancement stems primarily from the development of the technologies used to produce hatchery-reared juveniles (Bell *et al.*, 2006). The production of large numbers of juveniles and their subsequent release into the wild can affect a fishery resource in at least two ways (Bell *et al.*, 2006): 1) when stocking is done to restore a spawning biomass there is some scope for interbreeding between the natural population and the introgressed population and 2) there may be enough individuals used to restore the carrying capacity of the fishery.

From a genetic point of view, the main consequence of restocking may be the hybridization of non-native individuals with natural stocks, which can have important impacts on natural biodiversity. Fish are very prolific, and under many hatchery production systems a relatively small number of parents can provide sufficient numbers of juveniles for release, in which case the genetic variability of the fishery may be reduced. This situation can easily lead to genetic bottlenecks, the forthcoming generations of population being subjected to relatively high rates of inbreeding thus inadvertently reducing the genetic variability of the population (Povh *et al.*, 2008). This can have large effects on the sensitivity of individuals to environmental variations and could possibly cause the extinction of a population or species in a particular environment (Guttman and Berg, 1998). In addition, inbreeding can affect growth and reproduction.

The mating of wild fish with those released by restocking programmes can promote the loss of genes important for local adaptation (Vasemägi, Nilsson and Primmer, 2005; Sønstebø, Bergstrøm and Huen, 2006) in a genetic mechanism called outbreeding depression. While this concern has been effectively studied in terrestrial animals and in salmon populations in developed countries, this is not the case in other fisheries from developing countries.

Therefore, careful restocking procedures need to be developed in order to reduce the potential for the introgressed population to reduce the genetic variability and therefore the sustainability of the resource. Assessing the genetic diversity of managed stocks or highly selected populations is an important issue when pedigree information is lacking or in situations where some kind of quality assurance is needed.

The use of molecular markers and the principles of population genetics have proved very effective in assessing the actual levels of genetic variability within single populations and in measuring the extent of differentiation between populations. For example, the Centro Nacional de Pesquisa de Peixes Tropicais in Brazil has studied the use of RAPD markers for the Amazonian fish "matrinxa" (*Brycon cephalus*) and has shown a relatively large reduction in genetic variability in fish used for restocking purposes compared with the native Amazonian river population (Povh *et al.*, 2008).

In developing countries, the markers have been used mainly for assessing genetic variation in tilapia and carp populations in Thailand, the Philippines and India. Markers have been used for characterizing stocks and comparing levels of genetic variability in *Oreochromis* species. Agustin (1999) used markers to assess genetic differences between indigenous samples from Africa and populations from Asia, concluding that the low performance of *O. mossambicus* stocks can be explained by the effect of large bottlenecks in the populations used for aquaculture in Asia. Molecular markers have also been used to assess population differentiation of Nile tilapia (*O. niloticus*) for both domesticated and feral populations (Agnèse *et al.*, 1997). In both cases, moderate to great genetic differentiation was found between strains and the use of markers successfully correlated with the actual biogeographical data.

The escape of farmed fish from aquaculture may influence the genetic variability of native populations. The possible genetic impacts resulting from introductions and invasive alien species include: interbreeding between alien and native genotypes causing, in some cases, reduced reproductive efficiency and generating nonviable offspring; decreased fitness from loss of co-adapted gene complexes; and indirect genetic impacts resulting from other ecological interactions (FAO, 2005a).

Climate change and related climatic events such as the El Niño-Southern Oscillation (ENSO) can have serious impacts on the distribution of fishery resources between countries. Based on census numbers, mackerel fisheries were apparently depleted in Chilean coastal waters during the occurrence of ENSO episodes. However, markers have shown little differentiation with other populations in the Pacific Ocean (such those observed in New Zealand), and so it is likely that the drop in numbers is related to migration of the mackerel populations to colder waters in the Pacific rather than to fishery depletion (IFOP, 1996).

4.3.5 Concluding remarks

Compared with livestock and crop production, aquaculture is a novel production system in many developing and developed countries. As shown above, biotechnologies are being applied in fisheries management but their use is very limited compared with aquaculture. The use of successful and effective biotechnologies in aquaculture is very much confined to genetic manipulations and improvements, and to health management.

The success or failure in using biotechnologies in developing countries depends to a large extent on: 1) the markets for each of the products within the production sectors, and 2) the investment and acquisition capacity for the fisheries and aquaculture sectors. In the case of aquaculture, the latter is very important considering that the largest proportion of world production comes from developing countries and from small farmers (specifically in Asia). Most biotechnological interventions have been developed for improved production and the better management of aquaculture. Most have been targeted towards high value commercial aquaculture species generally produced for international markets. Although many small-scale farmers are producing for export markets, the significant uptake of many biotechnological interventions and innovations has generally been restricted to commercial or industrial aquaculture operations. This is certainly due to the cost of the technologies as well as the organized nature of industrial aquaculture.

Recently, however, as a result of better organization in the small-scale farming sector, certain biotechnologies have been effectively taken up by the small farmers in many parts of the developing world. They include DNA probes for detecting pathogens in some species (mainly PCR detection of major viral pathogens of shrimp), the use of SPF shrimp broodstock or postlarvae, the use of certain DNA vaccines, the all-male (genetically male) tilapia and, in some cases, markers for pedigree evaluation in salmon worldwide. In fact, almost everywhere in the world, shrimp farmers, whether small or large, currently use only PCR-tested postlarvae for stocking. For example, in India there are more than 90 laboratories providing PCR services for the shrimp sector – mainly for the screening of seed and broodstock. In Vietnam, there are over 40 laboratories. This pattern holds true in many countries of the region as the cost of using such biotechnologies has declined over the years and the benefits have increased tremendously.

As mentioned above, the majority of aquaculture produce comes from the small-scale farming sector, in many instances comprising low-input extensive production systems. Although there is scope for biotechnologies, and although they are already being employed by small-scale farmers, classical environmental improvements and better management practices such as conventional genetic selection of broodstock, conventional health management through the avoidance of pathogens etc., can also contribute significantly towards improving small-scale aquaculture production and sustainability.

4.4 CASE STUDIES

Biotechnologies are used in aquaculture for reducing losses due to diseases and improving production through genetic manipulation. These technologies are regularly used in almost all countries at different rates and levels based on the intensity and commerciality of the production system. Here, two case studies are presented, outlining specific successful applications of biotechnological tools in aquaculture in developing countries.

4.4.1 PCR-based pathogen detection in shrimp aquaculture in India

At present, shrimp is the most valuable aquaculture commodity sector in the world. This sector has been continuously facing the challenge of new diseases, particularly viral pathogens. Some 20 years ago, there was hardly any accurate molecular-based pathogen detection system available in any part of the world. Now, as a result of advanced molecular research and biotechnology, there are many DNA-based detection technologies such as PCR methodologies available for all the major shrimp viruses. A number of PCR, nested-PCR and hybridization tests have been developed for virus detection. The tests use a range of different PCR primers and hybridization probes targeted to different and poorly defined sites in the virus genome. Several RT-PCR tests are also available. The application of PCR detection of viruses of broodstock and postlarvae in both *Penaeus monodon* and *Penaeus vannameii* is now practised in all countries producing commercial shrimp at all levels (Lo, Chang and Chen, 1998; Karunasagar and Karunasagar, 1999; Peinado-Guevara and López-Meyer, 2006). Recently, lateral flow chromatographic immunodiagnostic strips similar to common drug store pregnancy tests have begun to appear for some shrimp diseases. Using these, unskilled farm personnel can easily diagnose shrimp disease outbreaks at the farm. The strips are relatively cheap and quick. Other methods comparable to PCR and RT-PCR are now available or are being developed for single and dual or multiple viral detection but they currently require advanced equipment and personnel.

This rapid detection technology has given a new dimension to the shrimp industry and losses due to viral diseases have been reduced tremendously by the use of PCR-tested postlarvae for stocking. Recent successes in farmer group or cluster formation and management in shrimp aquaculture, particularly in India and Indonesia, are to a large extent based on good health management which includes the use of PCR tested postlarvae for stocking in ponds. This demonstrates a scenario in which a successful biotechnology has not only contributed towards realizing its scientific objective, but also towards improving the overall governance of the sector (Subasinghe, Soto and Jia, 2009).

To consider a specific case study, the use of PCR detection technology was the key basic step towards developing an effective better management practice (BMP) for small-scale shrimp aquaculture in Andhra Pradesh. In India, aquaculture is mainly carried out by small- and marginal-scale farmers located in the remote villages of the country. They are largely unorganized, scattered and poorly educated. The farmers mostly opt for traditional methods for operating their farms and do not have access to technological innovations or scientific applications. A joint MPEDA-NACA (Marine Products Export Development Authority – Network of Aquaculture Centres in Asia-Pacific) project assisted by FAO was initiated in 2002 to support shrimp farmers in disease control and coastal management, leading to the participatory development of BMPs that provided significant improvements in profits and reduced shrimp disease risks for farmers. One of the key interventions that the farmers adopted in applying BMPs in their quest to reduce losses due to disease was the use of PCR-screened postlarvae for stocking.

The project supported farmers in the implementation of BMPs through the formation of self-help groups around local "clusters". An economic analysis of 15 farmer groups in Andhra Pradesh clearly demonstrated that farmers adopting BMPs including the use of PCR-screened postlarvae for stocking had higher profitability, lower production costs and were able to produce quality and traceable shrimp without using any banned chemicals.

The project has been highly successful in forming a self-help movement of farmers across India through a grassroots approach. From a mere five farmers who first adopted the cluster-farm approach and BMPs in 2002, the programme had swelled to more than 1 000 farmers in 30 aquaculture societies in five coastal states by 2007. Beginning in 2007, the MPEDA-NACA project became the National Centre for Sustainable Aquaculture (NaCSA). NaCSA is an outreach organization of MPEDA established to service the small-scale aquaculture sector and provide technical support to farmer groups. It aims to empower and build the capacity of small-scale farmers to produce quality shrimps in a sustainable and more profitable manner.

Perhaps one of the keys to the above success is the ability to reduce losses due to disease in production systems, and to a large extent this has been possible through the use of PCR technology for screening and detecting major viral pathogens in broodstock and postlarvae.

4.4.2 Specific pathogen-free stocks in shrimp aquaculture

Only a few species have so far been domesticated in the aquaculture sector. One group of species on which most research has been focused on the domestication and development of SPF strains is the penaeid shrimp. SPF shrimp are produced in SPF facilities using many biotechnological tools, particularly DNA-based pathogen detection and diagnostic techniques. The primary goal of SPF facilities is to produce strains of shrimp that are disease-free, domesticated and genetically improved for aquaculture. SPF lines are available for *P. vannamei*, *P. stylirostris* and *P. monodon*. The SPF status should signify that the shrimp have passed through a rigorous quarantine and disease-screening process that has found them to be free from specified pathogens of concern to culturists. This characteristic means that countries or regions which still do not have this species can be reasonably sure that importation of SPF animals will not result in the introduction of the specified pathogens from which the animal is declared free. This does not, however, guarantee against the animal being infected with unknown pathogens or known pathogens for which the animal was not screened.

Genuine SPF shrimp are produced in biosecure facilities that have been repeatedly examined and found free of specified pathogens using intensive surveillance protocols, and originate from broodstock developed with strict founder population development protocols. These founder populations are generated by extensive quarantine procedures that result in SPF F_1 generations derived from wild parents. Only stocks raised and held under these conditions can be considered truly SPF. There is not yet an internationally agreed protocol for the development of SPF shrimp, and certainly some variation exists in the quality of different SPF stocks. Once the animals are removed from the SPF production facilities, they should no longer be referred to as SPF even though they may remain pathogen-free. Once outside the SPF facility, the shrimp may be designated as High Health (since they are now subject to a greater risk of infection), but only if they are placed into a well-established facility with a history of disease surveillance and biosecurity protocols. If the shrimp are put elsewhere, for example into a non-biosecure maturation unit, hatchery or farm, they can no longer be called SPF or High Health as they are now exposed to a high risk of infection (FAO, 2005b).

One potential drawback of SPF animals is that they are only SPF for the specific diseases for which they have been checked. Typically this will consist of the viral pathogens which are known to cause major losses to the shrimp culture industry, including WSSV, YHV, TSV, IHHNV, *Baculovirus penaei* virus and Hepatopancreatic parvovirus as well as microsporidians, haplosporidians, gregarines, nematodes and cestodes. Despite this screening, new, hidden or "cryptic" viruses may be present, but because they are as yet unrecognized they may escape detection. Thus, it is believed that SPF shrimp shipped from Hawaii resulted in the contamination of shrimp in Brazil and Colombia with TSV. This was because, at the time, TSV was not known to have a viral cause and therefore went unchecked in SPF protocols.

In any case, the use of SPF stocks is only one part of a complete plan for minimizing disease risks in shrimp culture. The development of SPF strains is really designed to ensure that postlarvae stocked into grow-out ponds are free of disease, which is one, if not the most serious, source of contamination. Other areas of this strategy that must be implemented include ensuring that broodstock, eggs, nauplius, larvae and juveniles derived from SPF stock remain SPF.

Creating an enabling public sector environment is essential to improve governance at all levels of aquaculture development. There have been many regulatory rebounds in the aquaculture sector, in particular in shrimp farming in some countries. Uncontrolled and unregulated development of the sector has outstripped the carrying capacity in some locations, causing significant production losses mainly due to disease and resulting in the complete abandonment of farms. Significant improvements have been made in mitigating such catastrophic problems, and the negative environmental and social impacts of shrimp farming throughout the world have been significantly reduced. The use of wild-caught postlarvae in shrimp culture, which has a significant impact on aquatic biodiversity, has almost stopped or is little practised. The recent development of SPF broodstocks of some species of shrimp has reduced reliance on wild-caught postlarvae to a minimum.

SPF shrimp if produced and maintained under good biosecurity have proved successful. The success of SPF stocks may be more pronounced in large-scale industrial shrimp culture facilities where maintaining stringent biosecurity is possible. The use of this successful biotechnological approach in the rather disorganized small-scale shrimp aquaculture production sector poses another challenge (FAO, 2004b).

B. LOOKING FORWARD: PREPARING FOR THE FUTURE

4.5 KEY ISSUES WHERE BIOTECHNOLOGIES COULD BE USEFUL

Environmental sustainability

Aquaculture is the fastest growing food producing sector in the world. It is poised to expand, diversify and intensify over the coming decades to bridge the increasing global gap between the supply and demand of aquatic food. Responsible production through sustainable practices is the key to achieving this massive task. In the effort to maximize the contribution from aquaculture it is inevitable that many constraints and hurdles need to be overcome. The biggest hurdle is to maintain environmental sustainability,

Conventional methods of controlling diseases such as chemotherapeutants are ineffective for many new pathogens (notably viruses). Molecular techniques have therefore received increasing attention for pathogen screening and identification. In addition, these biotechnologies are providing significant insights into pathogenesis (disease development) and show strong potential for disease control and prevention programmes (e.g. DNA vaccines), as well as for treatments of diseases. The increased sensitivity and specificity conferred by DNA- or RNA-based probes has provided significant inroads for the early detection of diseases and identification of subclinical carriers of infections. This has had a direct effect on enhancing preventative management and control of disease in cultured species. Concomitant with this has been a decrease in the need for reactive treatments using traditional methodologies such as antibiotics or culling and disinfection. This has been particularly successful for shrimp broodstock selection and has broken the infection cycle perpetuated for years by accidental broodstock transmission of viral pathogens to developing offspring.

Biotechnologies can provide much assistance to improve aquatic animal health management in aquaculture in developing countries, in particular through the development of sensitive and accurate molecular diagnostic methods and tools as well as vaccines for tropical diseases. Bioremediation and probiotics also provide some further opportunities.

Climate change

In the future, one of the greatest constraints could be the impact of climate change on aquaculture. Climate change threatens fisheries and aquaculture through higher temperatures and changes in weather patterns, water quality and supply. Important differences in the magnitude and types of impacts on aquaculture are predicted for different regions. The ability to adapt will confer a major advantage and should be developed by countries and regions. There is a need for the aquaculture sector to join other economic sectors in preparing to address the potential impact of global warming. One of the practical responses to climate change for aquaculture could be to strengthen the adaptive capacity and resilience of the sector, particularly those of small farmers and aquatic resources users. Increased resilience is a desirable feature of any sector. It can mitigate the future impact of unforeseen events (e.g. economic change, disease epidemics, tsunamis, etc.), including those related to climate. There is some knowledge and experience from aquaculture itself, and from the broader area of agriculture and natural resource management, which could be used. Aquaculture, and particularly mariculture, could in fact provide adaptation opportunities to produce good quality protein when freshwater may become scarce. On the other hand, freshwater aquaculture can produce protein with higher water saving than other animal production sectors. Certain biotechnologies, particularly those dealing with genetic improvement, health and environmental mitigation should be of significant value for the discovery of adaptive technologies and interventions to counter the ever-present menace of climate change.

4.6 IDENTIFYING OPTIONS FOR DEVELOPING COUNTRIES

To bridge the future gap between demand and supply of aquatic food, production needs to be almost double in less than three decades. In the quest to meet this unprecedented demand, the aquaculture sector will face serious constraints. Four major constraints are inevitable: 1) disease prevention and health management, 2) genetic improvement and domestication, 3) environmental management and 4) food safety. These constraints are not new. They have been constantly addressed during the development of aquaculture over the past two decades, including through the use of biotechnologies.

Over the years, aquaculture biotechnologies and other technological innovations have had a positive impact on aquaculture diversification, investment potential, and international technology exchange. The development of biotechnologies in aquaculture should therefore provide a means of producing healthy and fast-growing animals by environmentally friendly means. However, this development will largely depend on the desire and willingness of producers to work hand-in-hand with scientists, and on the international donor community's readiness to assist developing counties in the related research, capacity building and infrastructure development. Improved exchange of information and discussion between scientists, researchers and producers from different regions about their problems and achievements will undoubtedly help this important sector to develop with a view to increasing sustainable global aquatic animal production.

Based on the overview and analysis contained in this Chapter, a number of specific options can be identified for developing countries to help them make informed decisions regarding the adoption of biotechnologies in the future, such as when – and if – they should deploy one or more biotechnologies and, if they decide to do so, how they can ensure the successful application of the chosen biotechnologies to enhance food security in the future.

- Few biotechnological advancements and tools are currently in use in small-scale aquaculture operations aiming at rural development, poverty alleviation and food security. However, there is a need to identify these, their application and socio-economic impact in developing countries. Developing countries should therefore collect information on the aquatic animal biotechnologies that may be used and analyse their national-level adoption and socio-economic impacts. Such information should be used to advise policy-makers on the cost/benefit implications of such applications. Increased efforts should be made to develop aquatic biosecurity policies within national research and development (R&D) programmes or national aquatic production programmes.
- The use of biotechnologies in aquaculture worldwide has increased incrementally over the past two decades. Several aquaculture biotechnologies have been used for improving aquatic food production in both developed and developing countries and have significant potential for future improvement. Since most aquaculture biotechnologies are still too technical and costly for small-scale farmers, efforts should be made to develop low-cost simple technologies that are easy to introduce to less advanced aquaculture farmers. Developing countries should give priority to developing aquaculture biotechnologies which are appropriate and conducive for both industrial and small-scale farmers.
- Major biotechnological achievements and advances in fisheries and aquaculture have been mainly restricted to aquaculture and to the fields of genetics, health and the environment. Genetic improvements using genetic manipulation (diploidy, triploidy) and hormonal therapy etc. have shown promise for producing fish and shellfish with improved and desirable production qualities. Disease prevention and health management in aquaculture have benefited significantly from advances in biotechnologies. Many reliable and accurate rapid diagnostic techniques have been developed which can be used by small-scale farmers. There are several efficient vaccines now available for certain aquaculture species which have significantly reduced the use of antibacterials in their culture. However, more research is required to develop vaccines for tropical species, particularly the major species of global production. Some environmental remediation tools and technologies have been developed using several biotechnologies. They are being applied in some production systems but their broad adoption across different production systems and practices is yet to be established.

  The potential contribution of biotechnologies for genetic improvement to improve production of culture aquatic species should be recognized. National research and development plans should include appropriate research in these areas. In aquatic animal health research, the development of molecular diagnostics, vaccines and probiotics should be prioritized and national research institutions should also carry out research using appropriate biotechnologies that can help the development of sustainable aquaculture in this area. National governments embarking on aquaculture development should also recognize that there is ample evidence for positive aquatic environmental impacts using various biotechnological interventions, and therefore the use of biotechnology for improving the aquatic environment should be considered.

- Until recently, perhaps because the application of biotechnologies in fisheries and aquaculture has been mainly restricted to the commercial and industrial aquaculture of temperate species, there has been little evidence in many developing countries of national-level efforts to prioritize the development and application of biotechnologies in aquaculture. Even when efforts were made to develop such technologies in the public sector of developing countries, they were not always directed towards or made available to improve small-farmer livelihoods. There is a need to create national policy environments in developing countries, including suitable investment and funding opportunities, to allow the development and application of appropriate biotechnologies in support of aquaculture development. National governments should pay special attention to the small-scale aquaculture sector. Preferential treatment of the sector towards capacity building in appropriate biotechnologies should also be considered.
- The funding required in developing countries for aquatic biotechnological research and applications should be found through national budgets or through extra budgetary resources. An integral part of funding should be directed towards investment in capacity building in the relevant fields of the aquaculture sector. A suitable investment environment and funding opportunities should be created to allow the development and application of appropriate biotechnologies in support of aquaculture development. The appropriate involvement of the relevant stakeholders in decision-making processes should be assured.
- The establishment of efficient institutional structures and enforceable legal frameworks are important for the responsible use of biotechnologies in aquaculture at the national level. Such institutional arrangements should also strengthen research and extension needs and enhance relevant human and infrastructural capacities. National legal frameworks in aquaculture biotechnologies should be developed within an integrated national biotechnology framework, which also complies with the legal or voluntary requirements of international treaties and agreements that the country has ratified.
- National biotechnology programmes in developing countries should include a special committee to oversee the aquatic biotechnology programme and research. Such committees should be formed in all countries and regional cooperation should be sought.

- Information gathering and dissemination on aquatic biotechnologies should be encouraged within and between countries in a given region, and developing countries should consider setting up dedicated websites for this purpose.
- Aquaculture products are facing increasing competition in accessing international markets. One of the key criteria is food safety and compliance with international food safety standards. Many such standards can be met through better farming that uses both simple and advanced biotechnological interventions. The aquaculture industry should therefore consider the importance of such biotechnological interventions in improving and maintaining food safety of cultured aquatic products. National governments in developing countries should consider R&D interventions on food safety within the broader framework of biotechnology.

4.7 IDENTIFYING PRIORITIES FOR ACTION FOR THE INTERNATIONAL COMMUNITY

The international community, including FAO and other UN organizations, NGOs, donors and development agencies, can play a key role in supporting developing countries by providing a framework for international cooperation and funding support for the generation, adaptation and adoption of appropriate biotechnologies. Here, a set of Priorities for Action is identified that can assist the international community in playing this role.

- Relevant international institutions, donors and development partners should recognize that biotechnological interventions can contribute to sustainable aquaculture development worldwide.
- Relevant international agencies should assist developing countries to collect, collate and analyse information about the biotechnologies in use in fisheries and aquaculture, and their contributions to national food security, poverty alleviation and social development.
- Relevant international agencies should make efforts to maintain databases and information systems to assist countries access information for national biotechnology development programmes relating to fisheries and aquaculture.
- Donors and international funding agencies supporting sustainable aquaculture development for food security and poverty alleviation should dedicate an appropriate share of their assistance projects to promoting and strengthening aquatic biotechnology R&D in developing countries. International research efforts should focus on developing interventions that are accessible to small-scale farmers.
- When supporting the application of biotechnologies in fisheries and aquaculture, the international community should consider that technical assistance in biotechnology R&D should not be done at the expense of funding for other key research fields and that it should support effective and intimate links to strong breeding and extension programmes.

- The international community assisting developing countries towards aquaculture sustainability should consider biotechnological advancement as an important area to be supported, and should assist developing countries in strengthening capacities for biotechnology policy development and long-term planning.
- The international community should assist developing countries to develop the capacities of their national agricultural research systems, which include aquaculture, to involve relevant stakeholders in decision-making processes.
- The international community should assist developing countries in establishing adequate institutional capacities for the development and enforcement of regulations related to use of biotechnologies in fisheries and aquaculture.

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CHAPTER 5

CURRENT STATUS AND OPTIONS FOR BIOTECHNOLOGIES IN FOOD PROCESSING AND IN FOOD SAFETY IN DEVELOPING COUNTRIES

SUMMARY

Food processing converts relatively bulky, perishable and typically inedible raw materials into more useful, shelf-stable and palatable foods or potable beverages. It also contributes to food security by minimizing waste and loss in the food chain and by increasing food availability and marketability. Food is also processed to improve its quality and safety. Biotechnology makes use of microbial inoculants to enhance properties such as the taste, aroma, shelf-life, texture and nutritional value of foods through fermentation which is also widely applied to produce microbial cultures, enzymes, flavours, fragrances, food additives and a range of other high value-added products. Fermentation processing in most developing countries is more art than science and, in low income economies, it often makes use of a rudimentary technological base with poor process control resulting in low yields and products of variable quality. Spontaneous fermentations and those which use "appropriate" starter cultures produced largely through backslopping (a process which uses samples of a previous batch of a fermented product as inoculants) are widely applied at the household and village levels in developing countries. With increasing research and development (R&D), a number of pre-cultured single or mixed strains of micro-organisms, called "defined starter cultures", have been developed and are being used by small manufacturers in their fermentation processing operations. Defined starter cultures are also imported by a number of developing countries for use in processing operations.

Traditional methods of genetic improvement such as classical mutagenesis and conjugation can be applied to improve the quality of microbial cultures. Hybridization is also used for the improvement of yeast strains. Molecular biology techniques are widely employed in R&D for strain improvement. While these techniques are common in developed countries,

they are only now beginning to be applied in developing countries for the improvement and development of starter cultures. For example, random amplified polymorphic DNA (RAPD) techniques have been applied in Thailand in the molecular typing of bacterial strains for the production of fermented pork sausage (nham), leading to the development of three different defined starter cultures, which are currently used for the commercial production of products with different flavour characteristics. Genetically modified (GM) microbial cultures are used in the production of enzymes and various food processing ingredients. Rennet, which is widely used throughout the world as a starter in cheese production, is produced using GM bacteria. Thailand currently uses GM *Escherichia coli* as an inoculant in lysine production. Many industrially important enzymes such as alpha-amylase, gluco-amylase, lipase and pectinase, as well as bio-based fine chemicals such as lactic acid, amino acids, antibiotics, nucleic acid and polysaccharides, are produced in China using GM starter cultures.

Food safety is defined as the assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use, and food safety along the food chain includes the good agricultural practices that establish basic principles for farming (including aquaculture), soil and water management, crop and animal production, post-harvest handling and treatment, good manufacturing practices for storage, processing and distribution to the consumer. Biotechnology is widely employed as a tool in diagnostics to monitor food safety, prevent and diagnose food-borne illnesses and verify the origins of foods. The techniques applied in the assurance of food safety focus on the detection and monitoring of hazards. Biotechnological developments have led to the widespread availability of methods of identification that are more rapid and less costly than those based on conventional techniques. Polymerase chain reaction (PCR) and enzyme-linked immunoabsorbent assay (ELISA) methods are now applied in the detection of major food-borne pathogens.

Genome sequence information coupled with the support of advanced molecular techniques have enabled scientists to establish strategies to protect consumers from pathogens and provided industry with tools for developing strategies to design healthy and safe food by optimizing the effect of probiotic bacteria, the design of starter culture bacteria and functional properties for use in food processing. These advances have, in turn, led to more precise diagnostic tools and the ability to quickly develop efficient, specific and sensitive detection kits for new microbial strains. Kits are now also available for the detection of mycotoxins which are major hazards associated with pulses and grains, the raw material inputs for a number of traditional fermented foods in many developing regions. The identification of food ingredients and the origins of foods through traceability studies have also been enhanced by molecular methods.

5.1 INTRODUCTION

Food processing makes use of various unit operations and technologies to convert relatively bulky, perishable and typically inedible raw materials into more useful shelf-stable and palatable foods or potable beverages. Processing contributes to food security by minimizing waste and losses in the food chain and by increasing food availability and marketability. Food is also processed in order to improve its quality and safety. Food safety is a scientific discipline that provides "assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use"[1].

Biotechnology as applied to food processing in most developing countries makes use of microbial inoculants to enhance properties such as the taste, aroma, shelf-life, texture and nutritional value of foods. The process whereby micro-organisms and their enzymes bring about these desirable changes in food materials is known as fermentation. Fermentation processing is also widely applied in the production of microbial cultures, enzymes, flavours, fragrances, food additives and a range of other high value-added products. These high value products are increasingly produced in more technologically advanced developing countries for use in their food and non-food processing applications. Many of these high value products are also imported by developing countries for use in their food processing applications.

This Chapter describes the prospects and potential of applying biotechnology in food processing operations and to address safety issues in food systems with the objective of addressing food security and responding to changing consumer trends in developing countries. It is important to note that food safety evaluation or risk assessment is not covered here, the Chapter instead focusing on the context of biotechnologies as applied to food safety.

Technologies applied in the processing of food must assure the quality and safety of the final product. Safe food is food in which physical, chemical or microbiological hazards are present at a level that does not present a public health risk. Safe food can therefore be consumed with the assurance that there are no serious health implications for the consumer. Recent food scares such as mad cow disease and the melamine contamination of food products have increased consumer concern for food safety. As incomes rise, consumers are increasingly willing to pay a premium for quality, safety and convenience.

A range of technologies are applied at different levels and scales of operation in food processing across the developing world. Conventional or "low-input" food processing technologies include drying, fermentation, salting, and various forms of cooking including roasting, frying, smoking, steaming and oven baking. Low income economies are likely to employ these as predominant technologies for the processing of staple foods. Many of

[1] Recommended International Code of Practice - General Principles of Food Hygiene (Codex Alimentarius Commission, 2009)

these technologies use a simple, often rudimentary, technological base. Medium levels of processing technologies such as canning, oven drying, spray drying, freeze drying, freezing, pasteurization, vacuum packing, osmotic dehydration and sugar crystallization are widely applied in middle and upper middle income economies. Higher-level, more capital-intensive food processing technologies such as high-temperature short-time pasteurization and high-pressure low-temperature food processing are widely employed in middle and upper middle income economies. Functional additives and ingredients produced using fermentation processes are generally incorporated into food processing operations that make use of higher-level technologies.

Traditional methods of food safety monitoring such as the detection of pathogenic bacteria are generally based on the use of culture media. These are the techniques of choice in low and lower middle income economies which lack the resources, infrastructure and technical capacity to utilize modern biotechnologies. Conventional bacterial detection methods are time consuming multi-step procedures. At least two to three days are required for the initial isolation of an organism, followed by several days for additional confirmatory testing. Biotechnology based methods can provide accurate results within a relatively short time frame. Biotechnological developments have resulted in the widespread availability of low-cost rapid methods of identification compared with the significant cost/time requirements of conventional techniques. Lower middle income economies apply both traditional and more sophisticated methods for monitoring the microbiological quality of foods and their conformity with international standards.

A number of case studies are described in the text to demonstrate the utility of biotechnology-based applications in food processing and food safety. These case studies provide the basis for the development of strategic interventions designed to upgrade food processing and food safety in developing countries through the application of biotechnology.

This paper is divided into two main Sections – "Stocktaking: Learning from the Past" and "Looking Forward: Preparing for the Future". In the first Section, Part 5.2 provides a brief definition of biotechnologies; Part 5.3 gives an overview of the current status of the application of biotechnologies in developing countries; Part 5.4 provides an analysis of the successes/failures of the application of biotechnologies in developing countries and underlying causative factors; and some case studies of applications in developing countries are described in Part 5.5. In the second Section, Part 5.6 deals with a key issue in the sector where application of biotechnologies might be useful; Part 5.7 proposes options for developing countries to make informed decisions about the application of appropriate biotechnologies; and Part 5.8 presents priorities for action for the international community.

5.2 BIOTECHNOLOGY: DEFINITION AND SCOPE

For the purpose of this Chapter, biotechnology is defined in accordance with the Convention on Biological Diversity (CBD), i.e. "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use".

Biotechnology in the food processing sector uses micro-organisms for the preservation of food and for the production of a range of value-added products such as enzymes, flavour compounds, vitamins, microbial cultures and food ingredients. Biotechnology applications in the food processing sector, therefore, target the selection and manipulation of micro-organisms with the objective of improving process control, product quality, safety, consistency and yield, while increasing process efficiency.

Biotechnological processes applicable to the improvement of microbial cultures for use in food processing applications include traditional methods of genetic improvement ("traditional biotechnology") such as classical mutagenesis and conjugation. These methods generally focus on improving the quality of micro-organisms and the yields of metabolites. Hybridization is also used for the improvement of yeasts involved in baking, brewing and in beverage production. *Saccharomyces cerevisiae* strains have, for example, been researched for improved fermentation, processing and biopreservation abilities, and for capacities to increase the wholesomeness and sensory quality of wine (Pretorius and Bauer, 2002). Methods employed in genetic R&D of wine yeasts are described in detail in Pretorius (2000) and some are summarized in Table 1.

TABLE 1

SOME METHODS EMPLOYED IN GENETIC R&D OF WINE YEASTS

Method	Comments
Hybridization	Cannot generally be used directly, but the method is not entirely obsolete. Has been used to study the genetic control of flocculation, sugar uptake and flavour production. Cross-breeding and hybridization of spore-derived clones of *S. cerevisiae* have also been accomplished.
Mutation and selection	For example, to induce autotrophic and de-repressed mutants for efficient sugar fermentation and ethanol tolerance.
Rare mating	Mixing of non-mating strains at high cell density (ca. 10^8 cells/ml) results in a few true hybrids with fused nuclei. Cytoduction (introduction of cytoplasmic elements without nuclear fusion) can also be used to impart killer activity (using karyogamy [nuclear fusion] deficient mutants).
Spheroplast fusion	Spheroplasts from yeast strains of one species, the same genus, or different genera can be fused to produce intraspecific, interspecific or intergeneric fusants, respectively. The possibility exists to introduce novel characteristics into wine yeast strains which are incapable of mating.
Single-chromosome transfer	Transfer of whole chromosomes from wine yeast strains (using the karyogamy mutation) into genetically defined strains of *S. cerevisiae*.
Transformation	Introduction of genes from other yeasts and other organisms.

Recombinant gene technology is widely employed in R&D for strain improvement. The availability of genetic manipulation tools and the opportunities that exist to improve the microbial cultures associated with food fermentations are tempered by concerns over regulatory issues and consumer perceptions. GM microbial cultures are, however, used in the production of enzymes and various food processing ingredients such as monosodium glutamate, polyunsaturated fatty acids and amino acids.

Biotechnology is also widely employed as a tool in diagnostics to monitor food safety, prevent and diagnose food-borne illnesses and verify the origins of foods. Techniques applied in the assurance of food safety focus on the detection and monitoring of hazards whether biological, chemical or physical. These applications are explored and discussed later.

5.3 CURRENT STATUS OF THE APPLICATION OF BIOTECHNOLOGIES IN DEVELOPING COUNTRIES

5.3.1 Methods of microbial inoculation in food fermentations

The fermentation bioprocess is the major biotechnological application in food processing. It is often one step in a sequence of food processing operations which may include cleaning, size reduction, soaking and cooking. Fermentation bioprocessing uses microbial inoculants to enhance properties such as the taste, aroma, shelf-life, safety, texture and nutritional value of foods. Microbes associated with the raw food material and the processing environment serve as inoculants in spontaneous fermentations, while inoculants containing high concentrations of live micro-organisms, referred to as starter cultures, are used to initiate and accelerate the rate of fermentation processes in non-spontaneous or controlled fermentation processes. Microbial starter cultures vary widely in quality and purity.

Starter culture development and improvement is the subject of much research both in developed and developing countries. While considerable work on GM starter culture development is ongoing at the laboratory level in developed countries, relatively few GM micro-organisms have been permitted in the food and beverage industry globally. In 1990, the United Kingdom became the first country to permit the use of a live genetically modified organism (GMO) in food. It was a baker's yeast, engineered to improve the rate at which bread dough rises by increasing the efficiency with which maltose is broken down. This modification was done using genes from yeast and placing them under a strong constitutive promoter. The United Kingdom has also approved a GM brewer's yeast for beer production. By introducing a gene encoding gluco-amylase from yeast, better utilization of carbohydrate present in conventional feedstock can be obtained, resulting in increased yields of alcohol and the ability to produce a full strength, low-carbohydrate beer. More recently, two GM yeast strains were authorized for use in the North American wine industry (Bauer *et al*., 2007).

Current literature documents the many research reports on the characterization of microbes associated with production of traditional fermented foods in developing countries. Relatively few of these studies document the application of diagnostic tools of modern biotechnology in developing and designing starter cultures. The development and improvement of microbial starters have been driving forces for the transformation of traditional food fermentations in developing countries from an "art" to a science. Microbial starter culture development has also been a driving force for innovation in the design of equipment suited to the hygienic processing of traditional fermented foods under controlled conditions in many developing countries.

Starter culture improvement, together with the improvement and development of bioreactor technology for the control of fermentation processes in developed countries, has played a pivotal role in the production of high-value products such as enzymes, microbial cultures and functional food ingredients. These products are increasingly produced in more advanced developing economies and are increasingly imported by less advanced developing countries as inputs for their food processing operations.

Spontaneous inoculation of fermentation processes

In many developing countries, fermented foods are produced primarily at the household and village levels using spontaneous methods of inoculation. Spontaneous fermentations are largely uncontrolled. A natural selection process, however, evolves in many of them which eventually results in the predominance of a particular type or group of micro-organisms in the fermentation medium. A majority of African food fermentation processes use spontaneous inoculation (Table 2). Major limitations of spontaneous fermentation processes include their inefficiency, low yields of product and variable product quality. While spontaneous fermentations generally enhance the safety of foods owing to a reduction of pH and through detoxification, in some cases there are safety concerns relating to the bacterial pathogens associated with the raw material or to unhygienic practices during processing.

"Appropriate" starter cultures as inoculants of fermentation processes

"Appropriate" starter cultures are widely applied as inoculants across the fermented food sector, from the household to industrial levels in low income and lower middle income economies. These starter cultures are generally produced using a backslopping process which uses samples of a previous batch of fermented product as inoculants (Holzapfel, 2002). Appropriate starter cultures are widely applied in the production of fermented fish sauces and fermented vegetables in Asia (Table 3) and in cereal or grain fermentations in African and Latin American countries (Tables 2 and 4).

The inoculation belt (Holzapfel, 2002) used in traditional fermentations in West Africa serves as a carrier of undefined fermenting micro-organisms, and is one example of an appropriate starter culture. It generally consists of a woven fibre, mat, piece of wood or woven sponge saturated with high quality product of a previously fermented batch. It is immersed into a new batch to serve as an inoculant. The inoculation belt is used in the production of the African indigenous fermented porridges uji and mawe, as well as in the production of the Ghanaian beer, pito (Table 2).

TABLE 2

AFRICAN FERMENTED FOODS AND INFORMATION ABOUT THEIR FERMENTATION PROCESSES

Raw material	Local product name	Region/country	Type of fermentation	Micro-organisms associated with the fermentation process	Methods of inoculation	State of development*
A. Fermented starchy staples						
Cassava	Gari	West and Central Africa	Solid state	*Corynebacterium mannihot*, *Geotrichum* species, *Lactobacillus plantarium*, *Lactobacillus buchnerri*, *Leuconsostoc* species, *Streptococcus* species.	Natural/chance	1, 2, 5, 7, 8
	Fufu	West Africa	Submerged	*Bacillus* species, *Lactobacillus* species *such as Lactobacillus plantarum;* *Leuconostoc mesenteroides*; *Lactobacillus cellobiosus*; *Lactobacillus brevis*; *Lactobacillus coprophilus*; *Lactobacillus lactis*; *Leuconostoc lactis* and *Lactobacillus bulgaricus*, *Klebsiella* species, *Leuconostoc* species, *Corynebacterium* species and a yeast of the *Candida species.*	Natural/chance	1, 2, 5, 6
	Lafun, Konkonte	West Africa	Submerged	*Bacillus* species, *Klebsiella* species, *Candida* species, *Aspergillus* species*;* *Leuconostoc mesenteroides*, *Corynebacterium manihot*, *Lactobacillus plantarum*, *Micrococcus luteus* and *Geotrichum candidum*	Spontaneous	1, 2, 5, 6
	Chikwangue	Central Africa / Zaire	Solid state	*Corynebacterium*, *Bacillus*, *Lactobacillus*, *Micrococcus*, *Pseudomonas*, *Acinetobacter* and *Moraxella*	Spontaneous	1, 2, 7
	Cingwada	East and Central Africa	Solid state	Corynebacterium, Bacillus, Lactobacillus, Micrococcus,	Spontaneous	1, 2

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Raw material	Local product name	Region/country	Type of fermentation	Micro-organisms associated with the fermentation process	Methods of inoculation	State of development*
B. Gruels and beverages						
Maize	Ogi	West Africa, Nigeria	Submerged	*Lactobacillus plantarum, Corynebacterium specie, Aerobacter,* yeasts *Candida mycoderma, Saccharomyces cerevisiae* and *Rhodotorula* and moulds *Cephalosporium, Fusarium, Aspergillus* and *Penicillium*	Appropriate starters produced by backslopping	1, 2, 3, 4, 5, 7
Sorghum	Abreh	Sudan	Solid state and Submerged	Lactobacillus plantarum	Appropriate starters produced by backslopping	1, 2
Millet	Uji	East Africa, Kenya	Submerged	Leuconostoc mesenteroides, Lactobacillus plantarum	Appropriate starters produced by backslopping/ inoculation belt	1, 2
Maize	Kenkey, Koko, Akasa	West Africa, Ghana	Solid state	Enterobacter cloacae, Acinetobacter sp., Lactobacillus plantarum, L. brevis, Saccharomyces cerevisiae, Candida mycoderma	Spontaneous	1, 2
C. Alcoholic beverages						
Palm	Palm wine, Emu	West Africa	Submerged	*Saccharomyces cerevisiae, Schizosaccharomyces pombe, Lactobacillus plantarum, L. mesenteroides*	Spontaneous	1, 2, 7
Various types of African cereal grains (maize, sorghum, millet)	Busa	East Africa, Kenya	Submerged	*Saccharomyces cerevisiae, Schizosaccharomyces pombe, Lactobacillus plantarum, L. mesenteroides.*	Spontaneous	1, 2, 7
	Mbege	Tanzania	Submerged	*Saccharomyces cerevisiae, Schizosaccharomyces pombe, Lactobacillus plantarum, L. mesenteroides.*	Spontaneous	1, 2
	Burukutu	West Africa	Submerged	*Saccharomyces cerevisiae, S. chavelieri, Candida sp.* and, *Leuconostoc meseteroides. Acetobacter sp.*	Spontaneous	1, 2
	Pito	West Africa	Submerged	*Geotrichum candidum, Lactobacillus* sp. and *Candida* sp.	Natural/chance Inoculation belt	1, 2

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Raw material	Local product name	Region/country	Type of fermentation	Micro-organisms associated with the fermentation process	Methods of inoculation	State of development*
D. Acid leavened bread/pancakes						
Various types of African cereal grains	Kisra	Sudan	Submerged		Appropriate starters produced by backslopping	
	Enjera, Tef, Injera	Ethiopia	Submerged		Appropriate starters produced by backslopping	
E. Legumes and condiments						
Locus bean, soybean	Iru, Dawadawa, Etchum, Kal Soumbara, Chu	West Africa		*Bacillus subtilis*, *B. pumilus*, *B. licheniformis* and *Staphylococcus saprophyticus*	Spontaneous	1, 2, 3, 6, 7
African oil bean	Ugba			*Bacillus subtilis*, *B. pumilus*, *B. licheniformis* and *Staphylococcus saprophyticus*	Spontaneous	
Melon seeds, castor oil seeds, pumpkin bean, sesame	Ogiri, Ogili	West, East and Central Africa		*Bacillus subtilis*, *B. pumilus*, *B. licheniformis*, *Staphylococcus saprophyticus*, *Lactobacillus plantarum*	Spontaneous	1, 2
Cotton seed	Owoh	West Africa		*Bacillus subtilis*, *B. pumilus*, *B. licheniformis*, *Staphylococcus saprophyticus*	Spontaneous	1
F. Animal products						
Goat milk	Ayib	East and Central Africa		*Canida* spp., *Saccharomyces* spp., *Lactobacillus* spp., *Leuconostoc* spp.,	Spontaneous	1, 2
Cow milk	Leben, Lben	North, East Central Africa		*Candida* spp., *Saccharomyces* spp., *Lactobacillus* spp., *Leuconostoc* spp.,	Spontaneous	1, 2, 3

Source: compiled from Odunfa and Oyewole (1997)

* Personal assessment of data, literature, Internet search and other information by O.B. Oyewole as at March 2009. Key to the codes is 1 = micro-organisms involved known; 2 = roles of individual micro-organisms known; 3 = genetic improvement carried on organisms; 4 = starter cultures available for the fermentation; 5 = varieties of raw materials that are best suited for the product known; 6 = improved technology available and adopted; 7: pilot plant production; 8 = industrial plant production.

TABLE 3

EXAMPLES OF TECHNOLOGIES USED IN INDIGENOUS FERMENTED FOOD PRODUCTION SYSTEMS IN ASIA

Substrate material	Indigenous fermented food	Country	Type of technology		Inoculum	Bioreactor production of starter		Nature of starter		Food safety techniques used in quality control and quality assurance
			Defined starter culture	Natural fermentation		Solid	Liquid	Dry powder	Liquid	
Soybean	Soy Sauce	China	Koji		Aspergillus oryzae					ELISA for detection of toxigenic fungi and mycotoxins
		Japan	Koji and Moromi		*Aspergillus* sp., *Saccharomyces rouxii*					ELISA and/or GC-MS to detect and/or monitor carcinogens 3-MCPD
		Thailand	Koji		*Aspergillus flavus* var *columnaris*	✓		✓		
Pork	Nham	Thailand, Vietnam, Lao and Cambodia	Defined Strains		Lactic acid bacteria *Staphylococcus xylosus*		✓	✓	✓	Selective cultural medium for pathogen detection (*Salmonella*, *Staphylococcus*)

TABLE 4

EXAMPLES OF FERMENTED FOODS PRODUCED IN LATIN AMERICA

Substrate	Local product name	Country	Micro-organisms associated	Uses
Maize	Abati	Paraguay, Argentina		Alcoholic beverage
Maize	Acupe	Venezuela		Beverage
Maize	Agua-agria	Mexico		Beverage
Rice	Arroz requemado	Ecuador	*Bacillus* spp., *Aspergillus* spp., *Actinomycete* spp.*	Porridge
Maize	Atole	Mexico	Lactic acid bacteria	Porridge
Black maize	Atole agrio	Mexico		Porridge
Maize, manihot or fruits	Cachiri	Brazil		Beverage

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Substrate	Local product name	Country	Micro-organisms associated	Uses
Maize or rice	Champuz	Colombia, Peru		Beverage
Maize, yuca, cassava, sweet potatoes, quinoa or ripe plantains	Chicha	Argentina, Bolivia, Brazil, Colombia, Ecuador, Peru	*Saccharomyces* spp., *Lactobacillus* spp., *Leuconostoc* spp., *Acetobacter* spp., *Aspergillus* spp., *Penicillium* spp.	Alcoholic beverage
"Pulque" syrup, chili and toasted maize leaves	Charagua	Mexico		Alcoholic beverage
Maize	Fubá	Brazil		Porridge
Maize	Jamin-bang	Brazil		Bread
Maize	Napú	Peru		Beverage
Maize juice and "pulque" or brown sugar	Ostoche	Mexico		Alcoholic beverage
Cassava**	Pão de Queijo	Brazil	*Lactobacillus cellobiosus*, *Streptococcus lactis*, *Corynebacterium* spp.	Bread
Maize	Pozol	Mexico	*Lactobacillus* spp., *Leuconostoc* spp., *Candida* spp., *Enterobacteriacea*, *Bacillus cereus*, *Paracolobactrum aerogenoides*, *Agrobacterium azotophilum*, *Alkaligenes pozolis*, *Escherichia coli* var. *napolitana*, *Pseudomonas mexicana*, *Klebsiella pneumoniae*, *Saccharomyces* spp. and moulds	Non-alcoholic acidic beverage
Aguamiel (*Agave atrovirens* and *A. americana*)	Pulque	Mexico	*Saccharomyces carbajali*, *Lactobacillus plantarum*, *Leuconostoc* spp.	Alcoholic beverage
Maize juice, toasted maize and pirú fruits	Quebranta huesos	Mexico		Alcoholic beverage
Maize and red chili	Sendechó	Mexico		Alcoholic beverage
Maize	Sora	Peru		Alcoholic beverage
Maize, pineapple, apple or orange	Tepache	Mexico	*Bacillus subtilis*, *B. graveolus* and the yeasts *Torulopsis insconspicna*, *Saccharomyces cerevisiae* and *Candida queretana*	Alcoholic beverage
Germinated maize ground and cooked with fragments of plants	Tesgüino	Mexico	*Lactobacillus* spp., *Streptococcus* spp., *Leuconostoc* spp., *Pediococcus* spp., *Saccharomyces* spp., *Candida* spp., *Cryptococcus* spp., *Hansenula* spp., *Brettanomyces* spp., *Pichia* spp., *Geotrichum* spp. and *Penicillium* spp.	Alcoholic beverage
Maize	Tocos	Peru		Dessert
Barley	Zambumbia	Mexico		Alcoholic beverage
Maize beer and zarzaparrilla bark	Zarzaparrilla bark wine	Mexico		Alcoholic beverage

Source: Information adapted and modified from FAO (1998 and 1999); * from Van Veen and Steinkraus (1970), ** from Ray and Sivakumar (2009)

Iku, also referred to as iru, is another example of an appropriate starter culture produced by backslopping. This starter culture is produced from concentrated fermented dawadawa (a fermented legume product) mixed with ground unfermented legumes, vegetables such as pepper, and cereals, such as ground maize. It is stored in a dried form and is used as an inoculant in dawadawa fermentations in West Africa (Holzapfel, 2002).

A range of appropriate starter cultures either in a granular form or in the form of a pressed cake are used across Asian countries as fermentation inoculants. These traditional mould starters are generally referred to by various names such as marcha or murcha in India, ragi in Indonesia and Malaysia, bubod in the Philippines, nuruk in Korea, koji in Japan, and Loog-pang in Thailand. They generally consist of a mixture of moulds grown under non-sterile conditions.

Defined starter cultures as inoculants of fermentation processes

Few defined starter cultures have been developed for use as inoculants in commercial fermentation processes in developing countries. Nevertheless, the past ten years have witnessed the development and application of laboratory selected and pre-cultured starter cultures in food fermentations in a few developing countries, primarily in Asia (Table 3). Defined starter cultures consist of single or mixed strains of micro-organisms (Holzapfel 2002). They may incorporate adjunct culture preparations that serve a food safety and preservative function. Adjunct cultures do not necessarily produce fermentation acids or modify texture or flavour but are included in the defined culture owing to their ability to inhibit pathogenic or spoilage organisms. Their inhibitory activity is due to the production of one or several substances such as hydrogen peroxide, organic acids, diacetyl and bacteriocins (Hutkins, 2006).

Defined starter cultures are mainly produced by pure culture maintenance and propagation under aseptic conditions. They are generally marketed in a liquid or powdered form or as a pressed cake. Loog-pang, a defined culture marketed in Thailand in the form of a pressed rice cake, consists of *Saccharomyces cerevisiae*, *Aspergillus oryzae* or *Rhizopus* sp. and *Mucor*. Loog-pang has a shelf-life of 2–3 days at ambient temperature and 5–7 days under refrigerated conditions. Ragi cultures are commercially produced by the Malaysian Agricultural Research and Development Institute by mixing a culture inoculum which generally consists of *Rhizopus oligosporus* with moistened sterile rice flour, and incubating it at ambient temperature for four days. This starter has a shelf-life of two weeks under refrigerated conditions (Merican and Quee-Lan, 2004). It is widely used as an inoculant in the production of traditional Malaysian fermented foods. Ragi-type starter cultures for the production of a range of fermented Indonesian products such as oncom, tape and tempeh are currently marketed via the Internet.

Defined starter cultures are also widely imported by developing countries for use in commercial production of dairy products such as yoghurt, kefir and cheeses and for alcoholic beverages. Many of these cultures are tailored to produce specific textures and flavours. In response to growing consumer interest in attaining wellness through diet, many yoghurt cultures also include probiotic strains. Probiotics are currently produced in India for use as food additives, dietary supplements and in animal feed. Methodologies used in the development and tailoring of these starters are largely proprietary to the suppliers of these starters. Monosodium glutamate and lactic acid, both of which are used as ingredients in the food industry, are produced in less advanced developing countries using defined starter cultures.

The use of DNA-based diagnostic techniques for strain differentiation can allow for the tailoring of starter cultures to yield products with specific flavours and/or textures. For example, random amplified polymorphic DNA (RAPD) techniques have been applied in Thailand for the molecular typing of bacterial strains and correlating the findings to flavour development during the production of the fermented pork sausage, nham (see Case Study 5.5.2). The results of these analyses led to the development of three different defined starter cultures which are currently used for the commercial production of products having different flavour characteristics (Valyasevi and Rolle, 2002).

GM starter cultures

To date, no commercial GM micro-organisms exist that would be consumed as living organisms. Products of industrial GM producer organisms are, however, widely used in food processing and no major safety concerns have been raised against them. Rennet which is widely used as a starter in cheese production across the globe is produced using GM bacteria. These are discussed in more detail below. Thailand currently uses GM *Escherichia coli* as an inoculant in lysine production. Many industrially important enzymes such as alpha-amylase, gluco-amylase, lipase and pectinase and bio-based fine chemicals such as lactic acid, amino acids, antibiotics, nucleic acid and polysaccharides, are produced in China using GM starter cultures. Other developing countries which currently produce enzymes using GM micro-organisms include Argentina, Brazil, Cuba and India.

5.3.2 Food additives and processing aids

Biotechnologies are currently used for the production of food additives and food processing aids such as enzymes, flavouring agents, organic acids, amino acids and sweeteners.

Enzymes

Enzymes occur in all living organisms and catalyze biochemical reactions that are necessary to support life (Olempska-Beer *et al.,* 2006). They are commonly used in food processing and in the production of food ingredients. The use of recombinant DNA technology has made it possible to manufacture novel enzymes that are tailored to specific food processing conditions. Alpha-amylases with increased heat stability have, for example, been engineered for use in the production of high-fructose corn syrups. These improvements were accomplished by introducing changes in the alpha-amylase amino acid sequences through DNA sequence modifications of the alpha-amylase genes (Olempska-Beer *et al.*, 2006). Bovine chymosin used in cheese manufacture was the first recombinant enzyme approved for used in food by the US Food and Drug Administration (Flamm, 1991). The phospholipase A1 gene from *Fusarium venenatum* is expressed in GM *Aspergillus oryzae* to produce the phospholipase A1 enzyme used in the dairy industry for cheese manufacture to improve process efficiencies and cheese yields.

Considerable progress has been made in recent times toward the improvement of microbial strains used in the production of enzymes. Microbial host strains developed for enzyme production have been engineered to increase enzyme yields. Certain fungal producing strains have also been modified to reduce or eliminate their potential for producing toxic metabolites (Olempska-Beer *et al.*, 2006). Food processing enzymes in the United States derived from GM micro-organisms are listed in Table 5.

TABLE 5

FOOD PROCESSING ENZYMES DERIVED FROM GM MICRO-ORGANISMS

Source micro-organism	Enzyme
Aspergillus niger	Phytase Chymosin Lipase
Aspergillus oryzae	Esterase-lipase Aspartic proteinase Glucose oxidase Laccase Lipase
Bacillus licheniformis	alpha-amylase Pullulanase
Bacillus subtilis	alpha-acetolactate decarboxylase alpha-amylase Maltogenic amylase Pullulanase
Escherichia coli K-12	Chymosin
Fusarium venenatum	Xylanase
Kluyveromyces marxianus var. *lactis*	Chymosin
Pseudomonas fluorescens	alpha-amylase
Trichoderma reesei	Pectin lyase

Source: Olempska-Beer *et al.* (2006)

Enzymes used in food processing have historically been considered non-toxic. Some characteristics arising from their chemical nature and source, such as allergenicity, activity-related toxicity, residual microbiological activity and chemical toxicity are, however, of concern. These attributes of concern must be addressed in light of the growing complexity and sophistication of the methodologies used in the production of food-grade enzymes. Safety evaluation of all food enzymes including those produced by GM micro-organisms is essential if consumer safety is to be assured (Spok, 2006). Enzymes produced using GM micro-organisms wherein the enzyme is not part of the final food product have specifically been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Safety evaluations have been conducted using the general specifications and considerations for enzyme preparations used in food processing (JECFA, 2006). Preparations of asparaginase enzymes have also been evaluated by JECFA (2008).

Flavours, amino acids and sweeteners

Volatile organic chemicals such as flavours and aromas are the sensory principles of many consumer products and govern their acceptance and market success (Berger, 2009). Flavours produced using micro-organisms currently compete with those from traditional agricultural sources. According to Berger (2009), more than 100 commercial aroma chemicals are derived using biotechnology either through the screening for overproducers, the elucidation of metabolic pathways and precursors or through the application of conventional bioengineering. Recombinant DNA technologies have also enhanced efficiency in the production of non-nutritive sweeteners such as aspartame and thaumatin. Market development has been particularly dynamic for the flavour enhancer glutamate (Leuchtenberger, Huthmacher and Drauz, 2005) which is produced by fermentation of sugar sources such as molasses, sucrose or glucose using high-performance strains of *Corynebacterium glutamicum* and *Escherichia coli.* Amino acids produced through biotechnological processes are also of great interest as building blocks for active ingredients used in a variety of industrial processes.

5.3.3 Current status of the application of traditional and new biotechnologies in food safety and quality improvement in developing countries

Food safety issues and concerns in food fermentation processing

Microbial activity plays a central role in food fermentation processes, resulting in desirable properties such as improvements in shelf-life and quality attributes such as texture and flavour. Pathogenic organisms are, however, of prime concern in fermented foods. Anti-nutritional factors such as phytates, tannins, protein inhibitors, lectins, saponins, oligosaccharides and cyanogenic glucosides are naturally occurring components of raw materials commonly used in food fermentations in developing countries. Contamination of the fermentation process can pose a major health risk in the final fermented product. Methodologies for identifying and monitoring the presence of chemical (pesticide residues, heavy metals, trace elements) and biochemical (aflatoxins) hazards in fermented foods are therefore a critical need. Furthermore, with growing consumer interest in the credence attributes of the products that they consume, and the premium currently being placed on quality linked to geographical origin, the traceability of foods with selected properties is of increasing importance.

Advances in microbial genetics

In recent times, genetic characterization of micro-organisms has advanced at a rapid pace with exponential growth in the collection of genome sequence information, high-throughput analysis of expressed products, i.e. transcripts and proteins, and the application of bioinformatics which allows high-throughput comparative genomic approaches that provide insights for further functional studies. Genome sequence information coupled with the support of highly advanced molecular techniques have allowed scientists to establish mechanisms of various host-defensive pathogen counter-defensive strategies and have provided industry with tools for developing strategies to design healthy and safe food by optimizing the effect of probiotic bacteria, the design of starter culture bacteria and functional properties for use in food processing. Characterization of the genomes of lactic acid probiotics has, for example, shed light on the interaction of pathogens with lactic acid bacteria (de Vos, 2001). Nucleotide sequences of the genomes of many important food microbes have recently become available. *Saccharomyces cerevisiae* was the first food microbe for which a complete genome sequence was characterized (Goffeau *et al*., 1996). This was followed by genome sequencing of the related yeast, *Kluyveromyces lactis* (Bolotin-Fukuhara *et al*., 2000) as well as filamentous fungi which are major enzyme producers and have significant applications in the food processing industry.

Genome nucleotide sequences of many Gram-positive bacteria species have also been completed. The *Bacillus subtilis* genome was the first to be completed followed by that of *Lactococcus lactis*. Genome sequences of food-borne pathogens such as *Campylobacter jejuni* (Parkhill *et al*., 2000), verocytotoxigenic *Escherichia coli* O157:H7 (Hayashi *et al*., 2001) and *Staphylococcus aureus* (Kuroda *et al*., 2001) have also been completed. Genome sequences of microbes that are of importance in food processing such as *Lactobacillus plantarum* (Zhang *et al*., 2009) are likewise available. The genome of *Clostridium botulinum,* responsible for food-borne botulism, was also recently sequenced (Sebaihia *et al.,* 2007).

Detection of pathogens

The rapid detection of pathogens and other microbial contaminants in food is critical for assessing the safety of food products. Traditional methods to detect food-borne bacteria often rely on time-consuming growth in culture media, followed by isolation, biochemical identification and, sometimes, serology. Recent technological advances have improved the efficiency, specificity and sensitivity of detecting micro-organisms. Detection technologies employ PCR, where short fragments of DNA (probes) or primers are hybridized to a specific sequence or template which is subsequently amplified enzymatically by the Taq polymerase enzyme using a thermocycler (Barrett, Fang and Swaminathan, 1997). In theory, a single copy of DNA can be amplified a million-fold in less than two hours with the use of PCR techniques; hence, the potential of PCR to eliminate or greatly reduce the need for cultural enrichment. The genetic characterization of genome sequence information has further facilitated the identification of virulence nucleotide sequences for use as molecular markers in pathogen detection. Multiplex real-time PCR methods are now available to identify the *E. coli* O157:H7 serogroup (Yoshitomi, Jinneman and Weagant, 2003). PCR-based identification methods are also available for *Vibrio cholerae* (Koch, Payne and Cebula, 1995) and for major food-related microbes such as *Campylobacter jejuni*, *C. coli*, *Yersinia enterocolitica, Hepatitis A virus, Salmonella* and *Staphylococcus aureus* (FDA, 2003).

Sophisticated culture media such as chromogenic or fluorogenic media are not readily used in low income economies but are relatively widespread in lower middle income and upper middle income economies. The use of immunoassays such as ELISA is also very limited in low income economies but is more widespread in the form of diagnostic kits in lower middle and upper middle income economies. DNA methods, which require elaborate infrastructure and high technical competence, find minimal application in lower income and some lower middle income economies. Biotechnologies applied in food safety assays in developing countries are summarized in Table 6.

There are movements toward implementing safety control programmes such as the application of Hazard Analysis and Critical Control Point (HACCP) in food fermentations in many developing countries. A HACCP plan for the production of the Thai fermented meat product nham is summarized in Table 7. The application of HACCP necessitates the deployment of good agricultural practices (GAPs), good manufacturing practices (GMPs), good hygienic practices (GHPs) and the monitoring of critical control points for potential microbial and chemical contamination during bioprocessing (FAO, 2006). Rigorous adherence to sanitary practices in the processing environment necessitates rapid, dynamic, sensitive, specific as well as versatile and cost-effective assay methods. The molecular approach of biotechnology entails near-time or real-time bacterial detection and offers levels of sensitivity and specificity unchallenged by traditional/conventional methods.

TABLE 6

BIOTECHNOLOGIES APPLIED IN FOOD SAFETY ASSAYS IN DEVELOPING COUNTRIES

Food production chain	Risk factor	Hazard profile	Biotechnology		Country level Development
			Traditional	New	
I. Pre-processing of incoming raw material from producers (farms)	Improper practice	Chemical • Pesticide residues • Unapproved chemotherapeutics	Chromatography TLC (thin layer chromatography GC (gas chromatography) HPLC (high-performance liquid chromatography)	Biosensors for pesticides, metals, antibiotics and micro-organisms ELISA for aflatoxins and natural plant toxins	Low income
	Presence of contaminants	• Heavy metals • Dioxins	Atomic absorption spectrophotometry Chromatography	GC-MS	Some lower middle and middle income
II. Processing raw material	Improper handling (time/temperature)	Chemical • Undeclared additives and supplements • Economic adulteration	TLC, GC, HPLC	Mass spectrometry (MS) methods for additives	Low, lower middle and middle income economies
	Fermentation procedures involving micro-organisms	Microbial	Growth in culture media	Chromogenic/fluorogenic indicator culture media ELISA, Antibody based biosensors PCR detection of specific genes	Middle income
	Quality parameters	• Consistency • Composition	Biochemical and enzyme assays pH measurements	Biosensing of fermentation-related enzymes Monitoring of sugars, alcohol, organic and inorganic ions Surface plasmon resonance	
III. Packaging and end product analysis	Contamination from packaging material	Chemical • Undeclared allergens and additives	Chromatography TLC, GC, HPLC, fast protein liquid chromatography	GC-MS	Some lower middle and middle income economies
		Microbial • Non-sterile conditions leading to microbial growth	Growth in culture media	Chromogenic/fluorogenic indicator culture media ELISA PCR detection of specific genes	
		Physical • Pieces, fragments of materials	Inspection and sampling	Metal detection systems	Middle income economies

Mycotoxin detection

The problem of mycotoxin contamination in food, including fermented foods, is a global concern. Mycotoxin contamination is particularly prevalent in tropical areas such as South Asia and Africa. High-performance liquid chromatography (HPLC) and gas chromatography-mass spectrometry (GC-MS) are two of the most widely used methods for the detection and quantification of mycotoxins in developing countries. These methods, however, are time consuming, difficult to use and require laboratory facilities. Immunoassays that are economical, sensitive and easy to use would greatly facilitate the detection and quantification of mycotoxins. A number of ELISA kits are now commercially available for the detection of aflatoxins, deoxynivalenol, fumonisins, ochratoxins and zearalenone (Schmale and Munkvold, 2009).

Detection and identification of foods and food ingredients

DNA-based identification systems rely on polymorphisms at the nucleotide level for the differentiation of living organisms at the variety and species levels. Currently, PCR-based methods are used either for the purpose of detecting single nucleotide polymorphisms (SNPs) giving rise to restriction fragment length polymorphisms (RFLPs) or for detecting small sequence length polymorphisms (SSLPs), often known as variable number tandem repeats (VNTRs). These methods facilitate the identification of unique polymorphisms of a variety of food commodities and can be used to identify their source or origin. These unique polymorphisms are often referred to as DNA barcodes (Teletchea, Maudet and Hänni, 2005). The DNA barcode is used for the identification of specific varieties in food detection and in food traceability and, for example, for the identification of many products for export in countries such as Argentina, Brazil, China, Cuba and Thailand. The DNA barcode of microsatellite markers has also been successfully used for differentiating and identifying fermented products such as premium wines, cheeses and sausages on the basis of their origins, as well as for differentiating Basmati rice varieties and olive cultivars used in olive oil production (Sefc *et al*., 2000).

5.4 ANALYSIS OF THE REASONS FOR SUCCESSES/FAILURES OF APPLICATION OF BIOTECHNOLOGIES IN DEVELOPING COUNTRIES

Socio-economic factors have played a major role in the adoption and application of microbial inoculants in food fermentations. In situations where the cost of food is a major issue, uptake and adoption of improved biotechnologies has been generally slow. Demand for improved inoculants and starter culture development has been triggered by increasing consumer income, education and new market opportunities.

Socio-economics of the consumer base

The consumer base of traditionally fermented staple foods in most developing countries is largely poor and disadvantaged. Price, rather than food safety and quality, is therefore a major preoccupation of this group when purchasing food. Fermented foods provide that target group with an affordable source of food and make a substantial contribution to their food and nutritional security. These foods are generally produced under relatively poor hygienic conditions at the household and village levels. Fermentation processing is practised largely as an art in such contexts.

Interventions designed to upgrade processes used in the production of these traditionally fermented staples have been largely carried out through donor-funded projects and have focused primarily on reducing the drudgery associated with the fermentation processes. Improvements have also targeted the upgrading of hygienic conditions of fermentation processes and the introduction of simple and "appropriate" methodologies for the application of inoculants such as the use of backslopping. While the uptake of simple backslopping technologies at the household level has, in general, been very good by that target group, the uptake of defined starter cultures has been less successful owing to cost considerations. Case Study 5.5.3 on the household level production of Som Fug in Thailand highlights the poor uptake of improved starter culture technologies by household-level processors, primarily on the basis of cost.

With growing incomes and improved levels of education in urban centres across a number of developing countries, dietary habits are changing and a wider variety of foods is being consumed. Fermented foods are no longer the main staples but are still consumed as side dishes or condiments by that target group. The demand of that target group for safe food of high quality has begun to re-orient the traditional fermented food sector and led to improvements in the control of fermentation processes through the development and adoption of defined starter cultures, the implementation of GHPs and HACCP in food fermentation processing, and the development of bioreactor technologies, coupled with appropriate downstream processing to terminate fermentation processes and thus extend the shelf-life of fermented foods. The packaging of fermented products has also improved. Case Study 5.5.1 on soy sauce production in Thailand highlights an example of how starter culture development coupled with bioreactor technology has improved yields and the efficiency of fermentation processes, while Case Study 5.5.2 highlights how consumer demand for safe food led to R&D into starter culture development designed to improve the safety of nham in the marketing chain.

Changing consumer demand trends

Apart from their changing dietary patterns and their demand for safety and quality, higher income consumers demand convenience and are increasingly concerned about deriving health benefits from the foods they consume. Many of these consumers also show a preference for shopping in supermarkets. Consumer demand for deriving wellness through food consumption has stimulated the development of industrial fermentation processes for the production of functional ingredients such as polyunsaturated fatty acids and probiotic cultures for use as food ingredients in developing countries. These functional ingredients are currently applied in the fortification of fermented foods as well as in the production of dietary supplements in countries such as India.

The growth of supermarkets in developing countries has promulgated the need for standardized products of a reasonable shelf-life that meet safety and quality criteria. Packaged fermented products such as kimchi, miso and tempeh, for example, are widely available in supermarkets across Asia. The production of traditional beer in a powdered format and in ready-to-drink containers in Zambia is a good example of product development that has taken place in response to consumer demand for convenience, both in local and export markets.

Shifting consumer preferences in South Africa away from basic commodity wine to top quality wine is yet another example of how market demand has led to research and biotechnological innovation in the wine industry. Biotechnological innovations in that country are currently focused on the improvement of *Saccharomyces cerevisiae* strains to improve wholesomeness and sensory quality of wines.

The enabling environment for starter culture development

A considerable amount of research in developing countries has focused on the identification of starter micro-organisms associated with the fermentation of staple foods. The greatest strides in starter culture development have, however, been realized in countries that have prioritized the development of technical skills, the infrastructural support base and funding support for research into the upgrading of fermentation processes. Linkages between research institutions and the manufacturing sector have also been critical to the successful introduction of starter cultures. Case Study 5.5.1 on soy sauce production exemplifies how success was achieved through such collaboration. Case Study 5.5.2 on nham production in Thailand also highlights how collaboration between the manufacturing sector and public sector research institutions resulted in the development of improved starter cultures and the uptake of these cultures by nham manufacturers to assure product safety.

Collaborative initiatives among research institutions have also had a major positive impact on biotechnological developments in developing countries. Collaboration among African institutions and their counterparts in the North has greatly facilitated improvements in biotechnological research and capacity development in the area of food biotechnology on the continent. One success story in this regard has been a series of collaborative projects on traditional African fermented foods involving research institutions in Africa and Europe (Mengu, 2009). The programme facilitated the typing and screening of microbial cultures associated with fermented African foods as a basis for starter culture development, and results of this work led to improvements in the production of gari, a fermented cassava product, and dawadawa, a fermented legume product.

Issues related to the protection of intellectual property rights (IPR) are of growing concern with respect to starter culture development. Case Study 5.5.4, describing flavour production using alkaline-fermented beans highlights the critical importance of IPR in reference to processes applied in the production of traditional fermented foods.

Proactive industrial strategies

Biotechnology developments have been most successful in areas where proactive approaches are taken by industry. The Thai food industry successfully creates perceived quality by launching new product logos and associating these new products with biotechnology or with the fact that they were developed using traditional biotechnology such as starter cultures. The goal of the industry is to project an image of itself as producing products of superior quality and safety that represent progress based on a higher level of technology.

Export opportunities for fermented products

Increasing travel due to globalization has changed the eating habits of consumers across the globe. Export markets for fermented foods have grown out of the need to meet the requirements of the developing country diaspora in these markets as well as to satisfy growing international demand for niche and ethnic products. Indonesian tempe and Oriental soy sauce are well known examples of indigenous fermented foods that have been industrialized and marketed globally. The need to assure the safety and quality of these products in compliance with the requirements of importing markets has been a driving force for the upgrading of starter cultures as well as for diagnostic methodologies for verifying their quality and safety. Growing interest and trade in fermented food products is also likely to lead to the greater use of the DNA barcode for identifying the origins of specific fermented food products produced in developing countries.

5.5 CASE STUDIES OF APPLICATIONS OF BIOTECHNOLOGIES IN DEVELOPING COUNTRIES

5.5.1 Fermented soy sauce production

This Case Study on the production of soy sauce highlights success in the application of starter culture technology and the use of improved bioreactor technology. It exemplifies the transition of a craft-based production system to a technology-based production system. Research leading to these developments was supported by an international organization, followed by funding support from the Government of Thailand and the Thai soy sauce industry. Developments of the process were largely driven by the demand pull created by a soy sauce industry consortium in Thailand in order to meet market requirements.

Soy sauce production involves a two-step fermentation process that makes use of koji inoculants in the initial phase followed by moromi inoculants in the second phase. The initial phase of the fermentation involves the soaking of soybeans in water for 1–2 hours, boiling for approximately 17 hours to hydrolyze the protein complex, and the addition of the koji culture *Aspergillus oryzae* for proteolysis of the soy proteins. Using this traditional method of production, the process of proteolysis takes between 40 hours and seven days depending on the method and the conditions used. The second phase of the fermentation process, referred to as a moromi fermentation, involves the addition of brine solution to the koji. *Saccharomyces rouxii,* a salt-tolerant yeast, is the predominant micro-organism in this phase of the fermentation which lasts as long as 8–12 months. Moromi fermentations are traditionally conducted in earthenware jars, which often pose a limitation to the manufacturers both in terms of expansion and in terms of production capacity (Valyasevi and Rolle, 2002). The soy sauce industry has moved up the ladder of development from an "art" to a technology-based process through the introduction of defined starter cultures and improvements in the control of the fermentation process. Physical and biological parameters of the fermentation process are controlled through the use of koji and moromi cultures and koji and moromi fermentors.

Use of the koji starter, *Aspergillus flavus* var. *columnaris*, was found to enhance product safety and uniformity. The introduction of pressure cookers as an innovation for hydrolyzing the soybeans reduced the time required for solubilization from 17 hours to 2.5 hours. Moreover, the use of starter culture technology facilitated the development of fermentation chambers with controlled temperature and humidity conditions, which resulted in shortening the duration of the fermentation process. The resulting soy sauce had a higher (6 percent) soluble protein content than that derived from boiled soybeans. These developments resulted in economic gain for the soy sauce industry and greater value added to the product in terms of quality and safety.

5.5.2 Traditional fermented pork sausage (nham)

This Case Study demonstrates how consumer demand for safe food resulted in the commercial use of defined starter cultures, with the collaboration and support of government agencies. The diagnostic role of biotechnology in starter culture development for the tailor making of cultures is also highlighted.

Nham is an indigenous fermented pork sausage produced in Southeast Asia. It is prepared from ground pork, pork rinds, garlic, cooked rice, salt, chili, sugar, pepper and sodium nitrite. It is traditionally consumed as a condiment in the uncooked state in Thailand. It is generally produced using an uncontrolled fermentation process. Fermentation of the product occurs during transportation from the manufacturer to the point of retail. The product is generally retailed under ambient conditions. Traditionally produced nham is considered high risk by the Thai health authorities, who require a warning label on the package stating that the product "must be cooked before consumption".

The first step in the transition to science-based technology for nham fermentations was the development of a starter culture. This starter was subsequently adopted by a nham manufacturer who also implemented HACCP in his operation to assure safety and to satisfy the compulsory standard requirements of GMP in the food processing industry imposed by the Thai Food and Drug Administration. A microbiological hazard profile was developed for nham by the manufacturer in collaboration with scientists from the Ministry of Science, who established that the prevalent pathogens in nham were *Salmonella* spp. (16 percent), *Staphylococcus aureus* (15 percent) and *Listeria monocytogenes* (12 percent) (Paukatong and Kunawasen, 2001). Nitrite, an additive used in nham production, was identified as a chemical hazard and the metal clips used for closing the package were identified as physical hazards. A HACCP plan which included four critical control points was developed for nham (Table 7).

The critical control point on nitrite was monitored by checking the pre-weighed nitrite prior to adding it to the product formulation. Scientific data from studies on starter cultures showed that a rapid increase in acidity within 36–48 hours of fermentation inhibited the growth of bacterial pathogens such as *Staphylococcus aureus* and *Salmonella* spp. (Paukatong and Kunawasen, 2001; Chokesajjawatee *et al.*, 2009). With the application of these starter cultures, the final product was sent to retailers after the fermentation reached its end-point (pH< 4.5). An innovative pH indicator which undergoes a colour change on attainment of the end-point of the fermentation process (pH<4.5) was included in the package. With these innovations and the implementation of a HACCP plan, local health authorities waived the requirement for the warning "must cook before consumption" on the package. This authorization was seen by the public as an endorsement of product quality and safety by the health authority. Subsequently, three medium-sized manufacturers followed suit in adopting the improved technology. Recognition of the starter culture technology as a food safety measure by the health authority was, of itself, an effective public awareness campaign.

RAPD markers were used for molecular typing of approximately 100 bacterial strains at 12-hour intervals during nham fermentations. These studies resulted in the development and commercialization of three different starter formulae for use by larger manufacturers of nham. These starter cultures are marketed in a liquid form which requires refrigeration. Dried starter cultures have a shelf-life of one month at ambient temperature. Further innovations have led to the incorporation of local yeast extracts into starter culture development, resulting in a 20 to 30 fold reduction in cost. The adoption of starter culture technology in nham fermentations has had a positive impact on the industry in terms of safety assurance to consumers and product consistency.

5.5.3 Traditional fermented fish paste – Som Fug

Som Fug is a traditional fermented minced fish cake. It is considered a healthy and highly nutritious product and is an excellent source of protein (protein content: 15.7 percent, fat: 3.2 percent and total carbohydrates: 4 percent). It is produced using a spontaneous microbial fermentation process similar to that used for producing nham and many other Southeast Asian fermented foods. This Case Study demonstrates that the uptake and use of starter culture technologies is still largely contingent on cost considerations and consumer appreciation of the nutritional value of the product.

TABLE 7

HACCP PLAN FOR THE PRODUCTION OF NHAM

Process step	Hazard	Critical limits	Monitoring procedures	Corrective actions	HACCP records
Weighing nitrite	Improper nitrite weight: if too high - chemical hazard, if too low - may result in microbiological hazard	100 ppm $\leq$ initial nitrite level $\leq$ 200 ppm	The quality control (QC) supervisor randomly checks the pre-weighed nitrite according to appropriate sampling frequency	Supervisor reweighs every bag of nitrite since last satisfactory check; record deviation; recalibrate the weighing balance	• nitrite weighing records • deviation records • balance calibration records
Stuffing	Failure to remove metal clips may contaminate product	No metal in product	Line worker to visually inspect each nham product during stuffing. Change worker every 30 minutes	Line worker notifies supervisor; separate contaminated product; segregate metal; and record deviation	• visual inspection log • deviation records
Labelling	Failure to provide microbiological safety information to the consumer	Label to contain information such as "safe if cooked before consumption" on each nham product	Line worker randomly checks the label on nham products	Line worker notifies supervisor; recheck nham product; label product; and record deviation	• visual inspection log • deviation records
Fermentation	Inadequate fermentation resulting in growth of pathogens	The pH of nham product lower than 4.6	QC worker randomly monitors pH of nham in each lot	QC worker notifies supervisor; hold lot; prolong fermentation; and record deviation	• monitoring pH records • holding records • deviation records

Source: Paukatong and Kunawasen (2001)

Compositionally, Som Fug consists of minced freshwater fish (mud carp, *Cirrhina microlepis*) 84 percent (by weight), garlic 8 percent, water 4 percent, salt 2 percent, boiled rice 1 percent, sucrose 0.1 percent and black pepper. It is fermented for about 2–4 days at ambient temperature. Lactic acid bacteria are the dominant microflora associated with the fermentation (Paludan-Muller, Huss and Gram, 1999). RAPD-PCR analyses determined that the garlic-fermenting lactic acid bacteria associated with Som Fug fermentations belonged to *Lactobacillus pentosus* and *Lact. plantarum* (Paludan-Muller *et al.*, 2002). Furthermore, the studies concluded that fructans from garlic are important carbon sources which catalyze the fermentation. The studies on Som Fug illustrate the high discriminatory power of biotechnology in differentiating lactic acid bacteria at the strain level. The Som Fug industry did not see the benefit of implementing starter culture technology. Although the important micro-organisms for Som Fug fermentation had been identified, there were no attempts to develop starter cultures. One major reason for the lack of development of starter culture technology was the widespread production of Som Fug at the household level. Household manufacturers do not see the benefit of starter culture technology but rather view starter cultures as a burden to the cost of production. Moreover, there is no scientific information to substantiate the nutritional value of Som Fug and hence there is very little public awareness of the nutritional value of the product.

5.5.4 Flavour production from alkaline-fermented beans

This Case Study on the indigenous fermentation of the locust bean is a classic example of how traditional fermentations can be exploited for the production of high-value products such as flavour compounds. The work, however, was undertaken by a large corporation with little involvement of local researchers. Returns on commercial successes derived from this study did not go back to the people who invented the traditional method of producing this indigenous fermented food. This Case Study, therefore, serves to highlight the critical issue of IPR in traditional production systems.

Dawadawa is produced by alkaline fermentation of the African fermented locust bean (Steinkraus, 1995). It is an important condiment in the West/Central African Savannah region (Odunfa and Oyewole, 1986). Similar fermented food products can be found throughout Africa with regional differences in the raw materials used as processing inputs or in post-processing operations. Similarly, fermented products are referred to as kinda in Sierra Leone, iru in coastal Nigeria, soumbara in Gambia and Burkina Faso, and kpalugu in parts of Ghana (Odunfa and Oyewole, 1986). Foods produced by alkaline fermentation in other parts of the world include natto in Japan, thua noa in Thailand and kinema in India (Tamang, 1998). These are mainly used to enhance or intensify meatiness in soups, sauces and other prepared dishes.

The production of dawadawa involves extensive boiling and dehulling of the beans followed by further boiling to facilitate softening. Spontaneous fermentation of the softened beans is subsequently allowed to take place over 2–4 days. Micro-organisms associated with the fermentation include *Bacillus subtilis* (Ogbadu and Okagbue, 1988), *B. pumilus* (Ogbadu and Okagbue, 1988), *B. licheniformis* (Ogbadu, Okagbue and Ahmad, 1990) and *Staphylococcus saprophyticus* (Odunfa, 1981). During the fermentation process, the pH increases from near neutral to approximately 8.0, temperature increases from 25 °C to 45 °C and moisture increases from 43 to 56 percent (Odunfa and Oyewole, 1986). At the same time, a five-fold increase in free amino acids takes place, and glutamate, a flavour enhancer, increases five-fold during the process. Mechanisms of flavour production during the fermentation process as well as flavour principles generated during dawadawa fermentation processing have been studied by international food manufacturers and used as a basis for the development of flavours for incorporation in bouillon-type products (Beaumont, 2002).

B. LOOKING FORWARD: PREPARING FOR THE FUTURE

5.6 EMERGING PATHOGENS: A KEY ISSUE WHERE THE APPLICATION OF BIOTECHNOLOGIES COULD BE USEFUL

The identification of infectious agents requires high-end technologies which are not usually available in developing countries. Developing countries must therefore seek assistance from countries with higher calibre technologies in order to characterize infectious agents, put in place surveillance and monitoring systems and develop strategies to contain the disease(s). Biotechnology can play a key role in facilitating the characterization of new emerging pathogens.

Traditional cultural methods for the detection and enumeration of microbial pathogens are tedious and require at least 12–18 hours for the realization of results. By that time, the food products would have been distributed to retailers or consumers. Immunoassay diagnostic kits facilitate near-real-time monitoring, sensitivity, versatility and ease of use. The emergence of multi-antibiotic resistance traits is prevalent in intensive farming in developing countries due to the abuse of antibiotics. The spread of multi-antibiotic resistant micro-organisms poses public health concerns because pathogens exhibiting such resistance would be difficult to control with the use of currently available antibiotics. The rapid detection of these pathogens with high sensitivity is one way of monitoring and containing the spread of multi-antibiotic resistant traits. A strategic approach being employed by some is the development of affinity biosensors with an antibiotic resistant nucleotide sequence as the detection probe.

5.7 IDENTIFYING OPTIONS FOR DEVELOPING COUNTRIES

It is important that countries recognize the potential of fermented foods and prioritize actions to assure their safety, quality and availability. Based on the stocktaking exercise in this Chapter, a number of specific options can be identified for developing countries to help them make informed decisions regarding adoption of biotechnologies in food processing and in food safety for the future.

Regulatory and policy issues

- Governments must be committed to protecting consumer health and interests, and to ensuring fair practices in the food sector.
- There has to be consensus at the highest levels of government on the importance of food safety, and the provision of adequate resources for this purpose.

- Government policy must be put in place that is based on an integrated food-chain approach, is science-based, transparent and includes the participation of all the stakeholders from farm to table.
- The importance of the regional and international dimensions of using biotechnologies in food processing and safety must be recognized.
- Priority must be accorded to promoting fermented foods in the food security agendas of countries.
- Governments must also provide an enabling environment that is supportive of the growth and development of upstream fermentation processes such as the production of high-value fermented products, such as enzymes, functional food ingredients and food additives.

International cooperation and harmonization

- The organization and implementation of regional and international fora are critical requirements for the enhancement of national organizational capability and performance and to facilitate international cooperation. Further, the setting up of administrative structures with clearly defined roles, responsibilities and accountabilities could efficiently govern processed foods and safety issues.
- Biotechnology-based standard operating procedures (SOPs) for food safety should also be documented for use in authorized laboratories.
- National food control databases for the systematic collection, analysis and reporting of food-related data (food inspection, analysis, etc.) with set regulations and standards based on sound science and in accordance with international recommendations (Codex) are key requirements.

Education policy

While the consumption of fermented foods is growing in popularity among higher income consumers thanks to increasing interest in wellness through diet, the consumption of fermented foods by lower income consumers in many developing countries is perceived to be a backward practice.

- Strategies should therefore be developed for the dissemination of knowledge about food biotechnology and particularly fermented foods. Targeted consumer education on the benefits of consuming fermented food products and on applying good practice in their production is required.
- Food biotechnology should be included in educational curricula in order to improve the knowledge base in countries on the contribution of fermented foods to food and nutritional security and to generate awareness of the growing market opportunities for fermented foods and high-value products derived from fermentation processes.

Information-sharing

Access to specialized technical information on biotechnology and biotechnological developments in the food processing sector are critical and necessary inputs and support systems for guiding and orienting the research agendas of countries. The necessary information systems should therefore be developed to facilitate rapid access to information on biotechnological developments across both the developed and the developing world.

Legislation and policy on technologies

Expertise in legislation and technology licensing as well as knowledge about how to nurture innovation and turn it into business ventures are critical requirements for developing countries. Successful technology transfer requires all of these elements and an environment that is conducive to innovation. Government policy in developing countries should therefore prioritize technology transfer that helps create new business ventures, an approach that requires government support such as tax incentives and infrastructure investment.

Intellectual property rights

- Many of the traditional fermentation processes applied in developing countries are based on traditional knowledge. Enhanced technical and scientific information is required to claim ownership of the traditional knowledge underpinning the craft of indigenous fermented foods. Lack of technical knowledge and official documentation has resulted in the failure to realize the benefits of the industrialization of indigenous fermented foods by individuals who are the rightful owners of the technology.
- Greater focus is also required on issues of relevance to IPR and on the characterization of microbial strains involved in traditional fermentation processes. Emphasis must be placed on IPR education for scientists. National governments should put in place the requisite infrastructure for IPR to facilitate the process. At the institutional level, this infrastructure would include technology management offices for assisting scientists in procedures relating to IP matters. The processes used in the more advanced areas of agricultural biotechnology are generally covered by IPR and the rights are generally owned by parties in developed countries.

Communication and consumer perceptions

- Communication between various stakeholders is critical in proactively engaging with consumers. Communication must be established with the public at large on processed food and associated hazards. Communication gradually builds confidence and will be critical to advancing the application of biotechnologies in food processing and safety. The primary role of communication in this respect is to ensure that information and opinions from all stakeholders are incorporated in the discussion and decision-making processes. The need for specific standards or related texts and the procedures followed to determine them should also be clearly outlined. The process, therefore, should be transparent.

- Public awareness and education are critical to the success of food bioprocessing and food safety in developing countries.
- Greater attention must be directed toward understanding consumer and producer (processor) perceptions on food safety and quality in developing countries.
- If foods are to be promoted as being safe and healthy, their nutritional and safety attributes must be transparently demonstrated by presenting scientific data to substantiate the nutritional and health benefits and by applying good manufacturing/hygiene practice and HACCP as safety measures to ensure that issues of consumer concern are addressed.

Technical capacities and technology transfer

- Traditional fermented foods should be viewed as valuable assets. Governments should capitalize on these assets and add value to them by supporting research, education and development, while building on and developing the indigenous knowledge base on food fermentations.
- Government agencies in developing countries should focus on the development of technical capacities to deal with emerging technical issues.
- The technical capacities of academic and research institutes should be strengthened in the fields of food biotechnology, food processing, bioprocess engineering and food safety through training and exchange programmes for researchers. Such programmes should emphasize collaboration with both developed and developing country institutions engaged in work on food biotechnology, starter culture development, bioprocess engineering and food safety.
- Training capabilities in food biotechnology and food safety should be developed within developing country institutions through the introduction of degree courses in order to broaden the in-country technical support base for food bioprocess development. Given the similarities among fermentation processes across regions, an inventory of institutions engaged in food biotechnology in developing countries would be an asset in facilitating networking among institutions. Food processors, policy-makers and equipment manufacturers should also be integrated into the networking activities.
- The development of appropriate levels of bioreactor technology with control bioprocess parameters will be necessary to improve the hygienic conditions of the fermentation processes.

- Research and infrastructural development to enable the cost-effective production of defined starter cultures in a stable format (i.e. cultures which do not require refrigeration and have prolonged shelf-lives under ambient conditions) should be prioritized.
- Infrastructure development to facilitate the transfer and adaptation of fermentation technologies developed at the laboratory level to the household and village and, where necessary, the enterprise level should be prioritized.
- Appropriate levels of equipment will also be required to facilitate the downstream processing of these products.
- Traceability systems that facilitate the differentiation and identification of food products should be prioritized in order to broaden market opportunities for these products.
- A food-chain approach to assuring food safety should be prioritized by governments.
- Food safety management systems should be strengthened by implementing systematic food safety measures such as GHP, GMP and HACCP in food fermentation operations. Diagnostic kits are important tools for monitoring and verifying the level of sanitation in processing plants.

  Highly sensitive and rapid diagnostic kits are invaluable for monitoring and rapidly detecting chemical and microbiological hazards with high precision and sensitivity that pose threats to human health. The development of low-cost diagnostic kits suitable for use by small processors would greatly facilitate food safety monitoring. Development should target the realization of multiplex diagnostic systems with the capacity to detect several pathogens or many chemical contaminants using a single diagnostic kit. The development of diagnostic kits at a national level could further reduce their cost of production. Given the regional specificity of bacterial pathogens at the species and subspecies levels, such diagnostic kits should be developed with specificity and sensitivity to the species or subspecies that are prevalent in a specific region. Investment is therefore needed for the development of expertise, facilities and infrastructure for the mass production of antibodies, cell culture technology and for the formation of technical know-how on assembling the requisite components of diagnostic kits.

  The development of national hazard profile databases that document the prevalent pathogens in different regions will be critical. Such information would be useful for further research into the development of diagnostic kits with high precision and sensitivity and in implementing HACCP as well as risk assessment research. The culture collection of identified infectious agents in the hazard profiles could play an important role for producing specific antibodies for use in developing immunoassay diagnostic kits.

5.8 IDENTIFYING PRIORITIES FOR ACTION FOR THE INTERNATIONAL COMMUNITY

The last decade has witnessed considerable change with respect to the applications of biotechnology in food processing and food safety. Market forces have been the major drivers of change in the food sector of developing countries. Modern biotechnological tools are likely to play a greater role in the development of efficient science-based processes for food processing and safety in order to respond to consumer demand. The production of high-value fermented products such as enzymes, functional food ingredients and food additives is likely to continue to increase in developing countries.

The international community (FAO, UN organizations, NGOs, donors and development agencies) can play a major role in assisting developing countries to maximize the benefit to be derived from food bioprocessing. The adoption of biotechnology-based methods in food processing and for food safety and quality monitoring is dependent on several factors that include capacity building in technical and regulatory areas, policy formulation, regulatory frameworks and regional networks.

Based on the analysis in this Chapter, a number of priority areas are identified for support by the international community. These are:

Capacity building and human resource development

- support basic and advanced education;
- prioritize specific areas for investment;
- develop policy options, priorities and action programmes that promote food fermentation as a means of addressing food security;
- support human resource development in a range of scientific disciplines – food biotechnology, food safety, bioengineering and enzyme technology;
- support capacity building initiatives for household-level, small- and medium-scale processors of fermented foods;
- support IPR development.

Technology transfer and support for R&D

- improve the relevance of national research to the needs of the food sector in developing countries;
- enhance competitiveness and the creation of an enabling environment that is conducive to private sector investment in research, development and innovation for the upgrading of food fermentation processes to respond to market demand;

- establish and strengthen the research and infrastructural support base for work on starter culture development, bioreactor design and for the development of diagnostic tests and equipment for monitoring food safety and traceability. This infrastructural support base would include laboratories, laboratory equipment and cell bank facilities for the proper preservation and storage of microbial culture preparations;
- develop scientific data to examine the nutritional, health and health-benefit claims associated with fermented foods;
- establish pilot processing facilities for the scaling-up and testing of technologies to facilitate their adoption.

Networking and clusters

- support the development of regulatory frameworks for food safety;
- support North-South and South-South training and exchange on food biotechnologies, bioprocess engineering and food safety;
- promote and facilitate networking among scientists, researchers, small- and medium-scale food processors and the retail sector to facilitate knowledge and information-sharing;
- support leveraging the traditional knowledge base in the upgrading of food fermentation processing operations.

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CHAPTER 6

LEARNING FROM THE PAST: SUCCESSES AND FAILURES WITH AGRICULTURAL BIOTECHNOLOGIES IN DEVELOPING COUNTRIES OVER THE LAST 20 YEARS – AN E-MAIL CONFERENCE

6.1 INTRODUCTION

The FAO Biotechnology Forum is an e-mail-based mechanism which was launched in 2000 with the aim of providing access to quality balanced information and to make a neutral platform available for all interested stakeholders to openly exchange views and experiences on agricultural biotechnology in developing countries. It covers applications in the crop, forestry, livestock, fisheries and agro-industry sectors. The Forum covers the broad range of tools included under the general term "biotechnology". Some of these technologies, such as the use of molecular markers or genetic modification, may be applied to all food and agricultural sectors, while others are more sector-specific, such as tissue culture (in crops and forest trees), embryo transfer (livestock) or sex-reversal (fish).

Each conference takes one particular theme that is relevant to agricultural biotechnology in developing countries and opens it up for debate for a limited amount of time. From 2000 to 2008 the Forum hosted 15 moderated e-mail conferences, with messages coming roughly equally from participants living in developing and developed countries.

For each conference, two key documents are produced. Firstly, before the conference takes place, a Background document is prepared to give a good overview of the conference theme, in a balanced neutral way, and written in easily-understandable language so that people with little knowledge of the area may understand what the theme is about. The document also highlights any particular issues of special relevance to developing countries.

Secondly, after the conference, a Summary document is prepared to provide an overview of the main issues that were discussed based on the messages posted by the participants.

This Chapter presents these two documents from conference 16 of the Forum, entitled "Learning from the Past: Successes and Failures with Agricultural Biotechnologies in Developing Countries Over the Last 20 Years ", that took place from 8 June to 8 July 2009 as part of the build up to ABDC-10. As for other conferences of the Forum, it was moderated by John Ruane from the FAO Working Group on Biotechnology.

For ABDC-10, FAO prepared five sector-specific technical documents on biotechnology applications in crops, forestry, livestock, fisheries and aquaculture, and in food processing and food safety (presented in Chapters 1 to 5 respectively of these proceedings). Their aim was to document the current status of application of biotechnologies in developing countries in the relevant sector, provide an analysis of the reasons for successes/failures in the application of biotechnologies in developing countries, present some relevant case studies, and provide options for the future. To complement these documents, the Forum hosted this cross-sectoral e-mail conference to bring together and discuss relevant, often undocumented, past experiences of applying biotechnologies in developing countries, ascertain the success or failure (partial or full) of these experiences, and determine and evaluate the key factors that were responsible for their success or failure. The sector-specific documents were in draft form when the Background document was being prepared; it therefore benefited from the information already available in these drafts. The Background document is presented in Part 6.2. In turn, the drafts also benefited from the discussions and case studies that emerged from the e-mail conference. The Summary document is presented in Part 6.3.

6.2 BACKGROUND TO THE ISSUES

In this e-mail conference, as well as in the context of ABDC-10, the term "agricultural biotechnology" encompasses a variety of technologies used in food and agriculture for a range of different purposes such as the genetic improvement of plant varieties and animal populations to increase their yields or efficiency; genetic characterization and the conservation of genetic resources; plant or animal disease diagnosis; vaccine development; and the improvement of feeds. Note, the term "agriculture" here includes the crop, livestock, fisheries and aquaculture, forestry and food processing sectors, and so the term "agricultural biotechnologies" encompasses their use in any of these sectors.

This Background document aims to provide information that participants will find useful for the e-mail conference. In Part 6.2.1 an overview is provided of the different agricultural biotechnologies to be considered, while Part 6.2.2 presents some specific guidance about the e-mail conference.

6.2.1 Overview of agricultural biotechnologies in developing countries

A short overview is provided below of the main kinds of agricultural biotechnologies that have been used in developing countries over the past 20 years and that should be covered in the e-mail conference. They are described separately, although in practice more than one may be used in certain situations (e.g. in wide crossing programmes, see later). Note, new biotechnologies that are still at the research level, be it in the laboratory or at the field trial stage, but have not yet been applied (i.e. used for commercial production by farmers) in developing countries are not included.

This overview also indicates what the biotechnologies are used for, the food and agricultural sectors involved, and gives some examples of their applications in specific developing countries. Regarding the examples, their inclusion in the document does not imply that these applications have been a partial or complete success (or, conversely, that they have been any kind of a failure). Indeed, these are the kind of issues to be addressed by participants during this e-mail conference. Although not the subject of this conference, it should also be kept in mind that the path from research, for example in the laboratory, to the eventual application of a product in the field (e.g. farmers cultivating a new genetically improved plant variety or using a new vaccine against an animal disease) can be long, resource-demanding and unsuccessful. Many biotechnologies of seemingly high promise at the experimental stage have had limited applications in developing countries so far.

As many of the biotechnologies described below are related to molecular biology and genetic material, some basic terminology is introduced here. Living things are made up of cells that are programmed by genetic material called deoxyribonucleic acid (DNA). A DNA molecule is made up of a long chain of nitrogen-containing bases. Only a small fraction of this DNA sequence typically makes up genes, i.e. that code for proteins, which are molecules essential for the functioning of living cells, made up of chains of amino acids. The remaining and major share of the DNA represents non-coding sequences whose role is not yet clearly understood. The genetic material is organized into sets of chromosomes (e.g. five pairs in *Arabidopsis thaliana* – a model plant species; 30 pairs in cattle), and the entire set is called the genome. In a diploid individual (i.e. where chromosomes are organized in pairs), there are two alleles of every gene – one from each parent – transmitted by gametes (reproductive cells) that are normally haploid (having just one of each of the pairs of chromosomes). A typical genome contains several thousand genes, e.g. about 30 000 genes in grasses like rice and sorghum (Paterson *et al.*, 2009). Definitions of technical terms used below can be found in FAO (2001).

6.2.1.1 Molecular markers

Molecular markers are identifiable DNA sequences found at specific locations of the genome and transmitted by standard Mendelian laws of inheritance from one generation to the next. They rely on a DNA assay, and a range of different kinds of molecular marker systems exist such as restriction fragment length polymorphisms (RFLPs), random amplified polymorphic DNAs (RAPDs), amplified fragment length polymorphisms (AFLPs) and microsatellites. The technology has improved in the past decade and faster, cheaper systems like single nucleotide polymorphisms (SNPs) are increasingly being used. The different marker systems may vary in aspects such as their technical requirements, the amount of time, money and labour needed and the number of genetic markers that can be detected throughout the genome.

Molecular markers have been used in laboratories since the late 1970s and are applied across all the food and agricultural sectors. They are very versatile and can be used for a variety of purposes. Thus, they are used in genetic improvement through so-called marker-assisted selection (MAS), where markers physically located beside (or even within) genes of interest (such as those affecting yield in maize) are used to select favourable variants of the genes (FAO, 2007a). MAS is made possible by the development of molecular marker maps, where many markers of known location are interspersed at relatively short intervals throughout the genome, and the subsequent testing for statistical associations between marker variants and the traits of interest. Marker maps are now available for a wide range of economically important agricultural species (see e.g. FAO, 2007a for details). Progress in the field of genomics (the study of an organism's entire genome) has also provided much useful information for MAS, enabling in some cases markers to be used that are located within the genes of interest.

Molecular markers are also used to characterize and conserve genetic resources where some of the approaches can be applied in each of the crop, forestry, livestock and fishery sectors (e.g. estimating the genetic relationships between populations within a species). Other uses are more sector-specific, such as their utilization to identify duplicate accessions in crop genebanks, monitor effective population sizes (N_e) in capture fish populations or carry out biological studies (e.g. of mating systems, pollen movement and seed dispersal) in forest tree populations (FAO, 2006a). They are also used in disease diagnosis to characterize and detect pathogens in livestock, crops, forest trees, fish and food (see later).

Molecular markers have been used in a number of developing countries. In livestock, for example, they have been used in four African countries for characterizing genetic resources and in eight Asian countries where six used them for genetic distance studies and two for MAS (FAO, 2007b). In Latin America and the Caribbean, most countries have used molecular techniques primarily for characterization purposes, while their use has been limited in the Near and Middle East (FAO, 2007b). In crops, several examples of new hybrids and varieties developed through MAS are available, and in progress, in different crops such as pearl millet, rice and maize, and in several developing countries such as Bangladesh, India and Thailand (Varshney, Hoisington and Tyagi, 2006). Different centres of the Consultative Group on International Agricultural Research (CGIAR) have been working with partners in developing countries to accelerate plant breeding practices through MAS.

6.2.1.2 Genetic modification

A genetically modified organism (GMO) is an organism in which one or more genes (called transgenes) have been introduced into its genetic material from another organism. The genes may be from a different kingdom (e.g. a bacterial gene introduced into plant genetic material), a different species within the same kingdom or even from the same species. For example, so-called "Bt crops" are crops containing genes derived from the soil bacterium *Bacillus thuriengensis* coding for proteins that are toxic to insect pests that feed on the crops. The issue of GMOs has been highly controversial over the past decade. Many countries have introduced specific frameworks to regulate their development, release and commercialization.

GM crops were first grown commercially in the mid 1990s. While the majority continues to be grown in developed countries, an increasing number of developing countries are reported to be cultivating them. Recent estimates (James, 2008) indicate that 10 developing countries planted over 50 000 hectares (ha) of GM crops in 2008: Argentina (21.0 million ha), Brazil (15.8), India (7.6), China (3.8), Paraguay (2.7), South Africa (1.8), Uruguay (0.7), Bolivia (0.6), Philippines (0.4) and Mexico (0.1). For comparison, in 1997 the only developing countries reported were Argentina (1.4 million ha), China (1.8) and Mexico (less than 0.1). Almost all GM crops grown commercially are genetically modified for one or both of two main traits: herbicide tolerance (63 percent of GM crops planted in 2008) or insect resistance (15 percent), i.e. Bt crops, while 22 percent have both traits (James, 2008).

The commercial release of GM forest trees has been reported in one country, China. In 2002, approval was granted for the environmental release of two kinds of Bt trees, the European black poplar (*Populus nigra*) and the hybrid white poplar clone GM 741, together representing about 1.4 million plants on 300–500 ha (FAO, 2004). Regarding GM livestock or fish, there has been no reported commercial release for food and agricultural purposes in any country.

Although documentation is generally quite poor, the use of GM micro-organisms (GMMs) in agro-industry and for animal feeds is routine in developed countries and is also a reality in many developing countries. In agro-industry, the use of enzymes (proteins that catalyze specific chemical reactions) is important. Many of the enzymes used in the food industry are commonly produced using GMMs. For example, since the early 1990s, preparations containing chymosin (an enzyme used to curdle milk in the preliminary steps of cheese manufacture) derived from GM bacteria have been available commercially (FAO, 2006b). Similarly, many colours, vitamins and essential amino acids used in the food industry are also from GMMs.

In animal nutrition, feed additives such as amino acids and enzymes are widely used in developing countries. The greatest use is in pig and poultry production where intensification has increased over the last decade, further accelerating the demand for feed additives. For example, most grain-based livestock feeds are deficient in essential amino acids such as lysine, methionine and tryptophan. For high-producing monogastric animals (pigs and poultry) these amino acids are added to diets to increase productivity. The amino acids in feed, L-lysine, DL-methionine, L-threonine and L-tryptophan, constitute over half of the total amino acid market. The essential amino acids are produced in some cases by GM strains of *Escherichia coli* (Chapter 3).

In the dairy industry, recombinant bovine somatotropin (rBST), a protein hormone from an *Escherichia coli* K-12 bacterium containing the bovine somatotropin gene, has been used to increase milk production in a number of developing countries. Chauvet and Ochoa (1996) report that rBST was first used in Mexico in 1990 and has been sold in a number of other developing countries, including Brazil, Malaysia, South Africa and Zimbabwe.

6.2.1.3 Chromosome set manipulation

As mentioned earlier, genetic material is organized into sets of chromosomes and each plant and animal species has a characteristic number of chromosomes. Manipulation of whole sets of chromosomes is possible and is used for a range of different purposes in agriculture. For example, fish and shellfish have been extensively studied in relation to the manipulation of their chromosomes during the early stages of development. Using relatively simple techniques such as cold and heat shocks it is possible to produce triploid individuals (i.e. with three sets of chromosomes), leading to the production of almost completely sterile populations. Sterility may be desirable in conservation programmes where it can prevent the introgression of escaped individuals from commercial stocks into natural populations. It may also be of interest in commercial fish operations, e.g. when developing hybrid stocks or to prevent the side-effects of sexual maturation on carcass quality (Chapter 4). As in fish, induction of sterility in crops may be desirable in certain breeding programmes, e.g. to produce seedless fruits, and one of the most rapid and cost-effective approaches is to create polyploids (i.e. with more than two complete sets of chromosomes), especially triploids. Triploid varieties have been produced in numerous fruit crops including most of the citrus fruits, acacias and the kiwifruit (Chapter 1).

Another example of chromosomal set manipulation in fish is the production of haploid individuals after eggs are fertilized by sperm that do not contribute genetic material (a process called gynogenesis) or else when normal sperm fertilize eggs whose DNA has been deactivated (a process called androgenesis). In both cases the haploid chromosomes can then be duplicated using shocks. The importance of gynogenesis/androgenesis is that it is possible to develop inbred individuals, which may be useful in fish breeding experiments aimed at producing clonal lines for detecting genomic regions affecting quantitative traits (Chapter 4).

In crops, chromosome doubling is one of the most important technologies for the creation of fertile inter-specific hybrids (wide crosses). Wide crossing involves hybridizing a crop variety with a distantly related plant from outside its normal sexually compatible gene pool.

Its usual purpose is to obtain a plant that is virtually identical to the original crop except for a few genes contributed by the distant relative. The technique has enabled breeders to access genetic variation beyond the normal reproductive barriers of their crops (Chapter 1). For example, the New Rice for Africa (NERICA) hybrids are derived from crossing two species of cultivated rice, the African rice and the Asian rice, combining the high yields from the Asian rice with the ability of the African rice to thrive in harsh environments.

Wide-hybrid plants are often sterile so their seed cannot be propagated due to differences between the sets of chromosomes inherited from genetically divergent parental species that prevent stable chromosome pairing during meiosis. However, if the chromosome number is artificially doubled, the hybrid may be able to produce functional pollen and eggs and be fertile. Colchicine has been used for chromosome doubling in plants since the 1940s and has been applied to more than 50 plant species including most important annual crops. More recently, several additional chromosome doubling agents, all of which act as inhibitors of mitotic cell division, have been used in plant breeding programmes. To date, with the help of chromosome doubling technology hundreds of new varieties have been produced worldwide.

In crops and forest trees, chromosome doubling has also been used, as for fish, to generate "doubled haploids". The haploid plants can be produced using anther culture which involves the *in vitro* culture of immature anthers (i.e. the pollen-producing organs of the plant). As the pollen grains are haploid, the resulting pollen-derived plants are also haploid (FAO, 2009a). Doubled haploid plants were first produced in the 1960s using colchicine and today, thermal shock or mannitol incubation can be used. They may also be produced from ovule culture. Breeders value doubled haploid plants because they are 100 percent homozygous, so any recessive genes are readily apparent. The time required after a conventional hybridization to select pure lines carrying the required recombination of characters is thus drastically reduced. Since the 1970s, doubled haploid methods have been used to create new varieties of barley, wheat, rice, melon, pepper, tobacco and several Brassicas. In the developing world, a major centre of such breeding work is China where numerous doubled haploid crops have been released and many more are being developed. By 2003, China was cultivating over two million ha of doubled haploid varieties, the most important being rice, wheat, tobacco and peppers (Chapter 1).

6.2.1.4 Biotechnology-based diagnostics

Applications of biotechnology for diagnostic purposes are important in crops, forest trees, livestock and fish as well as for food safety purposes. Two main kinds of methods are used: those based on the enzyme-linked immunosorbent assay (ELISA) and those based on the polymerase chain reaction (PCR).

ELISA systems are antibody-based techniques to determine the presence and quantity of specific molecules in a mixed sample. They are used in a range of formats, both for the detection of pathogens and for the detection of antibodies produced by the host as a response to the pathogens, and a range of commercial kits are available, e.g. to detect fish and shrimp pathogens (Adams and Thompson, 2008). Some of the ELISA-based methods use monoclonal antibodies, produced by a cell line that is both immortal and able to produce highly specific antibodies, or polyclonal antibodies, produced by many cell lines. In livestock, ELISAs form the large majority of prescribed tests for OIE-notifiable animal diseases, and many diagnostic kits are available in developing countries (Chapter 3).

The PCR-based methods rely on the fact that each species of pathogen carries a unique DNA or ribonucleic acid (RNA) sequence that can be used to identify it. PCR allows the production of a large quantity of a desired DNA from a complex mixture of heterogeneous sequences. It can amplify a selected region of 50 to several thousand DNA base pairs into billions of copies. After amplification, the target DNA can be identified using techniques such as gel electrophoresis or hybridization with a labelled nucleic acid (a probe). Real-time PCR (or quantitative PCR) enables the quantification of DNA or RNA present in a sample. The genomes of certain viruses, such as the influenza A virus, are made of RNA instead of DNA. To identify RNA from these viruses, a complementary DNA (cDNA) copy of the RNA is first synthesized using an enzyme called reverse transcriptase. The cDNA then acts as the template to be amplified by PCR. This method is called reverse transcriptase PCR (RT-PCR).

PCR-based techniques offer high sensitivity and specificity, and diagnostic kits allow the rapid screening of viruses or bacteria and have a direct use in situations where individuals show no antibody response after infection. For example, molluscs do not produce antibodies, and therefore antibody-based diagnostic tests are limited in their application to pathogen detection in these species. In fisheries, PCR-related tools are increasingly being used in developing countries, although they require detailed knowledge of the genomics of the pathogen itself and extensive validation in practice (Chapter 4).

In livestock, public sector production of diagnostic kits for animal diseases in Asia and Latin America can be found in Brazil, Chile, China, India, Mexico and Thailand. Research capabilities for development, standardization and validation of diagnostic methods are also well advanced in these countries. PCR-based diagnostics are increasingly being employed in developing countries to back up findings from serological analyses. However, their use is largely restricted to laboratories of research institutions and universities and to central and regional diagnostic laboratories run by governments (Chapter 3). In aquaculture, there are some highly integrated companies operating in developing countries (e.g. in shrimp production) and these companies commonly use PCR-based diagnostic systems where the analyses are either carried out by the laboratories of the companies themselves or are outsourced to specialized private laboratories.

Biotechnology-based diagnostics are also important in food analysis. Many of the classical food microbiological methods used in the past were culture-based, with micro-organisms grown on agar plates and detected through biochemical identification. These methods are often tedious, labour-intensive and slow. Genetic-based diagnostic and identification systems can greatly enhance the specificity, sensitivity and speed of microbial testing. Molecular typing methodologies, commonly involving PCR, ribotyping (a method to determine homologies and differences between bacteria at the species or subspecies/strain level using RFLP analysis of ribosomal RNA genes) and pulsed-field gel electrophoresis (a method of separating large DNA molecules on agarose gels), can be used to characterize and monitor the presence of spoilage flora (microbes causing food to become unfit for eating), normal flora and microflora in foods (FAO, 2006b). RAPD or AFLP molecular marker systems can also be used for comparing genetic differences among species, subspecies and strains depending on the reaction conditions used. The use of combinations of these technologies and other genetic tests allows the characterization and identification of organisms at the genus, species, subspecies and even strain levels, thereby making it possible to pinpoint sources of food contamination, trace micro-organisms throughout the food chain or identify the causal agents of food-borne illnesses (FAO, 2006b).

6.2.1.5 Vaccines developed using biotechnology

Immunization can be one of the most effective means of preventing and hence managing animal diseases. In general, vaccines offer considerable benefits for comparative low cost, a primary consideration for developing countries. In addition, the development of good vaccines for important infectious diseases can lead to reduced use of antibiotics, which is an important issue in developing countries.

As described by Kurath (2008), biotechnology has been used extensively in the development of vaccines for aquaculture, and is applied at each of the three main stages of vaccine development, as follows:

a) the identification of potential antigen candidates that might be effective in vaccines (where an antigen is a molecule, usually a protein foreign to the fish, which elicits an immune response on first exposure to the immune system by stimulating the production of antibodies specific to its various antigenic determinants. During subsequent exposures, the antigen is bound and inactivated by these antibodies);

b) the construction of a new candidate vaccine (where biotechnology tools can be used to produce different kinds of vaccines such as DNA vaccines, recombinant vaccines or modified live recombinant viruses. For example, a DNA vaccine is a circular DNA plasmid containing a gene for a protective antigenic protein from a pathogen of interest);
c) the assessment of candidate vaccine efficacy, its mode of action and the host response (where e.g. quantitative RT-PCR [see earlier] can be used to examine the expression of fish genes related to immune responses).

Of the countries that responded to a recent World Organisation for Animal Health (OIE) survey, four out of 23 and seven out of 14 African and Asian countries respectively indicated that they produce or use animal vaccines derived from biotechnology, including experimental use as well as commercial release (MacKenzie, 2005).

6.2.1.6 Reproductive biotechnologies (livestock and fish)

A number of reproductive biotechnologies have been applied in developing countries to influence the number (and sex) of offspring from given individuals in fish and livestock populations.

Artificial insemination

In artificial insemination (AI), semen is collected from donor male animals, diluted in suitable diluents and manually inseminated into the female reproductive tract during oestrus (heat), to achieve pregnancy. The semen can be fresh or preserved in liquid nitrogen and then thawed. The efficiency of AI can be increased by monitoring progesterone levels, e.g. using ELISA, to identify non-pregnant females, and/or by oestrus synchronization where females are treated with hormones to bring them into oestrus at the desired time.

AI is widely used in developing countries (Chupin, 1992; FAO, 2007b). For example, in India 34 million inseminations were carried out in 2007 while about eight million were carried out in Brazil (Chapter 3). For Africa, Asia and Latin America and the Caribbean regions, AI is mostly used for cattle production (dairy). Other species for which AI is used in all three continents are sheep, goats, horses and pigs. In addition, in Asia, AI is used for chickens, camels, buffaloes and ducks, and in Latin America and Caribbean regions for rabbits, buffaloes, donkeys, alpacas and turkeys. For the most part, semen from exotic breeds is used in local livestock populations. To a lesser extent, semen from local breeds is also used for this purpose. Most AI services are provided by the public sector but the contribution of the private sector, breeding organizations and NGOs is also substantial. In Africa and Asia, AI use is concentrated in peri-urban areas (FAO, 2007b). Progesterone monitoring and oestrous synchronization have been applied in a number of developing countries. Applications of oestrous synchronization have been limited to some intensively managed farms where AI is routinely used.

Embryo transfer

Embryo transfer (ET) involves the transfer of an embryo from a superior donor female to a less valuable female animal. A donor is induced to superovulate (produce several ova) through hormonal treatment. The ova obtained are then fertilized within the donor, the embryos are allowed to develop and then removed and implanted in recipient females for the remainder of the gestation period. Alternatively, the embryos can be frozen for later use.

FAO (2007b) reports that five, eight and twelve countries respectively in Africa, Asia and the Latin America and the Caribbean regions provided information on use of ET in their countries. In Latin America and the Caribbean, ET is increasingly used by commercial livestock producers and the species involved are cattle (in all twelve countries) and alpacas, donkeys, goats, horses, llamas and sheep (in one to three of the twelve countries). In Brazil and Chile, private sector organizations are involved in providing the technology.

Hormonal treatment in aquaculture

In the same way as female reproduction in livestock can be controlled by hormonal treatment, it is also an important tool in aquaculture where it is applied for two main purposes. The first is to control reproduction of fish and shellfish, primarily to induce the final phase of ova production in order to synchronize ovulation and to enable broodstock to produce fish early in the season or when environmental conditions suppress the spawning timing of females. The second is to develop monosex (single sex) populations, which can be desirable in many situations. This can be, *inter alia*, because one sex is superior in growth or has more desirable meat quality or to prevent sexual/territorial behaviour. For example, female sturgeons are more valuable than males because they produce caviar. Female salmon are more valuable because sexually precocious males die before they can be harvested, and salmon roe has an economic value. Male tilapia are more desirable than females because they grow twice as fast. In many fish and shellfish species, sex is not permanently defined genetically and can thus be altered in a number of ways, including through treatment with sexual hormones such as testosterone or estrogen derivatives in early stages of development. To develop all-male tilapia populations, methyltestosterone can be used, while monosex trout can be produced using androgens (Chapter 4).

Sperm/embryo sexing

In livestock, to obtain offspring of a desired sex (e.g. females are preferred for dairy animals, males for beef animals), the separation of X and Y sperm (e.g. based on staining DNA with a fluorescent dye) for AI and sexing of embryos (e.g. using specific DNA probes) can be used. These technologies are being developed and refined in a number of research institutions, but are not widely used by farmers or breeders in developing countries.

6.2.1.7 Cryopreservation

Cryopreservation – the preservation of germplasm in a dormant state by storage at ultra-low temperatures, usually in liquid nitrogen (-196 °C) – can be used to preserve biological material (e.g. seeds, sperm, embryos) of crop, livestock, forest or fish populations for potential use in the future (FAO, 2006a). The technology can be used for genetic improvement purposes and for the management of genetic resources. In livestock, cryopreservation is used in many developing countries and well-established genebanks exist in India and are being established in China and Vietnam (Chapter 3). In fish, the cryopreservation of embryos is not possible but sperm cryopreservation works for many species (FAO, 2006c) and has been used in carp, salmon and trout breeding, especially when the aim has been to "refresh" populations that have gone through a bottleneck.

Considering crops and forest trees, about 90 percent of the six million plant accessions in genebanks, mainly crops, are stored in seed genebanks. However, storage of seeds is not an option for crops or trees that do not produce seed such as banana, or that produce recalcitrant or non-orthodox seed (i.e. seed that does not survive under cold storage and/or the drying conditions used in conventional *ex situ* conservation) such as mango, coffee, oak and several tropical forest tree species. In these situations, as well as for long-term storage of seeds from orthodox species, cryopreservation offers an alternative strategy for *ex situ* conservation, although its routine use is still limited. Plants can be regenerated after plant cell, tissue or organ storage at low temperatures. For various herbaceous (i.e. non-woody plants), hardwood (i.e. broadleaf, deciduous trees) and softwood species (i.e. coniferous trees), cryopreservation of a wide range of tissues and organs has been achieved. There is large-scale application of shoot tip cryopreservation in fruit crop germplasm collections such as plum and apple. Seeds of most common agricultural and horticultural species can be cryopreserved (FAO, 2006a and 2006d).

6.2.1.8 Tissue culture-based techniques

Tissue culture refers to the *in vitro* culture of plant cells, tissues or organs in a nutrient medium under sterile conditions. It has been widely used for over 50 years and is now employed to improve many of the most important developing country crops (Chapter 1). There are a number of tissue culture-based technologies and they can be employed for a range of different purposes. Some of them, used with chromosome set manipulation, have been described earlier. Others include:

Micropropagation

Micropropagation is the laboratory practice of rapidly multiplying stock plant material to produce a large number of progeny plants using plant tissue culture methods. For instance, the shoot tips of banana or potato are excised from healthy plants and cultivated on gelatinized nutrient media in sterile conditions (in test tubes, plastic flasks, or baby-food jars), so that contamination with pests and pathogens is avoided. The plantlets obtained can be multiplied an unlimited number of times by cutting them into single-node pieces and cultivating the cuttings in similar aseptic conditions. Millions of plantlets can be produced in this manner in a very short time. The plantlets are then transplanted in the field or nurseries where they grow and yield low-cost, disease-free propagation materials ready to be distributed to farmers (FAO, 2009a). Even if healthy plants are not available initially, specific *in vitro* techniques can also be applied to produce disease-free propagation material.

Today, micropropagation is widely used for a range of developing country subsistence crops including banana, cassava, potato and sweetpotato; for commercial plantation crops, such as oil palm, coffee, cocoa, sugarcane and tea; for niche crops such as cardamom and vanilla; and for fruit trees such as almond, citrus, coconut, mango and pineapple. Some of the many countries with significant crop micropropagation programmes include Argentina, Cuba, Gabon, India, Indonesia, Kenya, Nigeria, Philippines, South Africa, Uganda and Vietnam (Chapter 1).

In vitro slow growth storage

Micropropagation procedures have been developed for over 1 000 plant species, many of which are today micropropagated commercially. The procedures include rapid multiplication, involving rapid growth and frequent subculture (regeneration) which is generally the objective of commercial micropropagation. Instead, the basis of successful *in vitro* storage of stock cultures is to increase the interval between subcultures by retarding the growth without any deleterious effects on the plants in culture. The strategy is used to conserve plant genetic resources, and *in vitro* slow growth procedures can be used so that plant material can be held for 1–15 years under tissue culture conditions with periodic subculturing, depending on the species. Normally, growth is limited using low temperatures often in combination with low light intensity or even darkness. Temperatures in the range of 0–5 °C are employed for cold-tolerant species and 15–20 °C for tropical species. Growth can also be limited by modifying the culture medium and reducing oxygen levels available to the cultures (Rao, 2004; FAO, 2006a).

In vitro embryo rescue

Wide crossing (see Part 6.2.1.3) has become possible only by advances in plant tissue culture. A particular challenge was to overcome the biological mechanisms that normally prevent inter-specific and inter-genus crosses, as a high proportion of wide-hybrid seeds either do not develop to maturity or do not contain a viable embryo. To avoid spontaneous abortion, embryos are removed from the ovule at the earliest possible stage and placed into culture *in vitro.* Mortality rates can be high, but enough embryos normally survive the rigours of removal, transfer, tissue culture, and regeneration to produce adult hybrid plants for testing and further crossing (Chapter 1).

First generation, wide-hybrid plants are rarely suitable for cultivation because they have only received half of their genes from the crop parent. From the other (non-crop) parent they have received both the small number of desirable genes and also thousands of undesirable genes that must be removed by further manipulation. This is achieved by crossing the hybrid with the original crop plant, plus another round of embryo rescue to grow up the new hybrids. This "backcrossing" process is repeated for about six generations (sometimes more), until a plant is obtained that is almost identical to the original crop parent except that it now contains a small number of desirable genes from the non-crop parent plant. Wide crossing programmes can take more than a decade to complete, although MAS and anther culture can be used to speed up the process (Chapter 1).

6.2.1.9 Mutagenesis

This involves the use of mutagenic agents such as chemicals or radiation to modify DNA and hence create novel phenotypes. Induced mutagenesis has been used in crop breeding programmes in developing countries since the 1930s. It also includes somaclonal mutagenesis, involving changes in DNA induced during *in vitro* culture. Somaclonal variation is normally regarded as an undesirable by-product of the stresses imposed on a plant by subjecting it to tissue culture. However, provided they are carefully controlled, somaclonal changes in cultured plant cells can generate variation that is useful to crop breeders (Chapter 1).

Almost 3 000 new crop varieties have been developed and released by countries using mutation-assisted plant breeding strategies and an estimated 100 countries currently use induced mutation technology (FAO/IAEA, 2008; IAEA, 2008). Case studies from Kenya (wheat), Peru (barley), sub-Saharan Africa (cassava) and Vietnam (rice) are described in IAEA (2008).

In the livestock sector, mutagenesis has also been used in developing countries**.** The sterile insect technique (SIT) for control of insects (e.g. screwworm and tsetse flies) relies on the introduction of sterility in the females of the wild population. The sterility is produced following the mating of females with released males carrying in their sperm dominant lethal mutations that have been induced by ionizing radiation. This method is usually applied as part of an area-wide integrated pest management (AW-IPM) approach and has been applied in developing countries in the livestock sector as well as for the control of crop pests. An estimated 30 countries use the SIT against insect pests, including Chile and Peru (FAO/IAEA, 2008).

Mutagenesis is also extensively used to improve the quality of micro-organisms and their enzymes or metabolites used in food processing. The process involves the production of mutants through the exposure of microbial strains to mutagenic chemicals or ultraviolet rays. Improved strains thus produced are selected on the basis of specific properties such as improved flavour-producing ability or resistance to bacterial viruses (Chapter 5).

6.2.1.10 Fermentation

Fermentation is the process of bioconversion of organic substances by micro-organisms and/or enzymes of microbial, plant or animal origin. During fermentation, various biochemical activities take place leading to the breakdown of complex substances into simple substances and resulting in the production of a diversity of metabolites including simpler forms of proteins, carbohydrates, fats, such as sugars, amino acids, lipids, as well as new compounds such as antimicrobial compounds (e.g. lysozyme, bactericins); organic acids (e.g. lactic acid, acetic acid, citric acid); texture-forming agents (e.g. xanthan gum); and flavours (esters and aldehydes). Apart from the various new products that are yielded during fermentation, the process is widely known for its preservative benefits (FAO, 2006b).

The new products that emerge following fermentation have been found to have potential for longer shelf-lives, and they have characteristics quite different from the original substrates from which they are formed. Fermentation is globally applied to preserve a wide range of raw agricultural materials (cereals, roots, tubers, fruit and vegetables, milk, meat and fish, etc.). Commercially produced fermented foods which are marketed globally include dairy products (cheese, yogurt, fermented milks), sausages and soy sauce (FAO, 2006b). Fermentation of sugars is also central to the production of bioethanol from agricultural feedstocks (FAO, 2008a).

Certain micro-organisms associated with fermented foods, in particular strains of the *Lactobacillus* species, are probiotic i.e. used as live microbial dietary supplements or food ingredients that have a beneficial effect on the host by influencing the composition and/or metabolic activity of the flora of the gastrointestinal tract (FAO, 2006b). They can also be used as feed additives for monogastric and ruminant animals, and have been applied for this purpose in China, India and Indonesia (Chapter 3).

In developing countries, fermented foods are produced generally at the household and village level using traditional processes that are uncontrolled and dependent on spontaneous "chance" micro-organisms from the environment. Modern fermentation processes employ the use of well-constructed vessels (fermenters/bioreactors), with appropriate mechanisms for controlling temperature, pH, nutrient levels, oxygen tension, among others, and also use selected micro-organisms and/or enzymes for their operations (FAO, 2006b; Chapter 5).

6.2.1.11 Biofertilizers

Soils are dynamic living systems that contain a variety of micro-organisms such as bacteria, fungi and algae. Maintaining a favourable population of useful microflora is important from a fertility standpoint. The most commonly exploited micro-organisms are those that help in fixing atmospheric nitrogen for plant uptake or in solubilizing/mobilizing soil nutrients such as unavailable phosphorus into plant-available forms, in addition to secreting growth-promoting substances for enhancing crop yield. As a group, such microbes are called biofertilizers or microbial inoculants. They can be generally defined as preparations containing live or latent cells of efficient strains of nitrogen-fixing, phosphate-solubilizing or cellulolytic micro-organisms that are applied to seed or soil with the objective of increasing the numbers of such micro-organisms and accelerating certain microbial processes to augment the availability of nutrients in a form that plants can assimilate readily (FAO, 2008b). Biofertilizers are used in a number of developing countries such as Kenya and Thailand, often involving nitrogen-fixing *Rhizobia* bacteria (FAO, 2009a).

6.2.1.12 Biopesticides

Living organisms that are harmful to plants and cause biotic stresses are collectively called pests, and they cause tremendous economic damage to plant production worldwide. Biopesticides are mass-produced, biologically-based agents used for the control of plant pests. They can be living organisms such as micro-organisms or naturally occurring substances such as plant extracts or insect pheromones. Micro-organisms used as biopesticides include bacteria, protozoa, fungi and viruses and they are used in a range of different crops (Chandler *et al.*, 2008).

For example, different biopesticides are available for controlling locusts. In one example of their application, a biopesticide containing spores of the fungus *Metarhizium anisopliae* was used to control a migratory locust infestation in 2007 in Timor-Leste, supported by FAO. Surveys revealed that an area of about 20 000 ha was infested with gregarious nymphs and that there was a serious threat to the rice crop. The target area was considered unsuitable for chemical spraying because of high density human settlement and many water courses. The infestation was therefore treated with the biopesticide which was targeted at flying swarms using a helicopter, with spraying in a time period of over one month (FAO, 2009b). Note that since biopesticides generally have a slower action than conventional chemicals, the latter are preferred if crops are under immediate threat.

6.2.2 Specific points about this e-mail conference

The general aim of the e-mail conference is to bring together and discuss relevant, often previously un-documented, past experiences of applying biotechnologies at the field level (i.e. used by farmers for commercial production) in developing countries, ascertain the success or failure (whether partial or total) of their application, and determine and evaluate the key factors that were responsible for success or failure. The conference does not cover experiences in developed countries.

Issues to be addressed in the e-mail conference

For any one (or combination) of the biotechnologies described above, considering its application at the field level in one of the different food and agricultural sectors (crops, livestock, forestry, fishery or agro-industry), in any particular developing country or region, and in any specific time period over the past 20 years:

- provide an overall assessment of the experience of applying the biotechnology (i.e. whether it was a partial or full success or failure, and provide a justification for this assessment); based on this, describe some of the key features that determined its partial or complete success (or failure)
- indicate, where possible, how transferable these results might be to other, 1) developing countries/regions, 2) biotechnologies, and 3) food and agricultural sectors;
- indicate any lessons that can be drawn from this experience that may be important for applications of agricultural biotechnology in developing countries in the future.

Defining success and failure

When considering a given situation where a biotechnology was implemented in a specific developing country, sector and time period, and attempting to assess whether it was a full or partial success (or failure), a number of different aspects may be taken into consideration such as any potential impacts its application had of a socio-economic, cultural, regulatory, environmental, agro-ecological, nutritional, health and hygiene, consumer interest and perceptions, sustainable livelihoods, equity, technology transfer or food security nature. For example, if the use of a reproductive technology such as AI in a certain livestock species (e.g. dairy cattle) in a given developing country is considered, some of the factors that might influence whether the technology can be judged to be a success or failure might include the impact of the biotechnology on:

- milk production (the trait of main interest);
- other traits, such as cow fertility and health, that can be indirectly affected (often negatively) by improvements in milk production;
- trade (e.g. did use of the biotechnology result in surpluses that led to creation of new trade opportunities? Alternatively, did its use result in closure of some existing markets, e.g. due to regulatory issues?);
- economic returns to the farmer, considering the increased financial returns from increased milk yields as well as any additional costs from using the biotechnology, such as the cost of inseminating the cow, any additional feed or veterinary bills, etc;

- food security (e.g. was more milk produced, leading to greater food security?);
- equity (e.g. was use of the biotechnology restricted to already rich farmers or did its use also extend to the more food-insecure smallholders; also who gained from sale of the biotechnology itself ? [e.g. were the AI services provided by a foreign multinational company or by a local farmers' cooperative?])
- consumer interests (did use of the biotechnology produce a negative consumer reaction, resulting in reduced milk consumption?);
- genetic resources (e.g. if AI was used to cross local females with semen from bulls of developed countries, did it result in erosion of valuable genetic resources in developing countries?);
- technical aspects related to applying the biotechnology (e.g. did it work properly, was much training/equipment needed for people to use it?);
- any unexpected impacts of using the biotechnology.

The number of factors that could potentially influence the overall assessment of the biotechnology as a success or failure (partial or complete) is therefore quite large and for any given case, some factors might be negative and others positive. Thus, the fact that a certain biotechnology has been used (and perhaps continues to be used) does not in itself mean it has been a success, although in certain cases it may be considered as an indicator of success.

A major hurdle to determining fully whether a specific application of biotechnology has been a success or failure is that there is normally a lack of solid, scientifically sound data and documentation about the impacts of its application on people's livelihoods and their socio-economic conditions etc. (FAO, 2009a). Indeed, one of the aims of this e-mail conference is to try and get a better insight into and more information about such areas.

Coverage of GM and non-GM biotechnologies

The conference will be moderated. One of the Moderator's main tasks is to ensure that all of the biotechnologies as well as all of the food and agricultural sectors are adequately covered. As anyone following this area knows, the topics of genetic modification and GMOs are of major interest and have been the object of highly polarized debates, particularly concerning GM crops. One of the consequences of this is that the actual impacts and the potential benefits of the many non-GM biotechnologies have tended to be neglected. However, to learn from the past regarding applications of agricultural biotechnologies in developing countries, the entire range of biotechnologies should be considered as there may be many specificities related to any particular biotechnology tool regarding aspects such as its financial, technical and human capacity requirements, its purpose (e.g. genetic improvement, genetic resources management or disease diagnosis), its potential impacts etc. For this reason, participants are asked to ensure that all the biotechnologies and all the food and agricultural sectors are covered adequately. In addition, regarding GMOs, discussion should not consider the issues of whether GMOs should or should not be used *per se* or the attributes, positive or negative, of GMOs themselves. Instead, the goal is to bring together and discuss specific experiences of applying biotechnologies (including genetic modification) in the past in developing countries.

6.3 SUMMARY OF AN INTERNATIONAL DIALOGUE

6.3.1 Executive summary

Participants in the e-mail conference shared a wealth of experiences regarding the use of agricultural biotechnologies across the different food and agricultural sectors in developing countries. They provided concrete examples where agricultural biotechnologies were benefiting smallholders. They also discussed at length why specific biotechnologies, as well as agricultural biotechnologies in general, had not succeeded in developing countries and they offered suggestions to increase their success in the future. The conference also indicated that there is no general answer to whether applications of a given agricultural biotechnology have succeeded or failed in the past, but that every application is different and its success depends primarily on the local context in which it is used.

A total of 834 people subscribed to the conference and 121 e-mail messages were posted, 74 percent of which were from people living in developing countries. Most contributions focused on whether applications of one or more biotechnologies had been a success or a failure in the crop, livestock, forestry or food processing sectors, as well as the factors that determined their success or failure. The remaining messages were cross-sectoral in nature, discussing agricultural biotechnologies in general without specifying a given sector, and focused on reasons for failures and suggestions for increasing their success in the future.

Of the different sectors, the greatest focus was on crops and here the use of genetic modification, in particular, as well as tissue culture, molecular markers, biofertilizers and induced mutagenesis were discussed. For GM crops, most of the messages focused on specific case studies, in particular Bt cotton in India and herbicide tolerant soybean in Argentina. For the former, it was considered a major success by some participants, while others indicated that the situation was more complex with performance depending on the hybrid background, growing conditions and institutional context, among others. For the latter, there seemed to be general agreement that GM soybean had resulted in substantial economic benefits in Argentina as well as some undesirable correlated environmental impacts which were not caused by the technology *per se* but by failures to incorporate appropriate planning and policy interventions. There was also considerable discussion about the impact of regulation on the success or failure of GM crops in developing countries. The practical benefits of establishing a regulatory system for GM crops were underlined as it enabled commercial release. Many participants also argued that GM crops were over-regulated, which was negatively impacting their adoption in developing countries, imposing additional costs and delays.

Discussions on tissue culture focused on its use for micropropagation and numerous participants described how it had been applied successfully in different countries such as Sri Lanka, India, the Philippines and Venezuela, for banana, cassava, cocoa and ornamental plants among others. It was also argued that more could be done to make it accessible to farmers, and practical suggestions including low-cost micropropagation and creation of small regional micropropagation laboratories were proposed. Apart from micropropagation, other successful uses of tissue culture were also discussed, including the release of new wheat varieties in the Sudan and the well-known NERICA varieties.

For MAS, a number of MAS-derived crop varieties that have been released in developing countries were discussed including rice tolerant to submergence, released in the Philippines, and pearl millet hybrids with resistance to downy millet disease, released in India. Success of the latter was attributed to long-term donor support and collaborative partnerships as well as good linkages between the upstream biotechnology end and the downstream product development, testing and delivery ends. CGIAR centres were mentioned as often playing an important role in these MAS developments. Many messages addressed the issue of slow progress in the field and a key factor identified was the lack of collaboration/interaction between plant breeders and biotechnologists.

Biofertilizers have been applied successfully in a number of developing countries including Mexico, the Philippines, Honduras and Peru. Most of the messages emphasized the importance of communicating with the farmers, particularly concerning the relative advantages of biofertilizers. Successful examples of applications of induced mutagenesis were also described, leading to the release of new varieties of banana, groundnut and sesame in Sri Lanka and banana in the Sudan.

Participants indicated that application of biotechnologies in livestock and forestry was less advanced than in crops. Most livestock-specific messages focused on biotechnologies for genetic improvement, in particular AI as well as ET and the use of molecular markers. AI was considered to have had a substantial impact in only few developing countries and numerous explanations were proposed for this, including the lack of extension services, economic incentives and appropriate policies. The lack of proper animal recording systems in developing countries was identified as one of the major constraints to applying biotechnologies for genetic improvement. Successful use of a DNA test for a major gene to increase the fertility of Deccani sheep in India was described.

In forestry, most discussion was about micropropagation with the remainder dedicated to biofertilizers, biopesticides and molecular markers. Clear messages emanating from the contributions are that there is a big gap between research developments and their use in the field; and that enhancing collaboration and understanding between researchers in the laboratory and forestry professionals in the field will enhance the application of forestry biotechnologies.

Several contributions were dedicated to the production and importance of traditional fermented foods in developing countries. There was general consensus about the need to develop defined starter cultures for indigenous fermented foods and to transform fermentation from being an "art" to a "technology-driven process", and successful examples from Thailand were provided.

Cross-sectoral discussions covered four main reasons for failures of agricultural biotechnologies in developing countries. The first was the lack of funds, facilities and trained professionals, where their negative impacts were highlighted. The second was brain drain which weakened national capacities, although some participants argued that it should not always be considered in a negative light. The third was inappropriate research focus, where it was argued that researchers were increasingly focusing on basic rather than applied research. The fourth was the lack of political will, where it was considered that there was government apathy to research in general, as well as biotechnology research in particular, while the positive enabling roles that government policies could play was underlined.

Cross-sectoral discussions also included four main suggestions for increasing the success of agricultural biotechnologies in the future. The first was that research should be focused on the real problems of the farmers, where discussions included practical recommendations to make this possible. The second was that extension systems should be strengthened, as they can ensure that relevant R&D results actually reach the farmer. The third was that regional and sub-regional cooperation should be increased, and establishment of sub-regional centres of excellence was proposed. The fourth was that public-private partnerships (PPPs) be formed, and participants described some recent examples and discussed the potential advantages and disadvantages of PPPs.

6.3.2 Introduction

This Summary document presents a concise account of the major issues discussed by the participants. A total of 834 people subscribed to the moderated conference and 121 e-mail messages were posted by 83 participants from 36 different countries. Most contributors discussed whether applications of one or more biotechnologies had been a success or a failure in a given sector, including the factors that determined their success or failure. Greatest attention was given to crops and least to the fishery sector. Although each sector has its specificities, some of the discussions, especially on the features that determined success or failure, are also of general relevance.

In Part 6.3.3 to 6.3.6 the main sector-specific issues discussed during the conference are summarized. Parts 6.3.7 and 6.3.8 cover cross-sectoral discussions, where participants discussed successes and failures of agricultural biotechnologies in general, without specifying a given sector or biotechnology, with Part 6.3.7 covering discussions about the reasons for failures and Part 6.3.8 focusing on suggestions for increasing their success in the future. Specific references to messages posted, giving the participant's surname and the corresponding message number, are included[1]. Part 6.3.9 provides a summary of information on participation in the conference, including the area of work and geographic distribution of the participants as well as the names and countries of those who sent messages that are referenced in this document.

6.3.3 Biotechnologies in crops

Participants focused particularly on the use of genetic modification, as well as tissue culture, molecular markers, biofertilizers and induced mutations.

6.3.3.1 Genetic modification

There was considerable discussion about the success or failure of GM crops in developing countries. Most discussion focused on specific case studies (i.e. a single GM crop cultivated in a specific country) although a few messages considered GM crops in general. There was also discussion about regulation and its impact on the success or failure of GM crops.

Regarding GM crops in general, Ahmed (95), C.S. Prakash (107) and Giddings (118) referred to the 2008 figures from the International Service for the Acquisition of Agri-Biotech Applications (ISAAA), estimating that GM crops were cultivated on 125 million ha in 25 developed and developing countries. Giddings (118) emphasized that the figures show that genetic modification is not merely promise and potential, but increasingly is already delivering value to farmers on the ground in developing countries. C.S. Prakash (107) similarly argued that GM crops had demonstrated value in terms of economic returns and environmental and social benefits and thus farmers were buying the GM seeds. Falck-Zepeda (20) noted that commercial diffusion so far was mainly in four crops (maize, soybeans, cotton and canola) and two traits (insect protection and herbicide tolerance), although other products were in the regulatory pipeline (some examples were provided in the conference for Brazil (Souza, 102), India (Prakash, 28), Nigeria (Beach, 18) and the Philippines (Tababa, 67)).

Falck-Zepeda (20) presented the results from a set of case studies that he and his colleagues from the International Food Policy Research Institute (IFPRI) had carried out, examining the impact on farmers of the adoption of insect resistant maize in Honduras

[1] The messages are available at www.fao.org/biotech/logs/c16logs.htm

and the Philippines; insect resistant cotton in Colombia; and herbicide tolerant soybeans in Bolivia. Results showed that the impact of adopting GMOs in developing countries had been "overall positive, but it masks significant outcome variability between countries, regions, households, crops and traits. Furthermore, we have seen that the level of economic benefits tend to be more dependent on the institutional context than on the technology itself. In essence, issues such as access to credit and complementary inputs, availability of knowledge and information flows about using the technology and about markets; are critical for determining the level of benefits".

Regarding individual case studies, there was considerable discussion about the cultivation of Bt cotton in India, i.e. containing genes derived from the soil bacterium *Bacillus thuriengensis* coding for proteins toxic to insect pests that feed on the cotton plants. For Gupta (2), Banerjee (15) and Prakash (28), it was a clear success story. For example, Prakash (28) wrote: "since its introduction in 2002, Bt technology in cotton is a huge success in India. Looking at the speed of adoption of this technology, now India has become the second largest producer of cotton in the world". Gupta (2), similarly, described it as a "major success" and looked forward to other GM crops benefiting farmers in India.

Glover (51) felt that the situation was more complex. Based on his own research and that of IFPRI, he argued that the overall picture regarding Bt cotton was of broadly beneficial impacts but that the general overview masked considerable variation between farms, farmers, regions and seasons. He suggested that at the aggregate level there is good evidence that the overall productivity of cotton had increased following the introduction of Bt technology but that, at the microscale, the picture was much more complicated, as the performance of Bt cotton depended on favourable growing conditions especially good soils and reliable water, farmer skills and the presence/absence of supportive institutional frameworks. He concluded: "to label Bt cotton as a great success would be just as crude as to dismiss it as a disastrous failure. We also cannot assume that Bt cotton must be a success merely because it has spread rapidly".

Banerjee (53) agreed with Glover (51) that the rapid spread of a technology should not be considered as the sole factor for deciding its success or failure, but argued that it was an important factor. Banerjee (53), supported by Glover (58), also underlined that the performance of Bt cotton depended not only on the Bt gene but also on the performance of the hybrid background. Responding to the comment of Glover (51) about the dependence of Bt cotton performance on favourable growing conditions, Banerjee (53) stated that this was true for all crops. Glover (58) agreed with Banerjee's comments and concluded that it was important to "consider the specific local circumstances (bio-physical, social and institutional) under which biotechnologies need to perform and to evaluate the positive and negative outcomes in developmental terms (e.g. their effects on labour, incomes, equity, empowerment etc.) - recognizing that these impacts will be different for different people in different places and circumstances. This last observation applies to all kinds of biotechnologies, of course, not just to GM crops".

Zambrano (59) followed up on this thread by reporting on the results of their IFPRI study on Bt cotton in Colombia where, overall, farmers benefited from the technology but that the results, nevertheless, were not generalized for all cotton growing regions or for all farmers in the country. The most successful results were seen in areas that had irrigation, better lands and more farmer-friendly associations which provided farmers with inputs and credit. Zambrano (59) also reported that results from herbicide tolerant cotton in Colombia seemed much less successful and that the lack of, or incorrect, information about crop management and herbicide application appeared to be implicated in losses[2].

There was also ample discussion about GM crops in Argentina, most of which are herbicide tolerant soybean and where the majority of soybeans planted is GM. Discussions highlighted that the technology could provide substantial benefits and that appropriate planning and policy interventions were needed to prevent undesirable impacts.

Trigo (33, 47) argued that GM crops had meant a "real agricultural production revolution" in Argentina and referred to a report he had co-authored in 2006, which estimated that the total accumulated benefit from 10 years cultivation of herbicide tolerant soybeans was about US$20 billion and that they may have contributed to the creation of almost one million jobs. Similarly, Sharry (25) noted that Argentina was one of the world's leading exporters of GM crops; that several GM and non-GM products had been developed; and that these developments usually start in the public sector and then the private sector develops and markets them. She (25) argued that this had been made possible by the development of a strong and transparent biosafety regulatory system; government support, including financial, communication and information aspects; support for the creation/hosting of companies that use or produce biotechnology inputs; and good interaction between government, scientists and producers.

Escandon (39) also underlined the role that the Technical Co-operation Network on Agricultural Biotechnology in Latin America and the Caribbean (REDBIO) had played in Argentina regarding acceptance of GMOs by the public, as public perception is one of the most important factors for the success of GM products (a point also made by Tababa (67) concerning the experience of Bt corn in the Philippines). The network had organized symposia, workshops and courses, which had facilitated the exchange of ideas between people. Escandon (39) proposed that it was an example that could be followed

2 Presentations by Zambrano and by Fonseca & Zambrano on GM cotton in Colombia were given at ABDC-10, available at www.fao.org/fileadmin/templates/abdc/documents/zambrano.pdf and www.fao.org/fileadmin/templates/abdc/documents/fonseca.pdf respectively.

in other countries. Indeed, Tchouaffé (75), in the context of dissemination of low-cost micropropagation, underlined the role that fora to exchange views between researchers and local populations could play and that governments could act as a facilitator in establishing such fora. Sharry (25) also pointed out the importance of REDBIO's role in communication in Argentina.

Echenique (41, 64, 73) agreed with Trigo (33) about the economic benefits of GM soybean in Argentina, stating: "it is a highly profitable extremely recent technology which has been widely accepted by farmers in a very short time period" (64). However, she also highlighted the need to consider environmental and social aspects related with adoption of the technology, focusing on two main issues. The first is the move towards soybean monocultures, strongly accentuated in some provinces, leading to nutrient loss and soil fertility problems unless appropriate measures are taken (such as crop rotation and application of fertilizers to replace nutrients taken from the soil). The second is the expansion of land areas dedicated to soybean cultivation at the expense of forest areas, horticulture, milk production, cattle and forage (41).

Echenique's comments evoked a number of responses, most of which generally agreed with her while arguing that the problem was not the technology *per se* but the related policy environment. Thus, Trigo (47) and Parrott (52) both pointed out that there were more economic incentives for farmers to grow soybean than maize, which triggered the monoculture problem, and that the social and environmental impacts in Argentina would be totally different if the incentives were different (52). Escandon (70) agreed in general terms with Echenique (64) and called for government policies to encourage farmers to practise crop rotation. Parrott (52) also noted there was growing recognition among farmers that current practices were not sustainable and that there was now a strong movement to implement more sound agronomic practices such as crop rotation. Regarding deforestation, Trigo (47) noted that while availability of herbicide tolerant soybeans may have contributed to the process and even sped it up, the problem existed before GM soybeans were released and was the result of policy failure in terms of forest protection and land use planning and was independent of GMOs. Echenique (73) concluded by stating that the problem was not the technology, but that planning of agriculture was needed when any new technology was introduced.

There was also discussion about the success or failure of two GM crops that had not been commercialized. The first was GM sweetpotato in Kenya, resistant to the feathery mottle virus, where GMOs developed in the United States were imported by the Kenya Agricultural Research Institute in 2000 for field testing, but they were not later commercialized. For Gurian-Sherman (26), the project was a failure as it involved substantial financial and scientific inputs over a decade without resulting in any product, whereas there had been a reported success in Uganda with conventional breeding. Kamanga (45) did not agree, saying instead that it had been a great success, as it had allowed GMO trials to be carried out in accordance with international standards; facilitated capacity building and building of partnerships in GMOs; led to development of an institutional framework in GMOs/biosafety in Kenya and, indirectly, to the passing of the national biosafety law. Bett (49) agreed, giving her personal testimony that the project had allowed her to get training in biotechnology and to get direct experience of carrying out GMO field trials.

The second was GM cassava resistant to the cassava mosaic virus disease (CMVD), where GM varieties of cassava developed by the Danforth Center were later found to have lost their resistance to the virus. Anderson (46) from the Danforth Center noted that the problem referred to experimental work carried out at their laboratories and that to speak of success or failure during the experimental phase of this or other research projects was not appropriate as meeting problems and solving them was a normal part of the scientific process. Usman (37) confirmed that the varieties had never been field tested in Nigeria, and stated that the development of improved cassava varieties was critical to Nigeria's food sustainability and agricultural development, a project in which the Danforth Center was a partner (Anderson, 46). Egesi (13) said it was important to avoid hype and propaganda and that this case did not mean that virus resistance cannot be acquired by genetic modification. Nassar (7) reported that CMVD resistant cassava cultivars had been produced by non-GMO methods from inter-specific hybridization with the wild species *Manihot glaziovii,* and estimated that they were cultivated on four million ha in Nigeria.

In addition to the many messages discussing specific examples of GM crops, there was considerable discussion about the impact of regulation on the success or failure of GM crops in developing countries. As noted by Nzeduru (27), the aim of regulation is to ensure that the benefits of GM crops can be harnessed without compromising human/animal health or environmental sustainability. Specific aspects of national regulatory frameworks were described by participants, for Kenya (Kamanga, 45), Nigeria (Usman, 86) and Brazil (Souza, 102). Pathirana (110) mentioned the difficulties involved in establishing a biosafety framework in Sri Lanka, including the fact that five government departments were involved in the process. Ahmed (95) noted that biosafety legislation had not yet been approved in most African and Arab countries and urged that it should be done.

The practical benefits of establishing a regulatory system for GM crops were underlined by some participants, with Roca (74) describing the establishment of a science-based biosafety regulatory framework in Honduras as a success since it had allowed the country to "deploy and legally commercialize herbicide tolerant and insect resistant GM maize since 2001". Similar sentiments were expressed by Sharry (25) and Tababa (67) for Argentina and the Philippines respectively.

Many participants also argued that GM crops were over-regulated, which was negatively impacting their adoption in developing countries. In India, Gupta (2) and Dudhare (24) considered that the regulatory process was too slow, discouraging work in this area (Gupta, 2), and was very costly (Gupta, 2; Keshavachandran, 82). Sharry (25) warned about the dangers of "excessive bureaucratic delays", which can limit investment and technology transfer. Van der Meer (115), noting the challenges of preparing and conducting GM crop field trials, proposed that a support network for public researchers be established so that they could help each other in this work. Roca (74, 119) wrote that regulation is often not science-based, which had dire consequences for public sector research. Trigo (71) argued that there was a very thin red line between "being careful" and over-regulation; that these were "the most watched-over technologies in agricultural history"; and that regulation should evolve based on the accumulation of scientific evidence. C.S. Prakash (107) agreed, and concluded that over-regulation was leading to excessive costs and needless delays in commercialization of GM crops for both the private and public sectors. Similarly, Giddings (118) argued that "scientifically unsupportable regulatory burdens" were blocking wider dissemination of GM crops.

6.3.3.2 Tissue culture

As described earlier, tissue culture refers to the *in vitro* culture of plant cells, tissues or organs in a nutrient medium under sterile conditions. There are a number of tissue culture-based technologies and they can be employed for different purposes. They include micropropagation, involving the rapid multiplication of stock plant material to produce disease-free propagation materials for dissemination to farmers; *in vitro* embryo rescue to enable wide crossing; anther culture and ovule culture to produce haploid plants; and *in vitro* slow growth storage to conserve plant genetic resources.

Discussions on tissue culture focused on its use for micropropagation, although its use for wide crossing, creation of doubled haploids and conservation of genetic resources were also briefly considered. The messages illustrated that application of micropropagation has been successful in realizing substantial benefits in countries such as Sri Lanka, India, the Philippines and Venezuela, although in some other cases it was seen to have failed. Important factors which influenced its success or failure included the degree of involvement of the extension system or the private sector.

Pathirana (81) informed participants that micropropagation together with the technique of mutation induction had resulted in successful development of early flowering, high-yielding banana clones in Sri Lanka, which were also free of banana bract mosaic virus, which significantly reduces yield in infected plants. An estimated 25 percent increase in annual income had been attributed to intensification of the production cycle through use of the early maturing mutant banana cultivars and Pathirana (81) stated that micropropagated bananas were now common and popular among farmers and encouraged by governmental authorities. He noted that a key component for success of the project was that the scientists involved in the project held many field days to inform farmers how to care for the micropropagated plants in the early period of growth.

After giving a brief history of commercial micropropagation in India, Dinesh Kumar (87, 101) estimated that over 135 million plants are currently produced by 300 tissue culture laboratories in India; production of tissue culture bananas was rising fast and nearing 100 million plants; and 30-35 million ornamental plants were exported annually. He noted that the Government of India had set up a committee to accredit all the commercial tissue culture laboratories in the country and had prescribed a detailed standard procedure for them. He concluded that commercial tissue culture production in India was "poised for a big leap forward" (87). Interest of the private sector for this biotechnology was also indicated by Pathirana (110) who noted that apart from micropropagation, the private sector in Sri Lanka had yet to play an important role in contributing to biotechnology development or research. The important work carried out by Indian public funded institutions in tissue culture was highlighted by Seshadri (113).

Tababa (67) wrote that in the Philippines, mass propagation through tissue culture, supported by both public and private institutions, had contributed to making large-scale banana plantations economically viable and led to the introduction of new varieties of flowers in the cutflower industry. Both the private sector and the backyard plant growers had benefited. Mass production of mutant coconuts through embryo rescue had, however, been less successful as production costs were high and productivity was relatively low (67).

Infante (38) wrote about successful cassava and cocoa micropropagation programmes in Venezuela. He noted that a key feature which allowed the cassava research results to reach the farmers was the creation of "transfer" laboratories, where small micropropagation laboratories were established in several regions, whose personnel were trained in the main research facility in Caracas. People in the regional laboratory were thus able to act as a two-way communication link between the research facility and the farmers so that farmers could receive inputs and provide eventual feedback. Muralidharan (63) commended this approach. He also argued that too little had been done around the world to harness the full potential of micropropagation, except perhaps by the ornamental plant industry. He highlighted the scope for simple "low cost micropropagation" in several crop species, noting that the orchid industry in Thailand was a good example, where micropropagation was carried out in small household laboratories (63).

Orellana (62) described the long history and wide range of tissue culture activities on potato, sugar cane and hybrid coffee in his institution's laboratory in El Salvador, and reported that the disease-free plants had been provided to farmers. Roca (74) also noted that there was a well established structure for tissue culture work in Honduras. Caesar (121) reported that in Guyana, successes had been achieved in tissue culture of pineapple, sweetpotato and plantain among others.

For Tonjock (9), the provision of tissue cultured seedlings at low cost was a success in Cameroon, although she noted that some farmers were still unable to afford them. Similarly, Loquang (97) argued that the production of disease-free banana planting material by tissue culture could be considered a success in Uganda as the clean planting material boosted food and income security. In Nigeria, micropropagation had also been used for the production of disease-resistant varieties of crops but doubts were expressed about its success (Chikezie, 48; Echereobia, 78; Oselebe, 57). Chikezie (48) argued that disease-resistant varieties of staple root crops resulting from research in Southeast Nigeria had not benefited many farmers in that part of the country, which could be because of inadequate funding to enable large-scale micropropagation of these staple root crops or the lack of well-developed agricultural extension networks. Echereobia (78) also mentioned the need for training and provision of technical support to sustain the technology.

Oselebe (57) reported on progress with micropropagation in plantains and bananas, noting also its potential as it could lead to rapid multiplication of disease-free plantlets for farmers. However, she concluded: "it is highly technical, can only be employed in very few research institutes (in most cases for other crops) and is not amenable to the resource-poor farmers who are the main producers of plantain and banana". Infante (85) noted that research activities may be carried out without focusing on eventual applications, reporting that some laboratories in Venezuela had carried out micropropagation work for years without it ever resulting in the release of plant materials to farmers.

In the Sudan, Gama (54) wrote that a tissue culture laboratory had been established under a long-term project and it had been extensively used for banana tissue culture and wheat doubled haploid production. He noted that the laboratory had been able to provide banana planting materials during critical times of post-flood devastation of banana plantations along the Nile banks and that anther culture techniques for production of doubled haploid wheat had yielded good results leading to the release of several cultivars.

Also in Africa, Manneh (35) described the successful combination of conventional breeding and biotechnology to produce the NERICA varieties by crossing Asian (*Oryza sativa*) with African rice (*Oryza glaberrima* Steud.), mentioning in particular the role of anther culture to create doubled haploids and fix desirable genotypes. While noting that upland NERICAs are now widely cultivated (over 200 000 ha) by farmers in Africa, he argued that one of the major impediments to the widescale use of these biotechnological products is the weak seed system in many developing countries especially those in Africa and that the present demand for NERICA seeds in developing countries surpassed their supply. He concluded by urging that to enable wider usage of these rice biotechnologies and their products "there is a need to reinforce national capacities especially those involved in the seed sector such as the national research and extension systems as well as farmers, farmers' organizations and the private sector"[3].

Tissue culture has also been used to conserve plant genetic resources in developing countries. Cruz (32) reported that in the Philippines, tissue culture was used in the national genebank to preserve a backup collection of banana and yam. Pathirana (116) also described the numerous activities of the Plant Genetic Resources Centre which is the focal point for promoting and facilitating the conservation and sustainable utilization of plant genetic resources in Sri Lanka. He reported that *in vitro* conservation protocols had been established for about 15 different species and that some accessions of cassava, sweetpotato, potato, yams, colocasia, innala and banana were maintained in storage under normal or minimal growth conditions.

6.3.3.3 Molecular markers

Several messages dealt with the use of molecular markers for genetic improvement in crops. It was suggested that marker-assisted selection (MAS) has been used with reasonable success in countries such as India and the Philippines. Using this technology, a number of improved varieties of crops such as pearl millet, rice, maize and wheat have been developed and are in use in some countries in Asia and Africa. The CGIAR institutions have often played an important role in these developments.

Banerjee (15) stated that MAS is becoming increasingly popular in India and that both public and private sectors are investing in it. Hash (44) provided a detailed overview of the successful development and adoption of "HHB 67 Improved", a pearl millet hybrid with resistance to downy mildew disease which was approved for release in India in 2005. In 2008, F_1 hybrid seed was produced to sow at least 300 000 ha with HHB 67 Improved, while he predicted that the 2009 area could exceed 500 000 ha, if sowing conditions are favourable (Hash, 44). He noted that the research product development and testing chain for the hybrid was long and had many partners in India and the United Kingdom, and estimated that economic benefits to farmers were substantial. To him, the success story had clearly demonstrated how research partners with widely disparate interests could come together, each contributing something for which they have a comparative advantage, to deliver an appropriate research product targeted to meet the needs of the poor. In conclusion, he felt that the most important factors for its success were long-term donor support (over

3 A presentation of the NERICA case study was given at ABDC-10, www.fao.org/fileadmin/templates/abdc/documents/nerica.pdf and further details on NERICA are given in Chapter 1.5.1.

15 years); long-term collaboration of the partners; and reasonably strong linkage of the "upstream" biotechnology end of the projects to the more "applied" plant breeding product development, testing and delivery ends.

In India, Gupta (2) maintained that MAS had been used successfully in crop improvement, with the development of products that were already commercially available or being field tested, namely superior hybrids of pearl millet and quality protein maize, high protein wheat cultivars, wheat resistant to rust, rice resistant to bacterial blight and rice tolerant to submergence. Nevertheless, he felt that the pace of work and adoption of marker technology was slow, attributing this to lack of expertise and motivation among those involved in breeding, lack of cooperation between molecular biologists and plant breeders and high costs of the technology compared with conventional plant breeding. Singh (60) agreed, arguing that the lack of interest of plant breeders had meant that few populations for molecular mapping and tagging had been developed for field crops in India. Predeepa (111) agreed that a lack of collaboration/interaction between breeders and molecular biologists was a hurdle in India. Murphy (100) felt it was not just an Indian phenomenon but also applied to developed countries to some extent although his impression was that it was much more serious in developing countries, possibly due to the more recent development/introduction of some biotechnologies there. Indicating that he had experienced the same phenomenon in Malaysia, he concluded: "it needs to be addressed by improved education of agricultural science graduates in ways that emphasize the unity of the discipline and especially the role of biotechnology as the servant of breeders and agronomists rather than their master" (100).

Based on his own experience, Jordan (83) argued that marker technology works well if breeders have the appropriate skills, understand the technology well and are involved in developing the technology for a particular application; biotechnologists have some understanding of plant breeding; there is appropriate balance between investments in traditional disciplines and marker technologies; skills in statistics and informatics are sufficiently advanced to support the use of molecular technology by breeders; and rational decisions are made regarding resource allocation in applied programmes based on true costs and returns. From his limited experience of plant breeding programmes in developing countries, he suggested that investments in conventional plant breeding and related disciplines often seem insufficient to allow technologies like markers to be used effectively and that, in many cases, much greater genetic improvements could be made by enhancing the conventional breeding programme rather than investing in markers. Trigo (93) agreed with Jordan (83) that appropriate and intelligent investment is essential. However, he argued: "molecular biology applications are the way of the future to make breeding more efficient and effective and we should push in that direction" and that strengthening conventional breeding alone "is not the solution even when we accept that there is still a lot to be achieved through conventional breeding" (93).

In the Philippines, Cruz (32) noted that molecular markers had been used to develop disease resistant rice varieties, analyse the purity of hybrid rice seeds and to study collection diversity and manage germplasm in the national genebank. Manneh (35) described some of the biotechnology work carried out on rice by two CGIAR institutes, the International Rice Research Institute (IRRI) and the Africa Rice Center. He noted that they and other research institutes were using MAS to introduce a number of traits (such as tolerance to salinity and low temperature, resistance to rice yellow mottle virus disease, and grain quality) into rice varieties already adopted by farmers. He reported that MAS had been used by IRRI to transfer submergence tolerance into stress-tolerant improved varieties such as Swarna and IR64, which are very widely cultivated in Asia and have already been tested and released in some Asian countries. Rigor (42) from the Philippine Rice Research Institute confirmed that through collaboration with IRRI, they had recently recommended release of IR64 with submergence tolerance. Using MAS and anther culture, they had also released rice varieties suited to irrigated lowland conditions and varieties tolerant to salinity. In his institute, Rigor (42) noted that the technical aspects of using DNA markers had not yet been optimized, so it was not possible to fully use markers in their breeding programme, and that the high rate of staff turnover was negatively impacting the sustainability of certain biotechnology projects.

Roca (74) wrote that biotechnologies have been successfully used in Honduras for the past 20 years and listed various examples including a strong regional MAS breeding programme for beans. Singh (76) underlined the role that markers could play in inter-specific hybridization, where markers could be used to accelerate transfer of novel genes for important traits such as disease resistance from related/wild species of field crops. He reported that these techniques had been used in wheat in India where genes for resistance to leaf rust, stripe rust, Karnal bunt, powdery mildew and cereal cyst nematode had been transferred. He concluded by highlighting the need for capacity building in developing countries on this subject, especially for crops that are solely/largely cultivated in developing countries (76).

6.3.3.4 Induced mutations

A small number of successful applications of induced mutagenesis were described in the conference. Thus, Pathirana (108) reported that its application (using gamma rays) in Sri Lanka had led to release of the "Malee" variety of sesame (resistant to fungal diseases, mainly *Phytophtera nicotianae* var. *parasitica*) and he suggested that its release had halted the decline in the area cultivated with sesame (which had been declining because of the disease). Mutation breeding had also resulted in release of the "Tissa" variety of groundnut (more drought resistant, early maturing and high yielding), which was in popular demand by the farmers (108). He reported that they were the only mutant cultivars of oilseed crops released in Sri Lanka and that they had been cultivated for almost two decades (108). Both Pathirana (81) and Gama (54) reported on the successful application of mutation breeding in bananas in combination with tissue culture in Sri Lanka and the Sudan respectively. The projects were supported by the Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture and led to the release of new varieties in both countries.

6.3.3.5 Biofertilizers

The application of biofertilizers has met with some success. For example, Tababa (67) stated that in the Philippines, biofertilizers for corn and rice had been successful, which could be attributed to the farmers' education on their use and benefits, inclusion of their use in the package of technologies adopted by the National Corn Programme, and the government's uninterrupted financial support to their production. Peralta (22) reported that in Mexico a *Rhizobium*-based biofertilizer for the common bean (*Phaseolus vulgaris*) had been developed by the university and was now successfully commercialized by a private company. Initial efforts to involve government agencies in promoting and using the product were unsuccessful. The biofertilizer is used mainly in central and northern Mexico (Peralta, 50) and he (22) felt that "this is the beginning of the common bean fertilizer era in Mexico". He pointed out that much educational/promotional work is required (22) and that the farmers who bought the biofertilizers also received access to printed material, sessions with agronomists and further assistance (50)[4]. Sangar (56) appreciated this example from Mexico and wondered whether biofertilizers had helped poor farmers in India, which suggests that documentation of such cases in India is weak.

Roca (74) stated that in Honduras, biofertilizers had also been used successfully, with strong programmes for *Rhizobium* and mycorrhizal fungi. Listing a selection of ongoing biofertilizer programmes in her country, Dávila (109) noted that biofertilizers are increasingly being used in Peru. She emphasized the need for training and that farmers need to have evidence that biofertilizers enhance crop performance, are more economical than chemical fertilizers, and are environmentally-friendly. Seshadri (113) argued that, despite long-term research and the fact that many products are already on the market, much more could be done regarding biofertilizers and biopesticides in India. Farmers were seldom convinced by them, primarily due to issues of profitability, and he urged that, with concerted efforts, biofertilizers and biopesticides could be presented in a better way. He highlighted that there was room for improvement in areas such as formulation, shelf-life, number of cells, packaging quality and price (113).

[4] A presentation of this case study was given by Peralta at ABDC-10, www.fao.org/fileadmin/templates/abdc/documents/peralta.pdf.

6.3.4 Biotechnologies in forestry

Several participants wrote about forestry biotechnologies. Their main focus was on micropropagation, although biofertilizers, biopesticides and molecular markers were also mentioned. Clear messages emanating from the contributions are that there is a big gap between research developments and their use in the field; and that enhancing collaboration and understanding between researchers in laboratories and forestry professionals in the field will enhance the application of forestry biotechnologies.

Muralidharan (89) thought it was important to draw attention to the subject of biotechnology in forestry, noting that any benefit from using technology in tropical forests would have a great impact on the environment and people's livelihoods. Similarly, Sharry (106) underlined the important role that forest biotechnology could play, but observed that the understanding of tree biology is poor compared with that of agricultural crops and that individual trees remain much longer in the landscape than short-lived agricultural crops, meaning they are subject to a much wider range of environmental stresses.

Sharry (106) summarized some results from FAO (2004) which indicated that most non-GMO biotechnology activities in forestry were still largely confined to the laboratory, although the application of micropropagation in field plantings was becoming more common. Indeed, most discussions about forest biotechnology in the conference focused on micropropagation. Sharry (106) wrote that it was the most applied forest biotechnology in Argentina. Muralidharan (89) also reported on the successful use of micropropagation and molecular markers for clonal propagation of teak in Malaysia, yielding superior quality planting materials for both the local market and export[5].

Muralidharan (89), however, was critical of the fact that, despite the availability of laboratory protocols for almost all of the important tree species in India, micropropagation had been rarely used in the field. He attributed this failure to the situation where biotechnologists worked in isolation instead of joining forces with the practising forest managers, i.e. the State Forest Departments. He quoted the example of teak, the most important and widely planted timber species, where almost three decades after they succeeded in cloning mature trees the technique was still barely used in practice although micropropagated plantlets would be better than conventional grafts for establishing clonal seed orchards (89). In addition, he argued that in the few cases where large scale micropropagation of a forestry species had actually been undertaken, it was done with insufficient scientific backing. He underlined that unless there was proper selection and testing of the material to be propagated, the technology would not disseminate material superior to plantlets raised from seed (89). Similarly, Rajalakshmi (104) felt that the application of forest biotechnologies such as

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[5] The Malaysian case study was presented at ABDC-10, www.fao.org/fileadmin/templates/abdc/documents/teak.pdf

micropropagation still had a long way to go in India and that key issues to be addressed were the existing gap between research and the field; limited funds and inadequate infrastructure; and the lack of trained professionals.

From his own experience, Muralidharan (63) indicated that low-cost and simple micropropagation technology for bamboo, teak and several medicinal plants now appeared feasible and he was looking at the possibility of training small groups, consisting mainly of rural women, and setting up small production units. In response to Muralidharan's (63) request for information on aspects to consider when transferring such technology to the field, Tchouaffé (75) suggested that it could be disseminated and transferred through capacity building and networking with communicators and the local population.

Regarding more advanced biotechnologies, Sharry (106) indicated that Brazil and Chile have developed a strong forest industry and are using all available biotechnologies including genomics. In her own country, Argentina, she reported that genetic maps and molecular markers had been developed to support eucalyptus breeding programmes; molecular markers had been used to identify areas of protection for native forest species; and research on GM poplar was ongoing. However, she argued that compared with the crop sector, these biotechnologies had not yet had a major impact at the forest chain level in Argentina. Similarly, Muralidharan (89) noted that molecular markers were increasingly used in studying the provenances and the breeding behaviour of some of the important tree species of India, but the results were not assimilated into ongoing breeding programmes.

Regarding microbial-based biotechnologies, Caesar (121) noted that the use of biofertilizers for inoculation of seedlings of the local forest species *Eperua grandiflora* ssp. *guyanensis* had met with partial success in Guyana. Rajalakshmi (104) also mentioned the importance of biofertilizers in India as they could boost agriculture and reduce the debt burden on farming communities. Muralidharan (114) presented a case study of the development of a biopesticide for the biological control of a serious insect pest of teak, the teak defoliator (*Hyblaea purea*). Based on a virus isolated from natural populations of the insect larvae, a biopesticide was successfully developed in India after nearly two decades of research, culminating in an "elegant solution to a serious problem" (114). However, the technology had not yet been applied in the State Forest Departments, and he underlined that biotechnology research had a much better chance of producing results when conceived, developed and implemented in a broader framework consisting not just of scientists and technologists but also involving at every stage the forestry professionals who work at the field level and, also at some level, the policy-makers who eventually have to give the green signal.

6.3.5 Biotechnologies in livestock and aquaculture

The majority of livestock-specific messages focused on biotechnologies for genetic improvement including AI, ET and the use of molecular markers. In the conference, only one message was dedicated specifically to the fishery sector and it is summarized at the end of this section.

For AI, Cruz (32) reported that in the Philippines its application in the genetic improvement programmes of local buffalo was a good example. He said that although also introduced for cattle and swine, AI had led to a more organized governmental genetic improvement scheme in buffaloes. Loquang (97) reported that AI had made significant contributions to the livestock industry in Uganda through its impact on milk and beef production and the emerging milk processing industry, which had created many jobs.

Traoré (88) observed, however, that AI is practised at a level that substantially impacts livestock production in only very few developing countries. Looking at the past, he felt that apart from some technical constraints (such as its relatively high costs, poor heat detection and nutrition), a major reason for the less successful development of AI in Mali in the 1970s and 1980s was that there were insufficient economic incentives for farmers to use it. Nevertheless, he was more optimistic about the future as he noted that the situation had changed drastically with the emergence of new market opportunities for milk and milk products in urban areas and subsequently the rise in demand for crossbred cattle. He argued that the main current constraint to AI development was the lack of infrastructure and appropriate policy. From his experience of dual-purpose cattle in Mexico, Moro (14) wrote that the reasons why farmers failed to adopt a technical package (including practices such as AI, record keeping, mineral supplements and generation of value-added products such as cheese) were the lack of trained extension agents; low income and/or limited access to credit; and poor documentation of the economic returns of adopting the technology package.

Apart from AI, another reproductive technology discussed in the conference was ET, where participants reported that it had been used successfully in Honduras (Roca, 74), was approaching the commercial stage in Pakistan (Ali, 77) and that embryos from the British Texel breed had been successfully transferred to local Blackbelly sheep in Guyana (Caesar, 121).

Ali (77) was upbeat about the potential benefits of applying biotechnologies to the livestock sector in Pakistan. He reported that molecular markers had been used for genetic characterization of the Nili, Ravi and Nili-Ravi buffalo breeds and that DNA fingerprinting had been successfully used in legal proceedings for paternity confirmation to resolve an issue regarding animal ownership. Nimbkar (55) described the successful introgression of the FecB mutation allele for fecundity from the small prolific Garole sheep into the larger Deccani sheep in Maharashtra in India, resulting in Deccani sheep that were more prolific while retaining their larger size, local adaptation and meat-producing ability. The FecB mutation increases ovulation rate considerably and a PCR-RFLP test was used to detect the mutation while backcrossing. She concluded (55) that the gene had provided farmers with the opportunity for moderate and sustainable intensification of production, which was a step towards raising the efficiency of resource use. She noted that it was possible to use the patented gene and DNA test without paying a royalty because those patents were not valid in India[6].

Lack of proper animal recording systems in developing countries was seen as one of the major constraints to using biotechnologies for genetic improvement. Moro (40) highlighted the importance of keeping accurate records and based on his experiences with dual-purpose cattle in Mexico, he stated that the lack of phenotypic recording was a reason for failure of the research/technology transfer programmes for genetic improvement (involving AI, planned crossbreeding, genetic selection). For farmers that might eventually join a milk recording scheme, he underlined the importance of enabling them to make quick and practical use of the records, e.g. to assist them with daily management issues (Moro, 40). In a similar vein, Satish Kumar (31) bemoaned the fact that in India good-quality phenotypic performance records are lacking and was critical of the fact that in this situation most of the animal breeding researchers "have gone high-tech". Unless some basic animal genetics experiments were carried out and there was collection of quality data, he argued that research into molecular markers would have no impact, concluding: "let us count our sheep before worrying about genes!"

For Africa, Adebambo (72) also highlighted the difficulties of animal improvement. Rather than importing poorly adapted exotic breeds, he urged that more attention be give to African livestock, and that issues of description and census of African livestock needed to be addressed first. Like Adebambo (72), Kumarasamy (29) argued that the use of biotechnology in the animal sector was far behind the crop sector. The reasons he cited for this included the lack of coordination between agencies and between the laboratory and the field; excessive bureaucracy and lack of encouragement from the administration; and short-term project funding (3–4 years), which is too short for animal breeding schemes because of the long generation intervals in animals (29).

A small number of messages were dedicated to biotechnologies applied to animal health. Pathirana (110) noted that R&D in biotechnology had progressed at a very slow pace in Sri Lanka, and that only plant micropropagation, AI in cattle and ELISA techniques for disease diagnosis in cattle and buffalo had made any impact at the field level. Roca (74)

[6] The Deccani sheep case study was presented by Nimbkar at ABDC-10, www.fao.org/fileadmin/templates/abdc/documents/chanda.pdf and further details are given in Chapter 3.6.1

also noted that good progress had been made on the use of immunological and molecular approaches for diagnosis of animal pathogens in Honduras. Ali (77) noted the major potential of producing indigenous recombinant DNA vaccines against highly prevalent livestock diseases (such as foot-and-mouth disease and hemorrhagic septicaemia), but indicated that the facilities were not yet available for this in Pakistan.

For aquaculture, Zidana (98) wrote about the use of hormonal treatment to generate single sex populations in tilapia, where males are more desirable as they grow faster than females. He reported the production of YY males in indigenous tilapias with improved growth rates as a success at the technical level in Malawi. However, due to the high cost of importing hormones from Asia, its use at the field level was not economically feasible and farmers had reverted to producing mixed sex tilapia. He also mentioned that it had not been possible to produce or buy the hormones locally or regionally or to get any collaborators to support the project (98).

6.3.6 Biotechnologies in food processing

Several messages were dedicated to the production and importance of traditional fermented foods in developing countries. There was general consensus regarding the need to develop defined starter cultures for indigenous fermented foods and to transform fermentation from an “art” to a “technology-driven process”.

Raheem (1) pointed out that many developing countries, especially those where cold storage is lacking, rely on fermentation to preserve food. Edema (79) argued that fermentation could be regarded as a success in Nigeria as virtually every household depends on fermented food for its daily meals. In addition, some of the fermented foods and their by-products are used as medicines, such as Omidun, the liquid derived from the fermented cereal gruel called Ogi, used to treat childhood diarrhoea. In a similar vein, Loquang (97) highlighted the importance of traditional fermentation in indigenous food processing among pastoralist communities in Uganda. He described how fermented milk was used to produce ghee and listed many of this product’s important functions, both food and non-food, in the communities. He concluded that since such techniques have sustained the livelihoods of pastoralists for generations, it is only fair to say they have been successful. Sivakumar (112), writing about Nepal, advocated applying biotechnology for fermented products, also because it could be an effective use of limited financial and infrastructural investments. The successful use of novel enzymes and micro-organisms for agro-industrial processes in Honduras was noted by Roca (74).

Olusegun (17) highlighted the importance of cassava-based fermented foods such as gari, fufu and lafun in Nigeria and said there was an urgent need to apply biotechnologies to these popular foods. He noted, however, that most research findings in this area had not led to anything concrete and concluded by advocating the production of starter cultures for traditionally fermented foods in Africa. Raheem (1) commended recent initiatives to diversify the industrial utilization of cassava such as the production of dried yeast, alcohol, L-lactic acid and phytase through fermentation, and wrote that cottage industries should be established to commercialize them.

Edema (79) argued that fermentation could also be considered a failure in Nigeria because more advanced biotechnologies had not been applied, as back-slopping (rather than application of defined starter cultures) was used at the household level. Highlighting the need to move production of indigenous fermented foods in developing countries from an "art" to a "technology-driven process", Olusegun (61) noted that starter culture development is one of the steps in this transition, mentioning the successful use of starter cultures in production of fermented pork sausage (nham) and soy sauce in Thailand[7].

Nevertheless, Olusegun (61) noted that although important micro-organisms for fermentation might have been identified, starter cultures had not been developed for most indigenous fermented foods in Africa and for some in Asia. He argued (61) that one of the reasons was that the industry was still at the household level and manufacturers view starter culture technology as a burden to the cost of production.

To improve traditional fermentation processes and products in developing countries, Olusegun (61) concluded that the way forward involved more research on process standardization and controls and on the nutritional benefits of fermented foods; capacity building in biotechnology, especially in starter culture technology; development of fermenters (bioreactors) with control parameters (to overcome the tedious and time consuming nature of traditional processing); and promoting public awareness of the potential of biotechnology and the need to improve traditional food biotechnology with modern knowledge.

6.3.7 Cross-sectoral discussions: Reasons for failures of agricultural biotechnologies in developing countries

In Parts 6.3.3 to 6.3.6, summaries were provided of messages that discussed the successes or failures of specific biotechnologies in specific sectors. A large number of messages were also posted which considered agricultural biotechnologies in general without specifying any sectors or biotechnologies. In this part, these cross-sectoral discussions about the reasons for failures in applying agricultural biotechnologies in developing countries are summarized.

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7 A presentation of the soy sauce case study was given at ABDC-10, www.fao.org/fileadmin/templates/abdc/documents/soysauce.pdf and further details are given in Chapter 5.5.1

Lack of funds, facilities and trained professionals

Chikezie (4) thought that a major reason for the failure of agricultural biotechnologies in developing countries was the lack of funds, facilities and properly trained personnel to use them. As a follow-up to this message, Oyewole (8) added that many scientists in developing countries who work in the field of agricultural biotechnologies have also limited possibilities to disseminate the outcomes of their research to the people who could benefit from them. Additionally, he noted that the lack of funds and facilities meant that much of the agricultural biotechnology research carried out by developing country scientists was done in advanced institutions in developed countries (8). Tonjock (9) also described the negative impacts that the lack of funding, facilities and training had on the use of agricultural biotechnologies to fight against plant diseases in Cameroon.

Apart from Chikezie (4), lack of availability of funds was reported in many messages as one of the reasons for the failure (e.g. Tchouaffé, 10; Moro, 11; Sharry, 15; Muchadeyi, 16; Oyewole, 36; Roca, 74; Pathak, 96; Ubi, 120). Van der Meer (115) also noted that the funding levels for biotechnology were far inferior to the levels promised in the past. However, Yongabi (19) cautioned that even if funds were available for biotechnology, the improvement of agricultural productivity might not be significant in developing countries unless sustainable locally-adapted technologies were used, concluding: "agriculture can be improved in developing countries if appropriate technologies are developed simply and accessible to everyone rather than the over reliance on high-tech which is usually expensive!". Moro (40) agreed that some failures of biotechnologies may be due to lack of appropriate (local) solutions aimed to solve local problems and that lack of funds was not necessarily the main problem.

The negative impacts of poor research facilities were mentioned in several messages. Ajambang (30), supported by Oyewole (36), noted some of the routine challenges that many researchers face in developing countries were high customs duties for importing scientific equipment; difficulties in getting spare parts for broken scientific equipment; and power failures. Ubi (120) also named inadequate power supply as one constraint to their research in Nigeria. Pathak (96) noted that in Nepal there was no local industry producing the reagents and chemicals required for biotechnology work so they had to be imported which meant that prices were high, thus discouraging investments in this area. Oselebe (57) indicated that apart from the International Institute of Tropical Agriculture (IITA), a CGIAR institute, there were few laboratories in Nigeria equipped with facilities to assist with molecular markers. Edema (79) noted that many scientists who visited advanced laboratories abroad often had problems continuing their work when they returned home due to limited facilities.

Several messages, including Sharry (25), Rajalakshmi (104) and Pathirana (110) pointed to the lack of trained professionals. For example, Manneh (35) stated that the lack of sufficient trained manpower was "most acute in Africa where there is a serious shortage of breeders and biotechnologists in many national research programs". For sub-Saharan Africa, Danquah (99), supported by Gama (103), emphasized the importance of education, stating: "we have to go back to basics and develop not only the post-graduate schools in sub-Saharan Africa but the entire plant science programmes in institutions of higher learning. Today, a number of universities in Africa are struggling and many cannot run a good practical class for science students and many people graduate without the necessary skills to confront the challenges of any workplace. It's important for us to recognize that many of these half-baked students are those who end up in higher offices, some as politicians who never appreciate the application of science to development". Similarly, Driss (117) concluded that training should be the priority, while both Chikezie (48) and Oselebe (57) urged that donors provide funding for training. Caesar (121) proposed that a global biotechnology capacity building project be established, possibly spearheaded by FAO and UNEP.

Brain drain

Another important reason cited for failures of biotechnology was brain drain. For example, Yifru (23) reported that in the past decade or so, a number of prominent African agricultural researchers and policy analysts had left their respective national agencies, which had weakened the capacity of national agricultural research organizations and created knowledge gaps. For Caesar (121), human capacity sustainability and brain drain in developing countries were a threat to effective biotechnology development. Specific examples of brain drain were mentioned with Caesar (121) naming two key professionals that had migrated from his country, Guyana, in the past decade and Rigor (42) reporting that many trained biotechnology staff in his institute in the Philippines stayed only a short time before migrating/moving, which normally led to their projects being suspended or prematurely terminated.

Some participants felt, however, that brain drain need not be only negative, and that the professionals who migrated from developing countries could still contribute to solving problems back home. Thus, Murphy (100) felt that brain drain was "real but need not be catastrophic". He cited the case of the 2009 World Food Prize winner, Gabisa Ejeta, an Ethiopian-born scientist who worked in the United States and who developed Striga-tolerant sorghum hybrids that were widely disseminated in Africa, noting that he had been able to leverage know-how from the United States for the direct benefit of subsistence farmers in Africa. Caesar (121) noted that this model of brain gain could be explored as a way to lever the knowledge and support of citizens of developing countries who are fully established in developed countries. Predeepa (111) thought that brain drain was a necessary evil, which made it possible to learn about science, share resources and transfer technologies between countries. Gama (103) agreed that the story of Gabisa Ejeta was inspiring, but argued that Africa needs to build its own expertise at home, a point which echoed Yifru's (23) conclusion: "at the end of the day, there will be no effective substitution for national capacity".

To act against brain drain, Caesar (121) proposed that scholarship programmes for developing country trainees in developed countries should be complemented by a subsequent home-country sustainability/support programme. C.S. Prakash (107) advocated government-sponsored building of a science-based infrastructure to prevent the problems of high staff turnover rates mentioned by Rigor (42).

Inappropriate research focus

Muralidharan (43) argued that, unlike some African countries, there was no lack of funds, facilities or expertise in biotechnology research in India, and yet agricultural biotechnology had hardly produced any benefits so far. He attributed this to excessive duplication of research; the lack of a clear objective or perspective in terms of eventual application; and over-emphasis in most organizations on purely academic aspects of research. The need to consider the end user was also emphasized in other messages such as Adebambo (72) and Tchouaffé (5), with the latter urging that national research should be re-oriented towards addressing practical problems in the country based on the farmers' needs and should be demand-driven, which was not the case currently. Murphy (80) argued that one of the reasons for the lack of capacity and focus on practical areas of agricultural research in developing countries was the general worldwide trend for scientists to shift from applied to basic research which is perceived as being more prestigious. He noted that this issue had been of concern to Norman Borlaug, the "father of the green revolution", who insisted that his staff focus on projects relevant to increasing production and discouraged "researches in pursuit of irrelevant academic butterflies". Both Jordan (83) and Yifru (84) agreed with Murphy (80), although Trigo (93) was not convinced that such a trend was seen in reality, explaining that his experience in national agricultural research systems in the Latin America and the Caribbean region was that the bulk of research was dedicated to more applied, problem solving efforts.

On a related issue, Kojo (21) argued that international donors had undue influence on the research agenda, supporting research projects in their own commercial interest and "leaving the problems facing Africa and the other developing countries still unattended to", calling it "indirect brain drain".

Lack of political will

Kojo (21) argued that another pressing issue which had contributed immensely to the failure of agricultural biotechnologies in developing countries over the last 20 years was the lack of political will in most developing countries, especially in Africa, to support research in general. Oyewole (36) also highlighted the challenge in developing countries of governmental apathy towards research including biotechnology research, as did Gama (103) who wrote that development of indigenous biotechnology capacity was damaged by the lack of awareness or willingness of policy-makers to support biotechnology projects.

Yifru (23) noted that Africa was still far behind in the development and dissemination of appropriate agricultural technologies and products and urged that governments should give utmost priority to reinvigorating their educational systems and institutions and creating a conducive environment for biotechnology R&D in agricultural colleges and universities. The positive enabling role that government policies could play for application of biotechnologies was mentioned in several messages (Tchouaffé, 5; Olusegun, 61; Edema, 79: Traoré, 81; C.S. Prakash, 107; Muralidharan, 114). Danquah (99) also emphasized the importance of policy development, mentioning that most countries in sub-Saharan Africa did not have a science policy or a biotechnology policy, and that international organizations such as FAO needed to place policy development high on their agenda. Some developing countries have, nevertheless, prepared national biotechnology policies, including Nigeria (Usman, 37) and Sri Lanka (Pathirana, 110).

6.3.8 Cross-sectoral discussions: Suggestions for increasing the success of agricultural biotechnologies in developing countries

In the conference, many participants also suggested ways to ensure that applications of agricultural biotechnologies would be successful in developing countries in the future. These discussions are summarized below.

Research should be directed to the real problems of farmers

To enhance the benefits of applying biotechnologies in developing countries, one of the key suggestions made by participants was that research should be directed to address the real practical problems of farmers in developing countries. For example, Kumarasamy (29) stated that for biotechnology to be more effective in the future, problems from the field should be identified, the research should be results-oriented and it should lead to applications in the field. Similar views were expressed by Tchouaffé (5), Satish Kumar (31), Muralidharan (43) and Infante (85). Nimbkar (55) agreed with Satish Kumar (31) and Muralidharan (43) that biotechnology research should fit into a comprehensive improvement programme for the given sector and be focused on applicability. Otherwise, she said, it would use scarce financial resources without delivering the expected progress (55).

To encourage researchers to focus on applied, more practical research than basic, more academic research, Murphy (80) suggested that the status of applied researchers should be boosted and they should be rewarded equally compared with their more academic colleagues;

the public sector in all countries should shift the emphasis to socially valuable applied R&D; and resource-strong bodies like the European Union should channel collaborative funding with developing countries towards such areas. Jordan (83) agreed, and advocated increasing the funding and status of the applied disciplines so that the potential gains from applying biotechnologies can actually be realized. Yifru (84) also agreed, stating that "national governments in developing countries and their international partners need to work towards revitalizing applied research in the public sector". To arrive at a successful application of biotechnology, however, Infante (85) and Trigo (93) argued that both basic and applied research are needed, with Infante (85) giving an example of his work in sequencing the cocoa genome to indicate why this was true, and Trigo (93) arguing that an examination of success stories indicates that most of them had both research components.

Strengthened extension services

As stated eloquently by Murphy (100): "R&D is like a hosepipe - there is little point in filling it with water if the outlet remains blocked!". Having directed R&D towards the real problems of the farmers, to ensure that these results actually reach and benefit farmers in developing countries, participants suggested that extension systems be strengthened (Tonjock, 9; Moro, 14; Cruz, 32). Tababa (67) reported that one of the factors that facilitated adoption of biotechnologies in the Philippines was strong agricultural extension. For rice biotechnologies and their products, Manneh (35) concluded that to enable their wider use there was a need to reinforce national capacities such as the national research and extension systems. The importance of providing appropriate and timely information to farmers was also highlighted by Falck-Zepeda (20) and Zambrano (59) in their IFPRI studies on adoption of GM crops in South America.

Increased regional and sub-regional cooperation

Several participants suggested that increased regional and sub-regional cooperation would increase the benefits of applying biotechnologies. For sub-Saharan Africa, Danquah (99) concluded that biotechnologies had failed to deliver on their promise in the past and to change this he highlighted the importance of education, capacity building and close collaboration between institutions and universities in sub-Saharan Africa. He also proposed the establishment of sub-regional centres of excellence and innovations in sub-Saharan Africa to train the next generation of African biotechnologists. Gama (103) agreed with this proposal as did Hash (105) who, however, underlined that the centres should be linked with agencies involved in technology delivery to ensure that research products were delivered and accessible to farmers. Hash (105) noted that for breeding programmes wishing to use molecular markers it would be very useful if service laboratories providing high quality and cost-effective marker data could be established at sub-regional hubs. Agreeing with Danquah (99), Caesar (121) stressed the need for capacity building and outlined the key features of a potential global biotechnology capacity building project, building on regional and sub-regional groupings of developing countries and including a comprehensive scholarship/fellowship programme for developing countries. Commenting on the many messages describing the lack of facilities and capacity for biotech R&D in developing countries, Murphy (100) felt it might be unrealistic for each country, however small, to have its own research programme and he advocated increased collaboration with neighbouring countries and with centres in developed countries. Gama (103), however, disagreed that it was unrealistic to have a national programme.

Regional collaboration can be promoted through South-South cooperation programmes and a number of UN and non-UN international organizations provide assistance for South-South cooperation. McGrath (69) described one such example from the Academy of Sciences for the Developing World (TWAS), which supports young scientists from developing countries to carry out research in centres of excellences in other developing countries.

Public-private partnerships (PPPs)

Several participants suggested strengthening collaboration between the public and the private sectors as, following Roca (74), it "can create a win-win outcome in addressing local problems". Some recent examples of PPPs were described, including the water efficient maize for Africa project, a PPP led by the African Agricultural Technology Foundation (AATF), involving five African national agricultural research systems, two donor foundations, the International Maize and Wheat Improvement Center (a CGIAR institute) and Monsanto (C.S. Prakash, 107). Launched in 2008, its goal is to produce drought-tolerant maize varieties and make them available to small-scale farmers in sub-Saharan Africa. Echenique (41, 64) also described the WheatBiotech project launched in 2008 and developed by 12 partners including seven private breeding companies in Argentina. Its goal is to exploit biotechnological tools to improve the competitiveness and sustainability of the Argentinean wheat chain.

The private sector is playing a significant role in commercializing products resulting from agricultural biotechnologies in various developing countries, and numerous messages in the conference documented this. Examples were provided for biofertilizers in Mexico (Peralta, 22, 50); genetic modification in the Philippines (Cruz, 32) and India (Banerjee, 15; Prakash, 28); MAS in India (Hash, 44; Banerjee, 15); and tissue culture in El Salvador (Orellana, 62), the Philippines (Tababa, 67) and Sri Lanka (Pathirana, 110). Both national and multinational companies are involved (e.g. Priyadarshan, 6; Moro, 11; Banerjee, 15; Prakash, 28).

Hash (68) underlined that use of biotechnology tools needed to be strongly linked to applied product development, testing and delivery systems that address any relevant regulatory, multiplication and marketing issues. He therefore concluded: "this means that public sector biotechnology research will generally need to have strong links to the private sector if it is to have a high likelihood of delivering successful applied products within a reasonable time frame". For species that are already the target of large-scale private sector research investments, he did not, however, exclude investments by the public sector, but advised that they be focused. Similarly, Trigo (93) argued that because of the lack of management capacities and resources most public sector institutions had difficulties in handling many of the downstream issues such as biosafety (for GMOs) and intellectual property rights, and so they often ended up making agreements with private companies to handle those stages. Hash (68) noted, however, that it may then be difficult to apply biotechnology in situations where there are very small markets or where much of the product delivery and dissemination occurs via informal or traditional technology exchange systems. In many African countries, more than 80 percent of seeds used in agriculture are supplied by the informal system (Manneh, 35).

Yifru (84) argued that when commercialization was dominated by the private rather than the public sector, the crops or traits of critical importance for poor farmers (such as "orphan crops") received less attention and there was an increasing shift in research/funding from food crops to export-oriented crops. To overcome these kinds of hurdles, he and others (e.g. Trigo, 93) called for increased public sector investments and to focus them on applied research so that the public sector can ensure that biotechnologies "are employed for the common good as well as for private profit" (Murphy, 100).

6.3.9 Participation in the conference

A total of 834 people subscribed, of whom 83 (i.e. 10 percent) submitted at least one message. Of the 121 messages that were posted, 33 (27 percent) came from people living in Asia; 32 (26 percent) from Africa; 24 (20 percent) from Latin America and the Caribbean; 16 (13 percent) from North America; 10 (8 percent) from Europe; and 6 (5 percent) from Oceania. The messages came from people living in 36 different countries, the greatest number coming from India (27 messages), Nigeria (12), Argentina (11), United States (9) and Cameroon (5). A total of 90 messages (i.e. 74 percent) were posted by participants living in developing countries.

Forty eight messages (40 percent) came from people working in universities; 34 (28 percent) from people working in research centres (28 in national institutes and 6 in CGIAR centres); 12 (10 percent) from people in the private sector; ten (8 percent) from participants from non-governmental organizations; eight (7 percent) from people working as independent consultants; six (5 percent) from people in Governments; two from the UN and one from a development agency.

Here below, the names are provided of participants with referenced messages, as well as the country in which they are living:

Adebambo, Ayotunde
Nigeria

Ahmed, Kasem Zaki
Egypt

Ajambang, Walter
Indonesia

Ali, Ahmad
Pakistan

Anderson, Paul
United States of America

Banerjee, Partha
India

Beach, Larry
United States of America

Bett, Bosibori
Kenya

Caesar, John
Guyana

Chikezie, Uche
Nigeria

Cruz, Von Mark
The Philippines

Danquah, Eric
Ghana

Dávila, Doris Zúñiga
Peru

Driss, Sadok
Tunisia

Dudhare, M.S.
India

Echereobia, Christopher
Nigeria

Echenique, Viviana
Argentina

Edema, Mojisola
Nigeria

Egesi, Chiedozie
Nigeria

Escandon, Alejandro
Argentina

Falck-Zepeda, José
United States of America

Gama, Peter
The Sudan

Giddings, Val
United States of America

Glover, Dominic
The Netherlands

Gupta, P.K.
India

Gurian-Sherman, Doug
United States of America

Hash, Tom
India

Infante, Diógenes
Venezuela

Jordan, David
Australia

Kamanga, Daniel
South Africa

Keshavachandran, R.
India

Kojo, Agyemang
Ghana

Kumar, Dinesh
India

Kumar, Satish
India

Kumarasamy, P.
India

Loquang, Thomas
Uganda

Manneh, Baboucarr
Senegal

McGrath, Peter
Italy

Moro, José
Canada

Muchadeyi, Farai
South Africa

Muralidharan, E.M.
India

Murphy, Denis
United Kingdom

Nassar, Nagib
Brazil

Nimbkar, Chanda
India

Nzeduru, Chinyere
Nigeria

Olusegun, Obadina Adewale
Nigeria

Orellana, Mario Antonio
El Salvador

Oselebe, Happiness
Nigeria

Oyewole, Olusola
Nigeria

Parrott, Wayne
United States of America

Pathak, Dhruba
Serbia

Pathirana, Ranjith
New Zealand

Peralta, Humberto
Mexico

Prakash
India

Prakash, C.S.
United States of America

Predeepa, Rachel
Australia

Priyadarshan, P.M.
India

Raheem, Dele
United Kingdom

Rajalakshmi, K.
India

Rigor, Alex
The Philippines

Roca, Maria Mercedes
Honduras

Sangar, Sunita
India

Seshadri, S.
India

Sharry, Sandra
Argentina

Singh, Harjit
Canada

Sivakumar, S.
India

Souza, Lúcia de
Brazil

Tababa, Sonny
Singapore

Tchouaffé, Norbert
Cameroon

Tonjock, Rosemary
Cameroon

Traoré, Adama
Mali

Trigo, Eduardo
Argentina

Ubi, Benjamin
Japan

Usman, Raheef Ademola
Nigeria

Van der Meer, Piet
The Netherlands

Yifru, Worku Damena
Canada

Yongabi, Kenneth Anchang
Cameroon

Zambrano, Patricia
United States of America

Zidana, Hastings
Malawi

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CHAPTER 7

TARGETING AGRICULTURAL BIOTECHNOLOGIES TO THE POOR

SUMMARY

Designing and implementing policies for targeting agricultural biotechnologies to the poor requires holistic or "joined up" analyses of proposed interventions to identify their possible direct and indirect, immediate and longer-term ramifications and to foster coherence with overarching national policies for economic and social development, including agriculture and food security, as well as for science and technology (S&T). Doing so requires taking account of the institutional arrangements for developing new agricultural technologies into tangible products and the social contexts that influence the incentives for farmers and markets to adopt these, and fostering collective and transparent processes for decision-making. Policies for agriculture itself now have to deal with a multitude of new and emerging issues, and decision-making is further complicated by influential legally-binding instruments negotiated globally, regionally and bi-nationally. This plethora of cross-cutting considerations cannot be tackled effectively by an individual ministry and different interests will drive negotiations towards particular outcomes and priorities. Competing economic and social interests do not favour targeting biotechnologies in food and agriculture (BFA) towards small-scale and often poor farmers living in resource-challenged areas – only strong and persistent political commitment can achieve this.

This Chapter begins by outlining some of the broader considerations within which national agricultural and wider rural development policies and policy-making operate nowadays, and some principles that should be followed for formulating a national policy or strategy for BFA – including the critical issue of deciding on the distribution of benefits from introducing technological change through biotechnologies (i.e. direct and indirect effects).

A rationale is provided for establishing a national biotechnology policy/strategy (NBS) framework – something which few countries actually have in place – as well as

some principles and examples of how some countries have gone about planning and implementing biotechnology applications. The Chapter describes the type of analytical work that should underpin preparation of the NBS; the essentiality of ensuring the widest possible engagement with the public, including with representatives of farmer/producer organizations, private companies, non-governmental organizations (NGOs), civil society organizations (CSOs) etc., the ultimate aim being "participatory decision-making". In addition, the Chapter makes suggestions for content, based on a consideration of core government roles and responsibilities as well as on the assignment of roles and responsibilities for its implementation. It recommends that notwithstanding the need to develop policies, strategies and programmes that are aligned with those existing for the agricultural sector and its sub-sectors and tailored to meet the requirements of BFA, the governance of agricultural biotechnologies at national level should be horizontal. It also deals with the question of NBS approval, providing examples of options available.

Coordination – across government ministries, across government departments (within ministries), with sub-national governance structures and with other governments via bilateral, regional and multilateral mechanisms – is a key issue in designing and following through on policies for BFA. Horizontal as well as vertical coordination are therefore essential for comprehensive and balanced biotechnology policies and several options are outlined for achieving this between and within individual ministries. Important issues to be resolved here include the "reach" of such mechanisms where working at the policy and at the operational levels has to be clarified, as does how to involve others who may not be "at the table", e.g. NGOs, the business community and other partners from civil society. A further consideration is securing independent advice, and several principles and options are provided for countries and institutions wishing to obtain such input.

The Chapter includes an analysis of the NBS documents that have been developed and approved by 15 selected developing countries. Few of the countries analysed have formal structures to oversee development of agricultural biotechnologies and in even fewer do these appear to involve collective government. The option chosen was to assign responsibility for implementation as an "add on" to the ministry assigned to lead development of the framework (normally the Ministry of S&T), with no indication given about delegation of responsibility for specific areas such as BFA or for bringing policy issues to the "top table" for discussion and decision-making. A further gap seems to exist in countries with federal and local systems of governance, i.e. the lack of a specific national forum for coordinating policy, raising the distinct danger of, e.g. policy and funding overlaps and production and trade distortions.

Priority-setting for biotechnologies in general and specifically for BFA is arguably the biggest challenge faced by government and sector-level policy-makers, particularly if the goal is to tackle hunger and poverty in rural areas. Options to aid decision-making include establishing a national system of biotechnology statistics and indicators; setting up systems of biotechnology foresight; and introducing instruments that encourage research and development (R&D) institutional transformation with a premium placed on multi-disciplinarity and networking (i.e. "innovation systems" approaches). Also, policy-makers have to decide on public sector research entry points – the appropriate balance between basic/fundamental and applied research, and between crops, livestock, aquaculture and forestry; the breadth of the R&D portfolio; and the division of labour, i.e. which technologies can or will be developed exclusively by, or in partnership with, local or international private sector companies. Here, it should be recognized that for the most part, the role of private sector R&D and delivery systems will remain limited without significant government inducements, particularly for small-scale/subsistence farmers in marginal areas. Irrespective of whether one or a number of ministries is responsible for "Agriculture", a collective decision-making forum for priority-setting and resource allocation for R&D within or between the ministries involved would seem appropriate. As noted in Chapter 8, a number of countries are beginning to establish such mechanisms for dealing with regulatory issues, but no country seemed to have a similar forum for biotechnology priority-setting across the agricultural sector as a whole.

The potential for R&D to improve productivity and reduce hunger and poverty will be strongly influenced by the types of farms and production systems, and by the strength of the research, extension and higher education institutions available. Its focus should be directed at areas where the largest number of poor people live and respond to their vulnerabilities and livelihood strategies. This type of information needs to feed into a process that considers all the technical options available for dealing with the issue(s) in question. This in turn may require expertise in *ex ante* impact assessment supported where possible by *ex post* assessments to assess whether a particular biotechnology "adds value" to more conventional and probably lower-cost and technically less demanding R&D approaches for improving livelihoods through productivity or quality enhancements, the effectiveness of government or private services and the returns on government investments. For some biotechnologies, assessment should take account of socio-economic issues like intellectual property rights (IPR), the associated costs and assumptions concerning user and consumer acceptability nationally and internationally for commodities earmarked for trade, and the skills and infrastructure needed to cover possible R&D as well as post-release costs of biosafety and food/feed safety regulations. Other priority-setting considerations include: the current status and likely future strength of the national breeding, management and disease/pest control programmes; the delivery systems for the technology in question and their sustainability; and the national and international S&T landscape.

A summary is provided of methods for conducting impact (mostly economic) assessments, the majority of which feed into top-down approaches. Some, however, like the sustainable livelihoods approach can be adapted to bottom-up mechanisms although in general the associated data requirements are substantial. Impact assessment should be part and parcel of priority-setting processes and overall research evaluation and management systems within research organizations and therefore should be institutionalized throughout.

Priority-setting ultimately comes down to assessing the appropriateness of the technological packages being considered i.e. their technical feasibility, economic viability, social acceptability, environmental friendliness, relevance to the needs of farmers, consumers etc. – issues that inevitably vary over time and space. Assessing appropriateness requires capacity to identify and make hard choices among the many critical problems facing rural communities that can be addressed better with agricultural biotechnologies than by taking other approaches. This, in turn, depends on the quality of the background information available, the methods used, and who participates and how, in informing decision-making. The results will always be speculative, open to uncertainties and different interpretations and certainly cannot reliably be extrapolated from one country to another or even from one location to another within a country. It is therefore important to review results against studies from other countries with similar and different socio-economic conditions.

Government-level policy-makers should encourage the introduction within their national agricultural research systems (NARS) of more rigorous and participatory mechanisms and methods to inform decision-making on these matters, including allocation of resources through specific programmes, projects and activities. However, new approaches are needed to assess, and compare with conventional approaches, the likely impacts – social as well as economic, immediate and long-term, positive and negative – of all major modern biotechnologies used in food and agriculture, particularly for smallholders in disadvantaged areas.

7.1 INTRODUCTION

ABDC-10 takes place against the backdrop of global food, energy and financial crises, and a number of worrying statistics and trends concerning hunger, food insecurity, the state of the world's climate, and its resources of land, water and biodiversity upon which everyone ultimately depends for their livelihood and very existence. It benefits from the comprehensive and thought-provoking insights provided by the World Development Report on agriculture for development (World Bank, 2007), the International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD, 2009) and the State of Food Insecurity in the World (FAO, 2008) into the challenges faced and the opportunities available through agriculture at regional and global levels for meeting hunger and wider sustainable development objectives, such as reducing poverty, food insecurity and environmental degradation.

These and other reports serve to highlight the fragility and vulnerability of the world's food system. They also raise serious concerns about the adequacy of the "business as usual" response that has characterized the individual and collective actions of so many countries since the World Food and Millennium Summits for avoiding the prospect of many millions more falling into poverty and chronic hunger and for getting back on track for meeting the Millennium Development Goals (MDGs) and other internationally agreed development goals.

The vast majority of the world's hungry people live and work in rural areas as do three-quarters of the 1.4 billion living on less than US$ 1.25 per day (Chen and Ravallion, 2008), and most depend on agriculture for their livelihood both directly and indirectly through rural off-farm activities. Addressing food insecurity therefore requires policies, strategies and programmes that (1) stimulate widespread and long-term increases in the production of staple foods and other products through enhanced productivity, (2) doing so in ways that protect the environment, conserve and use agricultural and wider biodiversity sustainably, (3) ensure food safety and quality to protect the health of consumers, and (4) promote fair trade.

At the same time, incentives must be provided for encouraging broad-based rural development and private sector investment through, e.g. diversification into higher-value horticultural, livestock and aquaculture products and providing greater access to services such as credit, insurance, market information and technical support. And while not neglecting the importance of larger scale and/or higher input commercial agriculture that is practised in more favourable environments, in order to cut poverty significantly the focus of national and international initiatives must be on empowering the roughly 1.3 billion smallholders and landless workers to broaden their opportunities for engaging in local, national and international markets, reducing food prices and generating demand for locally produced goods and services.

Technologies and knowledge that increase productivity, facilitate diversification and marketing of products, and improve natural resource management can be powerful forces for reducing hunger, food insecurity, poverty and environmental degradation. Earlier Chapters of this book document the main scientific and technological advances offered by biotechnologies in crops, livestock, fisheries/aquaculture and forestry for producing food, feed or fibre in developing countries and for processing, marketing and trading in agricultural products.

This Chapter (along with its companion Chapters 8 and 9), deals with policy[1] options for strengthening national capacities to make informed choices about using BFA. The Chapters recognize that views vary widely among countries, institutions and individuals about the contributions that biotechnologies, particularly advanced biotechnologies like genetic modification, can make to improve agricultural productivity and food security in developing countries, and whether, for example, strengthened intellectual property regimes are necessary to achieve these goals. Beneficial or regrettable, both are facts of life, and the Chapters do not advocate the use or avoidance of any particular biotechnology or approach towards their development and application, although each one highlights some key and unique issues that should be taken into account when considering its application.

The three Chapters also analyse the national biotechnology policy/strategy (NBS) documents that have been developed and approved by 15 selected developing countries (Table 1), as well as other relevant documents and policies from the same countries. These NBS documents may evolve and be revised by governments over time. However, by analysing the documentation from these 15 countries together with many peer-reviewed papers and global assessments, these Chapters set out to describe the range of policy/strategy roadmaps that have actually been prepared by a spectrum of developing countries from different regions for exploiting BFA, as well as to provide some additional options that may be considered by these and other countries.

The three Chapters are closely inter-connected because they include an analysis of the same 15 countries and by the reality that a national "biotechnology policy" covers the pursuit of many inter-linked policy objectives and strategies at any given point of time while striving for the best possible coherence among them to maximize benefits.

This Chapter therefore attempts to "paint the broad picture", covering some of the foundations and principles for countries to consider when targeting biotechnologies to the poor. Chapters 8 and 9 on the other hand – while not losing sight of these target end-user/beneficiary groups – emphasize policy options for dealing with the more specific technical, legal, regulatory and socio-economic dimensions of BFA for fostering their pro-poor development and diffusion.

This Chapter is divided into four main Parts, with Part 7.2 providing the broad context (national and international) within which agricultural policies operate, and stressing the essentiality of ensuring that biotechnology policy contributes to wider policies for agricultural and overall national development. Against some background of the key issues surrounding agricultural biotechnologies, Part 7.3 deals with the "why, what and how"

[1] For the purposes here a policy refers to a documented plan of action announced by a Head of State and/or agreed by a Government, Ministry, legislature, regulatory authority and national and international standard setting or other legally recognized body e.g. research institution, university, funding agency. Policy instruments can include laws, regulations, rules, standards, and politically and legally authorized funding instruments and programmes. A strategy refers to an integrated package of policies for the sector, a sub-sector, technology or issue. Policies may or may not be legally binding.

of developing, approving and implementing a NBS framework, including a list of the key policy issues that should be addressed at the governmental level. Part 7.4 provides options for the governance of BFA, dealing with both its structural and organizational aspects (e.g. leadership, coordination and options for independent advice), while Part 7.5 covers the all-important issue of R&D priority-setting at government, ministerial and research institution levels, including the "division of labour" between the public and private sectors. The Annex, in Part 7.6, provides concrete examples of processes and procedures followed by 15 selected developing countries.

7.2 AGRICULTURAL AND NATIONAL DEVELOPMENT POLICY CONTEXTS

Agricultural policies that address a single issue (e.g. BFA) in a piecemeal manner without considering the totality of its dimensions will not contribute positively to meeting the challenges faced by the sector or the people whose livelihoods depend directly and indirectly upon it. This is because each policy initiative (e.g. using semen or embryos to upgrade livestock as

TABLE 1

NATIONAL BIOTECHNOLOGY POLICY/STRATEGY (NBS) FRAMEWORKS OF 15 SELECTED DEVELOPING COUNTRIES

Country	Year	Lead Ministry	Prepared by	Approved by
Argentina	2004	Econ. & Prodn.	Secretariat of Agriculture, Livestock, Fisheries & Food	Ministry of Production
Brazil	2007	Science & Technology (S&T)	Interministerial Committee	Congress
Chile	2004	Econ.	Nat. Committee on Dev. Of Biotech.	Government
China	1988	S&T/ State Dev. & Planning Committee/ State Economic Commission	Ministry S&T	State Council
India	2007	S&T	Department of Biotech.	Government
Jamaica	2006	Nat. Commission on S&T	National Biotech. Coord. Committee	Government
Kenya	2006	S&T	Nat. Council S&T	Government
Malawi	2009	Educn., S&T	Nat. Res. Council	Government
Malaysia	2005	S&T & Innovn.	Ministry S&T & Innovn.	Government
Namibia	1999	Higher Educn., Vocational Training, S&T	Namibian Biotech. Alliance	Ministry
Peru	2006	Education	Nat. Council S&T & Innovn.	Congress
South Africa	2001	Arts, Culture, S&T	Universities, Private Sector and Research Council	Government
Thailand	2005	S&T Dev. Agency	Nat. Econ. & Social Dev. Board	Government
Uganda	2008	Finance, Planning & Econ. Develop.	Nat. Council S&T	Government
Zambia	2003	S&T & Vocational Training	Ministry S&T & Vocational Training	Government

part of a dairy development programme) can have enormous knock-on effects – positive and negative – on others, e.g. the people involved in small-scale integrated crop-livestock production systems and the suppliers of feeds and veterinary services.

Likewise, policies aimed at fostering agricultural biotechnologies for improving the livelihoods of small-scale/subsistence farmers will neither help them nor promote their interests without prior consideration of the constraints to the productivity of the plant and animal species used within the specific farming systems in which they are currently engaged. Holistic or "joined up" analyses of proposed interventions are therefore not just sensible, they are essential – in the first place for identifying the possible direct and indirect, immediate and longer-term ramifications of the intervention itself, and then for designing and implementing policies and practices that will give a "pro-poor" direction to intended improvements in national agricultural and rural development and food supplies.

The institutional arrangements for developing new agricultural technologies into tangible products and the social contexts that influence the incentives for farmers and markets to adopt them must also be taken into account. This cannot be based solely on a "science push". Scientists, industry, farming, consumer and other groups can legitimately "inform" but it is the role of governments and their delegated ministries and agents to "decide". In addition, essential to the process of deciding about BFA is that it fosters collective and transparent national ownership and an outcome consistent with meeting the country's priorities for economic and social development in general. Ensuring coherence with the country's overarching policies for agriculture and food security, as well as for science and technology (S&T) are also clearly essential for achieving this outcome.

Before dealing with policies for BFA a brief overview is given of some of the complexities of agricultural and associated rural development policy-making and of the basic principles for formulating sound policies and follow-up actions. Since these principles apply across all relevant sectors and irrespective of the particular issue within them, they are not discussed further in relation to policies for using agricultural biotechnologies. However, implementing them within national contexts is essential for developing sound policies for such applications, whether these are in connection with developing and applying the S&T; deciding on a regulatory framework for safety; dealing with IPR; or involving the public in decision-making.

7.2.1 National and international dimensions of agricultural policy-making and policies

The national settings within which public policy operate are wide, highly variable, complex and unpredictable, and since governments have obligations and are answerable to society, balances have to be struck and priorities set among a wide range of competing economic and social interests. For example, policies for agriculture have to deal not only with a multitude of different issues concerning the use of plants, animals, land and water within different production systems, they also have to include consideration of issues like food insecurity, poverty and wider rural development, environmental services, processing and marketing, human health, trade, S&T, intellectual and other property rights – and of course financial investments.

These cross-cutting issues cannot be tackled effectively by an individual ministry and clearly different interests will drive negotiations towards particular outcomes and priorities. Also, agriculture has to compete for treasury appropriations against other commercial and social sectors such as manufacturing, infrastructure, education and health, a task made increasingly demanding in the face of rapid urbanization and in nations where agriculture is no longer the backbone of economies, e.g. in countries characterized as "transforming" and "urbanized" (World Bank, 2007). In addition, within agriculture itself, small-scale subsistence-oriented farms, farmers and their organizations have to compete with larger, more commercial and possibly export-oriented systems and their better-organized representatives at the tables of decision-making regarding levels, locations and orientation of government policy and direct and indirect financial support. None of this favours targeting biotechnologies towards the poor – only strong and persistent political commitment can achieve this.

National agricultural policies, and the legal and regulatory frameworks that support them, are also increasingly influenced by legally-binding instruments negotiated globally, regionally and/or bi-nationally. While countries may choose not to take part in one or more of these international agreements, they increasingly set the scene e.g. for global trade, and their influence cannot be ignored. As discussed in Chapters 8 and 9, of particular relevance to biotechnology are the global rules that:

- govern trade, i.e. the Agreements of the World Trade Organization (WTO) and in particular those on Sanitary and Phytosanitary Measures (SPS) and related Codex Alimentarius and International Plant Protection Convention (IPPC) standards, Technical Barriers to Trade (TBT) and on Trade-Related aspects of Intellectual Property Rights (TRIPS);
- aim to conserve and sustainably use biodiversity and share the benefits from using it, i.e. the Convention on Biological Diversity (CBD) and its Cartagena Protocol on Biosafety (CPB);
- make special provisions for the plant genetic resources used in food and agriculture, i.e. the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).

Added to this are globally and regionally agreed commitments to tackle hunger, poverty, environmental degradation and trade disparities urgently and in a concerted manner through a combination of national and international private and public goods (e.g. the MDGs, the Plan of Implementation from the World Summit on Sustainable Development, the New Partnership for Africa's Development [NEPAD] and the Doha Development Round of trade negotiations).

This Chapter does not detail the history and current status of negotiations leading to these international agreements and their constituent provisions, nor does it attempt to describe the positions taken by individual or groups of nations in such processes. Interested readers are directed elsewhere for this information (e.g. Stannard *et al.*, 2004; Bragdon, 2004; Tansey and Rajotte, 2008). What is important to note, however, is the dynamic interaction that takes place between policies negotiated within different global fora (e.g. between trade and biodiversity).

Introducing, amending and implementing national laws, regulations, structures and practices to tailor the requirements negotiated through these fora in ways that are most appropriate for national development are challenges that policy-makers in even the most technologically advanced countries struggle to meet successfully. For low income and food deficit countries, crafting policies for protecting/balancing the interests of small-scale producers and the systems they manage against competition from within and outside their national borders is much more onerous. And yet, the decisions made and paths chosen by all countries for meeting the obligations embedded in these agreements will profoundly influence the speed and direction of R&D and diffusion of biotechnology products, as well as the distribution of any benefits (and risks) arising from them. This holds for all biotechnologies, but especially so for genetically modified organisms (GMOs)[2] which are singled out for "special treatment" within the framework of some international legally-binding agreements.

7.2.2 Towards comprehensive agricultural development policies and strategies

From the foregoing, it is clear that now and in the future, agriculture needs to contribute to a much more complex set of outcomes than simply producing more food and other primary products. There can therefore be no single strategy for putting all the pieces together for achieving sustainable food security and wider development objectives through national agricultural and food policies and there will be many potential entry points. For a start, policy-makers rarely begin with a clean sheet – they have a baseline of knowledge and experience which evolves over time, and it is a well-known maxim that "each policy

2 The CPB uses the term living modified organism (LMO), defined as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology", where modern biotechnology is defined as "the application of in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection". Technically, there are differences between a GMO and an LMO but for the purposes here the more commonly used term "GMO" is used, although reference may be made to an LMO. It is also questionable technically, whether some products referred to as GMOs are in fact GMOs since processing has removed all traces of the organism from which the product was obtained. Clear definitions are, however, essential when making laws and regulations transparent and predictable, and differences in these can lead also to misunderstandings between nations; this aspect is not expanded upon further here.

has its own politics" (IDB, 2006). Also, given the tremendous diversity of the agricultural and wider productive and socio-economic sectors across countries and within and even between sectors, and in the cultures of the institutions and individuals that make and implement policies or regulatory standards, it should not be surprising that the processes of reaching agreement nationally, and more particularly internationally, on a particular issue are inevitably protracted with many twists and turns.

While there are many options open to countries for developing agricultural policy (see e.g. FAO, 2007a), certain principles should be followed for formulating a national policy or strategy framework if it is to attract widespread legitimacy and "buy-in". In particular, the mechanisms that are set up should have the following overlapping features:

- The processes should be both forward and outward looking, e.g. based on informed predictions of climate, technological, demographic and other changes and look at how other countries are dealing with the sector.
- The information available should be evidence-based i.e. come from a wide range of sources that are transparent, take account of past lessons and consider a range of costed and appraised options.
- They should be inclusive, i.e. involve stakeholders directly and meet the needs and/or take account of the impact of the policy on all groups directly or indirectly affected by it, i.e. it should involve key stakeholders directly.
- Processes should take a holistic or "joined-up" view, looking beyond sector and institutional boundaries to ensure that the "sum" of agriculture's contributions to the nation's strategic sustainable development objectives are greater than the "parts" contributed by its different sectors.
- They should be "balanced", i.e. consider both the scientific and social and economic issues as well as the cultural and ethical dimensions. For example, just because something can be done doesn't necessarily mean that it should be done; consideration should also be given to how the policy will be communicated to the public, reviewed and evaluated.
- The anticipated outcomes should improve or at least should not disproportionately harm the sustainability of agriculture or the livelihoods of the most vulnerable groups that contribute directly to, or are affected by the sector.

Developing these frameworks requires consideration and prioritization of many different policy options – inevitably a very difficult call with many caveats and trade-offs since the contribution of agriculture to pro-poor growth will vary with the stage of development of the country and also between locations within countries, the key determinant being the existing conditions (Dorward *et al.*, 2004; Byerlee, Diao and Jackson, 2005; World Bank, 2007; Hazell, 2008).

Nevertheless, possibly the most fundamental policy issue faced by governments is deciding on the types and levels of public support that should be directed towards small and large farms for reducing hunger and poverty, e.g. through introducing technological change via biotechnologies. The dilemma arises because the benefits of a technology can be both direct and indirect. In the former, they arise through, e.g. improving growth rates in yields for home consumption and generating incomes for poor farmers thereby increasing food security largely at the household level. Indirect benefits, on the other hand, have a "wider reach", arising from the effects of adoption by both poor and non-poor farmers; they include improving food availability through lower food prices and creating employment opportunities both on- and off-farm, thereby improving the welfare of a broader spectrum of the poor, e.g. landless farm workers and rural and urban non-agricultural workers. So, although technological change in agriculture can help to reduce hunger and poverty, the distribution of these gains between direct and indirect effects is highly dependent on, e.g. the structure of the economy, the location of hunger and poverty, and on the focus of the envisaged technological change. If the technologies used to produce these two effects are not the same, there may be trade-offs in allocating public funds such that using a particular (bio)technology to improve smallholder welfare leads to a lesser aggregate gain in total productivity and a lower reduction in poverty and access to food (de Janvry *et al*., 1999; Hazell *et al.*, 2007*)*. Relying on the direct route to hunger/poverty reduction therefore requires knowledge of national land distribution patterns, the specifics of production systems (e.g. crops, livestock, biotic and abiotic constraints), access to markets and institutional support etc. of poor small-scale producers. In highly diversified systems, the biotechnology option could be costly if restricted, e.g. to changing any one crop since the overall effects on household income may be small (de Janvry *et al.,* 1999). On the other hand, over time and certainly in climate- or input-challenged areas, positive effects may be more significant.

Other considerations include the reality that in some localities (e.g. where soils are fertile, water readily available and where input and output markets and other infrastructure are relatively well developed), smallholder development can drive growth and equitable development through the rural non-farm sector and more widely through rural-urban linkages. Conversely, in areas where significant and widespread increases in productivity cannot be achieved (e.g. those with poor resources and high population pressure), agriculture will not be able to drive the growth needed for significant hunger and poverty reduction. In these situations, it still has an essential role in protecting livelihoods and the natural resource base and therefore the policy dilemma is whether to invest in technology and other services or provide safety nets and help people out of farming. Thus, while few would question the need to substantially re-direct public investments to rural areas, policies concerning technologies and other means of support for smallholders need to be tailored to context, in particular to location and resource endowments.

Much of this comes down to setting wider fiscal and monetary policies since these have as much to do with how well the sector achieves its objectives as do more traditional agricultural and food policies *per se*. Recent reports (World Bank, 2007; UNCTAD, 2008) provide useful analyses of the roles of macroeconomic, price and trade policies and of public spending and development assistance bias towards urban needs, and describe how the effects of these on agricultural production and socio-economic development have been far from benign. This again reinforces the need to go beyond policies for improving crops, livestock, fisheries and forestry when developing agricultural and food policies, and to ensure that inter-sectoral, economic, environmental and trade policies are mutually supportive. Success in doing so depends very much on the quality of the coordination mechanisms used to shape, implement and sustain policies. While participation will depend on country-specific ministerial and other structures, these mechanisms should provide a basis for effective interministerial relations, foster partnerships with all stakeholders, and build open and transparent processes to increase public understanding and confidence. Options used by countries for establishing such mechanisms to deal with BFA are described below.

7.3 NATIONAL BIOTECHNOLOGY POLICY/STRATEGY FRAMEWORKS

7.3.1 Biotechnology issues from a policy perspective

Government and agricultural policy-makers have to make hard choices amongst the many legitimate demands made on public finances, and in considering their options they will inevitably be confronted with questions like why agricultural biotechnologies?; which biotechnology?; is it safe?; what will it cost and who will benefit?; and can the products be traded freely?

In addressing these and other questions, a number of pertinent issues should be considered. Firstly, contrary to the impression given by the popular and scientific press, biotechnology is much more than GMOs. The first five Chapters document the fact that biotechnology represents a broad collection of tools that are being used for a variety of different purposes in food and agriculture in developing countries. Notable examples include: genetic improvement of plant varieties and animal populations to increase their yields or efficiency; genetic characterization and conservation of genetic resources; plant and animal disease diagnosis; vaccines to protect livestock and fish from disease; and improvement of feeds. There are therefore many potentially useful tools included in BFA – both “traditional” and “modern” – to be considered by policy-makers for contributing to the “technological mix” needed to advance sustainable agriculture and rural development, and which will continue to offer wide choice in the types of agriculture being pursued. GMOs also have potential. However, their development and use, as well as the use of products derived from them, require attention to scientific, legal, regulatory, financial and other considerations that are not generally encountered with other biotechnologies (see below and Chapters 8 and 9).

In addition, at its "top end", biotechnology is best described as a "platform" or generic technology, embracing applications of genomics and bioinformatics, microarray technologies, high-throughput DNA sequencing, genotyping, polymerase chain reaction (PCR), transgenesis, robotics, mass spectrometry etc., across sectors and biological boundaries, i.e. it is both sector- and scientifically cross-cutting and requires the determined pursuit of multi-disciplinarity. Policies and strategies for research involving the wider application of modern biotechnologies should therefore be developed in ways that maximize the opportunities arising from their cross-fertilization features. This requires strong inter-ministerial coordination and collaboration.

Biotechnology approaches to agricultural research are not alternatives to conventional technologies but are complementary. However, whereas developments in conventional technologies are generally driven from within applied science research settings, modern biotechnology evolves from discoveries, knowledge and innovations coming from the basic sciences. There is therefore an institutional "disconnect" between these two research environments, e.g. between institutions involved in mapping, isolating and discovering the function of genes and producing gene constructs and those using genetic markers, gene constructs, and strands of DNA to characterize or provide improved germplasm, vaccines, diagnostic tests etc. Even at the more downstream end of modern biotechnology (e.g. using validated molecular markers, diagnostic reagents, tissue culture and micropropagation), biotechnology R&D comes at additional cost. Working further upstream (e.g. in structural and functional genomics, basic immunology and cell biology, bioinformatics and genetic transformation) increases both start-up and maintenance costs considerably. This is particularly so in the veterinary field or when dealing with diseases transferred from livestock to man (zoonotic diseases) where laboratories and animal facilities with high levels of physical containment may be required.

Another consideration is that biotechnology R&D needs physical facilities, expensive and sophisticated equipment and a critical mass of scientists with new skills to complement existing expertise in the traditional agricultural specialities like plant and animal breeding, disease management etc. Shortcomings in either these new or conventional knowledge arenas (arising from quantitative or qualitative deficiencies in school and tertiary education, opportunities for continuous learning and funding of more traditional research including monitoring the status and trends in agricultural and wider biodiversity and the environment) will seriously limit the potential of BFA.

Realizing the full potential of agricultural biotechnologies takes more than laboratory-based research. Innovations from upstream research need to be developed and scaled up through further innovations into tangible products (e.g. seeds, plantlets, diagnostic kits, vaccines, batches of enzymes, foods) that are useful, affordable and acceptable to farmers, to diagnostic and other support and input providers, and to consumers. Of course, to be useful, these products have to be delivered to them. Assuming regulatory requirements are satisfied (see Chapters 8 and 9), these critically important aspects – development/scaling up and delivery – are invariably the major "missing links" or stumbling blocks to deploying most technologies, including biotechnologies, in developing countries i.e. the capacity to "commercialize" biotechnology through the creation or support of demand-driven private sector firms or public-private enterprises that can deliver to end users is key for success. Underpinning the success of such firms and arrangements is the availability of entrepreneurial and business management skills and financial capital.

An additional issue to consider is that the international legal and regulatory framework surrounding biotechnology R&D and the diffusion of some of its products are complex and constantly evolving. They also add significantly to the cost of innovations and to uncertainty about returns on investments. While certainly not restricted to GMOs, the following should be noted:

- Research involving, and products derived from recombinant DNA (rDNA) techniques, need to satisfy additional scientific and other requirements for ensuring the safe use of laboratory techniques and field testing of new products before they are released for general use, i.e. biosafety[3] (Chapter 8; see also National Research Council, 2002 and 2008). Products may also require environmental monitoring after commercial release and restrictions may be placed on how and where they are cultivated or used (National Research Council, 2002; FAO, 2007b). Products entering food and feed chains also have to meet safety regulations. Meeting regulatory requirements requires additional legal and scientific skills and laboratory, administrative and management infrastructures. Ideally, these should be independent from those available within public and private research and product development institutions;
- GMOs and products derived from them and other evolving technologies (e.g. animal cloning) can potentially come up against trade restrictions due to national differences in approaches to, interpretation of, or enforcement of laws and regulations (e.g. labelling and IPR), as well as asynchronous approvals (Chapter 8). These differences may increase if, as expected, new products with additional features come to market, but they may also decrease if adoption of the technology and products becomes more widespread;

3 The CPB does not define biosafety. Judging by the scope of their primary laws and regulations on biotechnology, countries surveyed for Chapters 7-9 employed the term variously in relation to protecting agricultural or agricultural and wild biodiversity, or the "environment" as a whole (i.e. both the biotic and abiotic components of landscapes or ecosystems); they may or may not include human health in all its dimensions or one particular aspect e.g. food safety. For the purposes of these Chapters, the term biosafety refers to assessing and managing the potential risks to the environment and human health, including food and feed safety arising from R&D, use (contained and not contained), and marketing for food and feed uses of GM products and the processed materials derived from them.

- Related to the above, there are many social and economic issues surrounding the use of modern BFA. These require more complex ways of organizing the interplay between science, decision-making and society to address public concerns about risks and benefits. In any event, a number of international instruments, such as the CPB, specifically address the issue of public awareness and participation regarding GMOs (Chapter 9).
- Many of the tools and much of the biological information used for some of the biotechnologies considered at ABDC-10 have intellectual property and tangible property (IP/IT) protection (Chapter 9). Also, access to some genetic resources (particularly animals, micro-organisms and from plant and tree species not covered by the ITPGRFA) will inevitably be subject to bilateral access and benefit-sharing arrangements. In addition to private sector companies, public sector universities and research institutes as well as the international research centres of the Consultative Group on International Agricultural Research (CGIAR) increasingly seek IP/IT protection for the fruits of their research. All of these increase substantially the complexity of R&D management, can restrict "freedom to operate" and can be barriers to technology transfer and diffusion. As shown in Chapter 9, a range of options, including public-private partnerships, are available that may be useful for reducing such barriers.

Introducing any technique and product into the research mix is one thing – introducing it into the marketplace is quite another. Both require careful consideration and priority-setting. However, in view of the costs and the legal, scientific, managerial and other complexities involved, using some modern biotechnologies to develop products that will be released into the wider environment for producing foods and feeds for marketing nationally, and particularly internationally, does "raise the bar" very substantially in terms of identifying "opportunity" and justifying "need".

Countries have many options for tackling these challenges through public policy. The instruments they choose will be determined by the prevailing macro-economic environment, the structure of the sector, the legal and regulatory environment within which it operates, and the strength of their innovation systems (scientific, technological, marketing) including the regional and global links that support them. But choices will also be determined by vision, i.e. belief based on realistic analysis that if biotechnology is integrated appropriately with other science-based and traditional knowledge, then it will make R&D more efficient and farming more productive and competitive while not by-passing the most vulnerable in society.

While there is general agreement within scientific establishments and international bodies regarding the scientific principles underpinning most biotechnologies, positions between and within countries differ on a variety of issues connected primarily with applying genetic modification and using GMOs for agriculturally important species. These include their potential compared with other technologies and economic and social policy instruments for contributing to reduced hunger and poverty; their potential risks and the adequacy of the regulatory frameworks to deal with them; the roles of multinational companies and public institutions; the appropriate role of communities in decision-making; and their ethical dimensions.

Increasingly, developing countries and regional groups are beginning to "come to grips" with these and other related issues by pursuing dialogue with key stakeholders and ordinary citizens and developing longer-term policy and strategy frameworks and specific laws and regulations for using biotechnologies within their agrifood sectors. Some principles and examples of how some countries have gone about doing this are now described.

7.3.2 Purpose and content of biotechnology frameworks

The foundation for appropriate governance of agricultural biotechnologies is a comprehensive NBS framework. Research for this Chapter shows that most countries do not have a single "joined up" NBS. What they have is usually a patchwork of many sector and sub-sector specific policies and strategies overlaid by cross-sectoral frameworks at international, national, state and even local levels. There appears to be a general absence of overall responsibility and control, indecision, ineffective priority-setting and therefore a high likelihood of duplication of effort and wastage of resources.

As noted earlier, biotechnology cuts across several sectors and is of interest to a wide spectrum of stakeholders. Therefore, notwithstanding the need to develop policies, strategies and programmes that are aligned with those existing for the agricultural sector and tailored to meet the requirements of BFA, the governance of biotechnology at national level should be horizontal.

A NBS framework should provide a shared longer-term vision and a coherent and integrated framework for how government intends to work with key stakeholders to capture the benefits and deal with the challenges presented by agricultural biotechnologies, describing the core priorities and linking the key issues that emerge from the setting up of a national horizontal coordination mechanism. As such, it should cover the strategic goals that will support that vision, and the guiding principles that will be followed in the process of implementation. Each goal should have specific objectives and a set of actions/strategies to achieve these objectives. These can include actions already underway or new initiatives, and some objectives and actions can contribute to more than one goal. Objectives should be specific, measurable, achievable and time-bound with performance indicators against which progress can be measured.

In essence, therefore, a NBS sets out the roles and responsibilities of government in realizing the opportunities from biotechnology and dealing with the challenges it poses. These should be based on a detailed audit/inventory of the current situation nationally with respect to human, financial, and institutional assets, of national laws and regulations, and a detailed knowledge of international obligations and developments. All this helps to identify the specifics of where, why and in what areas biotechnology is important for the country's future development as well as what can reasonably be expected to be achieved over a given time period, such as 10 years. A NBS should also describe "who" will be responsible for "what" and how progress will be monitored and any necessary changes introduced. The NBS document should not be considered as "set in stone" but rather act as a guide that can be revised to take care of new technological advancements or unforeseen developments.

Putting all this together is a formidable challenge, requiring much effort to collect and analyse national baseline data and information, as well as information on how other countries have approached the issues in question. In addition to close interministerial coordination at scientific, technical, legal, administrative and financial levels, it requires the widest possible engagement with the public, including with representatives of farmer/producer organizations, private companies, NGOs, CSOs etc., the ultimate aim being "participatory decision-making" (Chapter 9). Bijker (2007) provides an excellent description of the key criteria for building policies via a policy dialogue and a methodology for carrying out a diagnostic study, emphasizing the importance of ensuring that the policies and strategies identified support institutional reforms, including greater cooperation at national, regional and international levels; strengthen national capacities; and identify new funding mechanisms.

7.3.3 Developing and approving national frameworks

The institutions involved in developing and approving the frameworks in the 15 selected countries analysed for this Chapter are shown in Table 1. Key features regarding the development and approval of these frameworks, as well as of those from the two countries that have prepared strategies specifically for BFA, are described in the Annex (Part 7.6.1). Most national biotechnology policy documents are available from the FAO biotechnology website[4] while other information was obtained from ISAAA's AfriCenter and from other Internet sources.

While there were several commonalities to the mechanisms established to develop these frameworks, the Annex indicates that there were also significant differences between the 15 countries – particularly with respect to the level and degree of cross-ministerial engagement, but even more noticeably in terms of involving or consulting non-ministerial and non-scientific entities in the process. For most countries, the process could be described as "top down" and lacking involvement of both industry and civil society groups. For most countries also, the NBS was directed at modern biotechnology and particularly at

[4] www.fao.org/biotech/country.asp

the governance of R&D and diffusion of GMOs and their products. Moreover, within that context, virtually every country stressed as a fundamental principle the importance or essentiality of protecting health and sustaining the environment as pre-conditions for success in applying biotechnology. Many also mentioned precaution, liability and redress, and labelling of GMOs and their products as important regulatory principles, with one country placing a moratorium on the use of genetic use restriction technologies (GURTs). Others emphasized the importance of integrating and protecting indigenous knowledge, resources and practices, and of benefit-sharing.

Countries took, or intended to take, one of three routes for approving their NBS documents, i.e. creating new primary legislation that embraced substantial elements of the entire document; obtaining full government approval for the NBS and, separately, creating primary or secondary laws and regulations to cover specific aspects e.g. on biosafety, IPR, funding instruments etc.; and obtaining approval from the ministry with lead responsibility for the issue and creating non-binding guidelines for specific matters.

A comparatively recent development in an increasing number of countries is the development of biotechnology policies and strategies at sub-national levels. An important policy issue for countries that have moved, or are moving, towards decentralized decision-making is therefore the extent to which powers are invested in sub-national governments and agencies to make laws or regulations with respect to R&D, technology diffusion, and local and international markets, and any risks to these markets associated with the introduction of e.g. GMOs.

7.3.4 Issues for policy consideration

Core government roles and responsibilities identified within most NBS frameworks were:

- coordination nationally, regionally and globally;
- strengthening the scientific knowledge base and scientific infrastructure;
- encouraging investment in commercial development (particularly Argentina, Brazil, Chile, China, Malaysia, Peru, Thailand and South Africa);
- providing strategic investments and other incentives to foster partnerships between universities, public research institutions and commercial companies (Argentina, Brazil, China, India, Malaysia, Peru, Thailand and South Africa);
- providing a regulatory system that is both transparent and effectively assesses and manages the risks from developing and introducing new and modified products while allowing innovation (all countries);
- introducing, reviewing and/or, if necessary, proposing amendments to laws and regulations concerning intellectual property and access to and benefit sharing from plant and other biological resources (all countries with reference to GMOs);

- fostering community understanding about biotechnology by improving access to understandable information and providing the means by which citizens can express their views;
- providing opportunities for considering cultural and ethical issues (some countries).

How the countries concerned proposed to deal, or have actually dealt, with each of these issues forms the basis of much of the remainder of this Chapter and the two following Chapters. An attempt has also been made to identify "gaps" or "areas in need of further attention" within each of these themes both nationally and internationally (regionally and globally). However, although many countries have established biosafety frameworks (see Chapter 8), very few countries have actually prepared NBS frameworks and even fewer have done so for BFA, leaving considerable scope for the remainder to consider their options on both fronts.

7.4 GOVERNANCE STRUCTURES AND ORGANIZATION

7.4.1 Leadership and coordination: principles and options

Because of its inherently science-driven character and with applications across a range of sectors and activities being undertaken within different jurisdictions, successful governance of biotechnology requires policies and strategies that address all stages of the innovation chain, i.e. from fundamental through to adaptive research, from there to the development of tangible products and then on to their diffusion to end users, i.e. both farmers and consumers. This, as well as related trade issues, requires coordination across governments, across government departments, with sub-national governance structures as well as with other governments via bilateral, regional and multilateral mechanisms.

Without active and specific government-level intervention, individual development sectors (including sectors within food and agriculture) are unlikely to coordinate effectively, including for dealing with issues that require reconciliation. Government coordination is clearly appropriate also from an efficiency perspective, as a total government approach reduces duplication, enhances consistency of work and should facilitate more effective international networking and formation of strategic alliances by putting out a single consistent message. It could also facilitate investment by donors, private companies, and national and regional investment banks, thereby facilitating achievement of other policy/strategy objectives.

Coordination, horizontal as well as vertical, is therefore essential for a comprehensive and balanced policy on biotechnology, the key issue being to ensure that whatever approach is taken within each will be effective in achieving concrete objectives which should include:

- reinforcing the importance of biotechnology as a government priority;
- providing leadership in developing and implementing relevant laws, regulations, policies and practices;
- integrating strategies and activities and avoiding duplication of effort;
- ensuring that initiatives advance a common vision and do not work at cross purposes;
- informing and educating government officials and the public.

Horizontal coordination

While the options for a horizontal coordinating mechanism include a national working group, commission, council or task force with a coordinator, the most important consideration is that its composition is organizationally sound i.e. interministerial and engages those ministries that form the nucleus of competencies involved in a coordinated response. Inclusion of the Economic Ministry would improve understanding of biotechnology and the role it plays, or could play, in economic development and for maintaining dialogue on budgetary issues. These links would also be vital for advocating increased budgetary allocations.

One issue that has an important influence on the effectiveness of a horizontal coordinating mechanism is its reach. Irrespective of the number or identities of the ministries involved, the officials serving on a horizontal coordinating mechanism will only have some of the competencies, jurisdiction and expertise needed to successfully coordinate biotechnology efforts, and it is therefore important to determine how to involve others who are not at the table. This will be a major challenge since jurisdictions and competencies among and within ministries may overlap while at the same time being highly specialized and compartmentalized.

Another factor to be considered is the scope of its work. The distinction between working at policy and at the operational level is a significant one, although the lines between the two are often blurred. The policy level relates to establishing, strengthening and coordinating the overall legal, regulatory, institutional and strategic frameworks used to plan and implement biotechnology. The operational level, on the other hand, is geared towards building or enhancing the professional capacities and effective implementation of service providers, e.g. NARS, universities, regulatory bodies, NGOs, CSOs.

While countries have the option of separating these roles and responsibilities, a fully functioning horizontal coordinating mechanism should be able to develop, support and advance both policy and operational elements of the government's NBS framework. This makes the structural challenge all the more demanding since the coordinating body needs to be able to accommodate and bridge distinct but overlapping policy and operational activities even though these may be organized in different ways in the relevant offices by different nations (for example, when "agriculture" is covered by separate Ministries for Agriculture, Livestock, Fisheries and Forestry and, as noted earlier, when Ministries of Environment, Trade, Natural Resources etc. engage on specific issues).

Also, although setting the membership of a horizontal coordinating body at a sufficiently high level to have policy decision-making authority will increase the likelihood that coordination will be effective at the level of national policy, it has to be recognized that ministers themselves or high level ministerial representatives such as permanent secretaries are unlikely to be engaged in, or responsible for operations, on a day-to-day basis. In practice, therefore, it is the work of lower ranking officials (heads of departments, directors of research institutes, university faculty heads etc.) who have these responsibilities for planning and implementing specific programmes, projects and activities that need to be effectively coordinated.

If the coordination mechanism does not have the official authority to provide policy leadership or engage in operational decisions itself, but primarily gives advice to those who make those decisions, then it can be weighted more heavily towards individuals possessing technical expertise who are not necessarily policy and/or operational decision-making officials. One option then is to delegate much of the work of the high level interministerial mechanism to a more technical mechanism that provides information to all the relevant offices and officials within each of the represented ministries and in the government, thereby making it possible for them to be involved and coordinated.

Vertical coordination

Setting up working sub-groups to incorporate some of the broader range of expertise needed is one mechanism. Since efforts to promote responsible development of biotechnology centre on planning and delivery at the sectoral level, an appropriate action by government would be to direct sector ministries to work with their stakeholders and other interested parties by setting up a vertical coordination mechanism based on sub-groups to refine or develop sector–specific strategies and plans. As noted earlier, only two developing countries appear to have done so for BFA, although it is possible that others have embedded these in national S&T frameworks.

Because not all of the relevant competencies, expertise and perspectives that are needed to respond most effectively and appropriately to the opportunities and challenges posed by biotechnology reside within government or a particular ministry, there are important roles to be played by NGOs, the business community and other partners from civil society within coordination mechanisms. Recognizing this, some relevant international treaties (e.g. the CBD) contain specific provisions calling for coordination, cooperation or strategic partnerships with NGOs and CSOs in the process of developing national coordination mechanisms, strategies and other components necessary for pulling together measures and activities. This aspect is expanded upon later, but it is part and parcel of engaging all relevant stakeholder groups in providing inputs to the development and implementation of both a NBS and a strategy for BFA that is consistent with the NBS.

Analysis of the 15 selected developing countries (Annex, Part 7.6.2) shows that while all governments recognized that no single ministry could hold all responsibilities in moving their national agendas forward, and therefore the need for effective inter- and intra-ministerial coordination and decision-making, in only a few cases have new formal structures been established or proposed to oversee biotechnology's development and in very few cases do these appear to involve collective government.

In most countries, the option chosen was to assign responsibility for implementation as an "add-on" to the ministry assigned to lead development of the framework (normally the Ministry of S&T), with no indication given about delegation of responsibility for specific areas such as BFA or for bringing policy issues to the "top table" for discussion and decision-making.

A further gap seems to exist in countries with federal and local systems of governance, i.e. the lack of a specific national forum for coordinating policy, raising the distinct danger of, e.g. policy and funding overlaps and production and trade distortions.

In the case of the African Union, an African Ministerial Council on Science and Technology was set up as the overall governance body to provide political leadership and make recommendations on policies while the AU Commission and the NEPAD Office of Science and Technology are responsible for mobilizing financial and technical resources to implement programmes and projects.

7.4.2 Independent advice: Principles and options

Institutional arrangements are needed at all levels of government to advise on both generic and specific biotechnology issues and ensure that appropriate government or ministerial responses or actions can be established which are both cost-effective and expeditious. There are many options available in terms of roles and responsibilities, size, terms of appointment and range of expertise. Membership should, however, be based on individual expertise, knowledge and experience. It should be "balanced", i.e. represent a broad spectrum of society including science, private sector, further education, law, ethics, etc., and it should engender trust, credibility and inclusiveness.

Issues should be addressed in an inter-disciplinary manner and there should be opportunities to introduce emerging issues such as the role of biotechnologies in mitigating climate change, dealing with avian influenza etc. In addition, the committee should meet regularly (say twice annually), be prepared to provide *ad hoc* inputs between meetings and its reports should be made widely available. Appointment should be through a nomination and selection process agreed by the members of the horizontal and vertical coordinating mechanisms as appropriate.

Options for advisory structures include:

- an individual acting as chief scientific advisor to the Head of State or to the government and chairing a broad-based panel of well-respected individuals;

- establishing permanent advisory committees within sectoral ministries;
- dealing with specific/emerging issues through *ad hoc* committees;
- engaging the expertise available within a national science academy or research council, one of whose roles is to ensure that the best possible evidence and advice are available to policy-makers.

While some of the 15 selected developing countries established an independent biotechnology advisory committee or council to provide strategic policy advice to government, more often the mechanism was set up to advise an individual ministry or department (see Annex, Part 7.6.3, for details). Concerning the representation of NGOs and CSOs in advisory mechanisms, there was no evidence for this having been done or intended in any of the countries reviewed. Only Argentina appeared to have set up an advisory mechanism to cater specifically for food and agriculture, the remaining countries relying on a broad-based/horizontal mechanism reporting to government or more often to the Ministry for S&T. Other countries should consider their options for obtaining more focused advice relating to BFA rather than leaving this up to "generalists".

7.5 SETTING PRIORITIES FOR R&D

7.5.1 At the level of government

Agricultural research can provide high returns on investments but, as noted earlier, investing in biotechnology can be an expensive business. Because the demand for research outstrips the available resources, priority-setting involving biotechnology in general and specifically for BFA is arguably the biggest challenge faced by government and sectoral level policy-makers, particularly if the goal is to tackle hunger and poverty in rural areas.

Priority-setting is fraught with difficulties due to the widespread lack of credible socio-economic information (e.g. about where poor people live, their vulnerabilities and livelihood strategies), and because many priority-setting processes lead to decisions that tend to be *ad hoc* and occur more by chance than by well-founded choice. Priority-setting is also value-laden and there is no consensus either about the values or the criteria that should guide it. For example, although relevant, cost-benefit analysis should not be the only approach when dealing with "pro-poor" technology choices, since this would almost certainly bias investments towards commercial crops and high potential areas.

Priority-setting reflects the values of the people and institutions involved and apart from lack of information, the major challenges in trying to "get it right" involve overcoming the disconnects between who is setting priorities, and who should be setting them; between the values that are driving priority-setting and those that should be; and the limited capacities of the institutions and people who are making decisions.

As the principal funder of public research institutions, the government's main business is to maximize the effectiveness of its investments in building and sustaining national capacities to produce innovations that benefit society. It should therefore have a more outcome and impact-oriented approach to the governance of R&D than, for example, the typical university and research institute approach which is geared towards outputs of scientific publications (and in biotechnology, increasingly of patents). As such, government level policy-makers should ensure that research investments are closely aligned to national development priorities and that both structures and transparent and fair mechanisms are in place not only for selecting, funding and monitoring research performance but also for improving priority-setting.

A number of approaches can be considered. One is to establish a national system of biotechnology statistics and indicators to inform policy actions, bearing in mind that this should include more than data about biotechnology R&D (e.g. funds allocated, number of researchers involved). Data on, e.g. productivity improvements, environmental impacts and socio-economic benefits are also required. The first step in this process is to define the term biotechnology, a list-based definition being probably the most useful when the policy interest relates to benefits (e.g. Van Beuzekom and Arundel, 2009).

Another strategic direction is to set up reliable systems for biotechnology foresight, to monitor and assess the relevance for national agricultural and rural development of global patterns of technological change as well as demand from both home and export markets for biotechnology products including market potential, acceptability by users and consumers, and pricing. This helps guide formulation of technology policies and strategies. Currently, only some industrialized countries appear to have such systems in place.

A third approach is to introduce instruments that encourage the transformation of traditional research institutions and related higher education centres from "silos" of often pure discipline-oriented activity into innovation systems that put a premium on multi-disciplinarity and networking and a much greater number and diversity of actors. Of the developing countries reviewed, only Argentina, Brazil, China, India and South Africa signalled their intention to move in this direction and, as illustrated in Chapter 8, have actually done so. Other countries were silent on such initiatives.

7.5.2 For biotechnologies in food and agriculture

7.5.2.1 Strategic considerations

Although not specifically addressing priority-setting for BFA, the papers by Hazell and Haddad (2001), Byerlee and Alex (2003) and Meinzen-Dick *et al.* (2004) provide many useful pointers for making pro-poor investments in agricultural R&D and should be consulted for further information.

As noted earlier, essentially all countries have accorded high priority to BFA in their NBS frameworks and, in these and very many more countries, research institutions and university departments are increasingly undertaking biotechnology research in fields relevant to food and agriculture (see e.g. FAO, 2005; Cohen, 2005; Spielman, Cohen and Zambrano, 2006). In many cases, the research appears fragmented, uncoordinated "horizontally" with other national biotechnology initiatives, and "vertically" within agriculture or one its sectors, e.g. plant breeding and seed production systems, and internationally. In other cases, the range of activities being pursued is so vast and resources thereby so widely and thinly spread that the attainment of successful outcomes within a reasonable timeframe has to be seriously questioned. Clearly, most countries do not seem to be prepared to make critical choices about their investments in BFA, reflecting no doubt absence or insufficient rigour in priority-setting, and perhaps undue influence from donors, supporters of particular technologies and scientific journals.

Of course, all the technologies being used within the confines of laboratories or experimental stations could potentially play a role in improving productivity, incomes and trade and thereby contribute to reducing food insecurity and poverty. But what was the rationale behind their introduction?; who asked for them?; what was the process that led to their initiation?; what steps were taken to assess the need for, and to identify, partnerships to achieve the project's aims?; how will the R&D and subsequent transfer to end users be conducted and funded?; how will the risks be managed and the benefits captured by those who need them most – directly, or indirectly by "trickling down" from others able to capture them earlier?; were regulatory (environmental, food/feed safety and IPR) implications considered before the work was started?

These are questions not normally requiring answers from scientists, but they are questions for which convincing answers are needed to produce and transfer technologies that are supposed to improve livelihoods irrespective of whether the products are being developed and disseminated by public and/or private sector entities. Answers to these types of questions are critically important for setting priorities for R&D. If the research simply "bubbles up" through the initiative of an individual researcher rather than being embedded in a more structured and hunger/poverty outcome/impact-driven process that involves not simply the public sector but also the private sector and, e.g. voluntary organizations, the possibility of anything coming out of it by way of contributing to "pro-poor growth" is remote indeed.

This is not to imply that more fundamental and curiosity-driven research is unimportant or that biotechnologies used in laboratory settings (or, for example, as penside tests by agricultural protection and extension agents) are not worthwhile. In fact, probably most biotechnology research aims to generate innovative intermediate products, protocols, markers, information, and new "tricks" for getting answers to research questions etc. that can be used by other researchers, rather than products that can be taken up directly by farmers and government and private support services. Diagnostic and genetic characterization tests/methods certainly have a proven track record for improving disease surveillance and control by increasing the efficiency of tackling some national, regional and global constraints. The virtual eradication of rinderpest using vaccines supported by immunoassay and molecular diagnostics is one excellent example. Rather, it means that in setting priorities, decision-makers have to decide on research entry points appropriate to different national objectives (basic or applied research?; cell or tissue culture?; immunoassay or molecular methods?; molecular or other markers?; rDNA or other methods for developing new plant varieties, animal vaccines, bacterial strains etc?), bearing in mind that producing scientific knowledge is one thing but having it absorbed and appreciated by society is something else.

A related strategic policy consideration is to ensure adequate breadth in the R&D portfolio and thereby an appropriate balance between what's available and can be relatively easily applied through local adaptation (e.g. immunoassays for some animal and plant diseases; cell and tissue culture methods), and what needs more upstream, and therefore much longer-term, work but which may make the research enterprise or service more efficient and the products potentially more useful to beneficiaries (e.g. molecular markers, GMOs). The point here is that despite the claims of some scientists and commentators, there is no reason to believe that, in the absence of much smarter policies and institutions for development, diffusion and possibly regulation, the uptake of any new technology (including GM crops with their claimed advantage of shorter development timescales relative to traditional breeding methods), will generally be other than slow and incremental (see Pardey and Beintema, 2001; Nightingale and Martin, 2004). That said, and as demonstrated by Bt cotton in China and India, with supportive policies some technologies can be taken up very rapidly indeed if beneficial to farmers and their communities.

A further fundamental consideration is ensuring that priorities for public sector engagement in R&D take due account of which technologies can or will be developed exclusively by, or in partnership with, local or international private sector companies. The strategic importance of ensuring an appropriate "division of labour" between the public and private sectors has been highlighted by Byerlee and Fischer (2001) and Naseem, Omamo and Spielman (2006). Although rapidly evolving, particularly in relation to plant breeding (FAO, 2004) and poultry production (Narrod, Pray and Tiongco, 2008), and therefore requiring continuous adjustment to the scope and intended beneficiaries of public goods research interventions, trends in financing agricultural R&D by developing countries coupled with the generally low investment of the private sector in all but a handful of these countries suggest that without significant government inducements, the role of private sector R&D and delivery systems will remain limited particularly for small-scale/subsistence farmers in marginal areas.

The reasons for this include the strengthening of IPR on biological innovations (Chapter 9), and because private R&D investments will be largely directed at medium- and large-scale commercial agriculture (especially export crops, fruits, vegetables, flowers, aquaculture and livestock products) and food processing. Also, some technologies – particularly the key platform technologies employed in genetic modification, disease diagnosis and molecular analysis which are needed for downstream and adaptive research – are controlled by private firms. Most of these are not applied to the crop or animal-trait or disease combinations important to small-scale and resource-poor farmers, and therefore there is substantial "space" for the public sector to engage in pro-poor biotechnology R&D by complementing and not duplicating or substituting for private initiatives and filling gaps relevant to the poor who cannot pay. It does, however, mean that the NARS are going to have to largely "go it alone". This reality has substantial policy implications for governments, not least of which is the need to decide on the emphasis to be placed on "home grown" production/self-sufficiency of particular commodities, and on the proposed beneficiaries of R&D investments.

Some argue that by putting the emphasis on local rather than national problems and on small-scale farmers, the "pay off" from R&D investments in biotechnologies in terms of aggregate poverty and hunger alleviation would be compromised, and that other "social" policy instruments would be more appropriate for tackling household food insecurity particularly in resource-poor environments. On the other hand, there is now growing pressure to change research strategies and target research on the production systems within disadvantaged regions to generate direct benefits for the poor.

This pressure is both political and, in some situations, justified on the grounds that the combination of market liberalization and private sector investment is already reducing the need for continued public sector research investment (e.g. in areas most relevant to commercial farmers). Are these issues being factored into national and international R&D priority-setting processes? For example, in addition to the small number of well-known major global crops such as maize, rice, wheat and cotton, many more crops are regionally and nutritionally as important (if not more so) for poor farmers and households (examples include sorghum, millets, bananas and plantains, roots and tubers like cassava and yams, groundnuts and indigenous crops like tef and quinoa). These under-researched "orphan" crops are nutritious, well adapted to harsh environments, and genetically diverse and have great potential for improving food security, livelihoods, cropping system stability and genetic diversity. Is the biotechnology being considered targeting the crops and animals of small-scale and poorer farmers and their traits of interest?

Yet another challenge is setting priorities between agricultural sectors, e.g. between crops, livestock, aquaculture and forestry. Here again, although not by any means suggesting that R&D on crop biotechnologies is even close to adequate, policy-makers should be aware that livestock and livestock products now constitute 40 percent of global agricultural GDP and that in many countries forestry and aquaculture are assuming increasing importance. Irrespective of whether one or a number of ministries is responsible for "Agriculture", a collective decision-making forum for priority-setting and resource allocation for R&D within or between the ministries involved would seem appropriate. As noted later, a number of countries are beginning to establish such mechanisms for dealing with regulatory issues, but no country seems to have a similar forum for biotechnology priority-setting across the agrifood sector as a whole.

Clearly, the potential for R&D to reduce hunger and poverty will be strongly influenced by the types of farms and production systems and by the strength of the research, extension and higher education institutions available. In addition, its focus should be directed at areas where the largest number of poor people live and respond to their vulnerabilities and livelihood strategies (FAO, 2007a). For subsistence farmers, this means reducing production risks for staple food and feed crops for home and on-farm livestock/fish consumption and encouraging marketing of higher value crops, milk, eggs, fish etc. Is the biotechnology package being considered "matched" to the location, livelihoods and vulnerabilities of the people living there and engaged in agriculture (farmers/livestock keepers/landless labourers), and do these locations intersect with high levels of hunger and poverty?

This type of information then needs to feed into a process that considers all the technical options available for dealing with the issue(s) in question. Depending on the level and source of investments being considered, this may require a team of competent economic and social analysts to conduct an *ex ante* impact assessment, supported where possible by *ex post* assessments, to assess whether a particular biotechnology "adds value" to more conventional (and probably lower cost and technically less demanding) R&D approaches for improving livelihoods through productivity or quality enhancements; the effectiveness of government or private services; and the returns on government investments.

Particularly, but not only for GMOs and derived products, this *ex ante* assessment should also take account of socio-economic issues like IPR and the associated costs and assumptions concerning user and consumer acceptability nationally and internationally for commodities earmarked for trade. Also, there is a need to consider the additional skills and infrastructure to cover possible R&D as well as post-release costs of biosafety and food/feed safety regulations. Have these costs/issues been assessed and factored into the research agenda/priority-setting exercise?

7.5.2.2 Assessing impact

Several methods are available for conducting impact assessments, most of them feeding into top-down approaches, but some can be adapted to bottom-up mechanisms. The most common are:

- **Precedence**: uses previous funding levels as the basis for the next programme cycle; quick, not to be recommended, but all too common;
- **Congruence**: ranks alternative themes on the basis of a single criterion; quick, demands very little data, questionable rigour;
- **Weighted scoring**: ranks alternative programmes and projects by identifying and weighting multiple criteria; easy, does not require advanced quantitative skills, relatively transparent, promotes multi-disciplinarity and stakeholder involvement. The analytical hierarchy process (Braunschweig, 2000) is one variation of this. It involves breaking the decision problem down into a number of more easily understood sub-problems. These elements are then played off against each other in pairs using both evidence-based and subjective data, and with uncertainty in cost, benefit etc. The essence of the approach is that human judgements and not just hard factual data are used to inform decision-making;
- **Cost-benefit analysis methods**: widely used, the simplest involving examining the streams of both costs and benefits of a particular technology in financial terms only. Another approach takes into account the costs of alternatives;
- **Economic surplus models**, such as the Dynamic Research Evaluation for Management (DREAM) model (Alston, Norton and Pardey, 1998), are also available to guide priority-setting based on the expected financial return to investments from research or uptake of a particular technology. The economic analysis by Foltz (2007), supporting priority-setting for investment in modern biotechnologies to deal with biotic and abiotic constraints to crop production in countries in West and Central Africa, is an excellent example of this approach. Similarly, Vitale *et al.* (2007) have employed the approach to assess the economic impacts of introducing Bt technology in smallholder cotton/maize production systems in Mali, concluding that the use of the technology in cotton would have a much higher priority than in maize due to the price differentials between these crops, and the fact that farmers spray cotton but not maize for controlling insect pests – a conclusion consistent with studies conducted elsewhere (Brookes and Barfoot, 2005). This approach requires a great deal of data, is done independently of stakeholder input and, while appropriate for ranking benefits from research or user uptake from particular commodities, it is not well suited to ranking upstream research or bringing in social issues.

Traditional economic impact studies make important contributions to decision-making on the appropriateness and priority to be given to different technological approaches, but they do not take into account their environmental, human health, food insecurity and poverty dimensions (Falck-Zepeda, Cohen and Komen, 2003; Hazell, 2008; IAASTD, 2009). Falck-Zepeda, Cohen and Komen (2003) have suggested a "sustainable livelihoods" approach to examine the context in which poor people live in a rural community. It includes issues of vulnerability, natural, physical, financial, human and social assets that are valued by the community and how policies, institutions and processes affect the use of, and access to, these assets in pursuing different livelihood strategies. Simulation models such as computable general equilibrium models (Lofgren, Harris and Robinson, 2002; Dorward *et al*., 2004) are increasingly being used for tasks ranging from the collection and analysis of socio-economic data to the conduct of model-based policy simulations. These could also respond to some of the constraints associated with economic-based models and to the need for combining social and economic data in biotechnology R&D decision-making. However, like the sustainable livelihoods approach, data requirements are substantial.

Getting well grounded information and answers using one or a combination of these methods is important. Yet, the methods themselves should not drive the process – they should inform it. They should not be used to replace sound judgement, experience and ingenuity or to leave so little room for manoeuvre that freedom to explore new avenues is inhibited. Nevertheless, impact assessment should be part and parcel of priority-setting process and of the overall research evaluation and management systems within research organizations, and therefore should be institutionalized throughout. Further information on impact assessment for agricultural research is available elsewhere[5], while Anandajayasekeram *et al.* (2007) provide specific examples of using these methods in an African context.

7.5.2.3 Other considerations for R&D priority-setting

These include the current status and likely future strength of the national breeding, management and disease/pest control programmes for the crops, trees and animals in question and for processing their products, bearing in mind that the biotechnologies being considered would normally complement rather than fully replace the technological package available to the farmer or used by the plant protection and veterinary services; and in the case of improved genetic traits, that these would need to be "added on", singly or more likely combined, to local germplasm containing other agronomic traits valued by farmers and rural households (e.g. higher yield, tolerance to drought, resistance to other diseases or pests, high nutritional value, better cooking quality etc.) and not included in the new technology itself.

5 http://impact.cgiar.org/

They also include the delivery systems for the technology in question and their sustainability. How and by whom will the new technology be disseminated? Is there a formal market for seeds or planting materials of the crops concerned or for the semen, embryos, chicks and broodstock for the livestock and aquaculture enterprises? Will dissemination be carried out by public agencies, the private sector, NGOs or the local community? Pointedly, in Cohen's (2005) paper dealing with GM crop development in a range of developing countries, few of the research groups surveyed had considered how their products would be diffused to farmers, let alone identified partners for doing so.

Another consideration is the national and international "science and technology landscape", to decide, for example, whether to rely on spillovers from R&D conducted through other national or international initiatives or engage actively in the entire basic-applied-adaptive research continuum, the decision on which to choose being determined by the assumptions made about the "strings attached" to each (see Chapter 9). Information that has to be gathered here includes availability of the technology; who owns it; best guesses of the effort, time and costs to develop it from scratch or adapt it for local use; interest of, and conditions for, private sector investment in the required R&D, mechanisms of product delivery and skills in its use through partnership with the public sector and availability of policy instruments to encourage such partnerships (Chapter 8); and acceptability of the product to farmers and communities in terms of both price and cultural considerations.

In relation to costs of GM crop development, Manalo and Ramon (2007) estimated the cost of developing MON 810 Bt corn in the Philippines from the confined greenhouse stage at US$2.6 million. Costs in the United States which preceded the work in the Philippines (i.e. for gene discovery, making the gene construct, introgression of the gene, selection of transformed plants, laboratory and greenhouse testing, confined field trials, multi-location field trials) were US$29 million. Over 65 percent of the costs in the Philippines were for meeting government regulatory requirements. Other estimates of regulatory costs include those for virus resistant papaya and herbicide resistant soybeans in Brazil (US$700 000 and US$4 million respectively, in the latter case due to requirements for animal studies), and US$160 000 for insect resistant maize in Kenya (Atanassov *et al.,* 2004). Also, a study of regulatory costs in 10 countries concluded that the cost of introducing a GM trait can range from US$6–15 million (Kalaitzandonakes, Alston and Zilberman, 2007). These costs will, of course, be heavily dependent on national regulatory requirements (Chapter 8).

Also, the introduction of GM crops (whether obtained in the form of the owner's protected variety, by backcrossing this with a local well-adapted variety, or by introgressing an imported or local gene construct into a local variety), will inevitably involve charging farmers a "technology fee" – in effect, a higher price for the seed. The price at which this is set will influence both adoption rates and social welfare benefits and will vary with the profitability of the crop, in general being higher for industrial/export crops than for traditional subsistence crops (see, for example, Vitale *et al.,* 2007). At the same time, consideration needs to be given to the issue of collecting technology fees. Inability of technology owners to collect these at the time of seed sale due to lack of appropriate IP laws or their enforcement (see Chapter 9) could significantly affect estimates of social and economic benefits.

Policy-makers must therefore consider these and other cost, price and benefit variables when setting priorities for BFA development and diffusion but few, if any, of the *ex ante* approaches currently available build assessment of these costs into models of cost-benefit analysis.

It is also important to stress here that technologies described by some scientists as being on-the-shelf, simple or quicker, are nevertheless new for many countries and can require substantial and consistent investments in building knowledge, know-how, infrastructure etc. to adapt and use them appropriately within local contexts. Policy-makers should be aware of the tendency of some academics, the biotechnology industry and some governments to exaggerate the ease of developing and commercializing technology and transferring it between countries and institutes.

Advanced biotechnologies in general, and GMOs in particular, have not been immune from inappropriate expressions of optimism. For example, the costs and time savings involved in establishing traits through genetic modification in crops compared with conventional breeding are sometimes exaggerated. It took approximately 16 years from the cloning of the first gene coding for the Bt toxin until the commercialization of maize Bt hybrids (Goodman, 2004). While advances in genomics and breeding technologies may accelerate that process, since most traits that would be useful for farmers and consumers are polygenic, the tasks of finding, cloning and inserting the requisite gene combinations, and more particularly getting such products through regulatory processes, may not be any quicker or less costly than introducing, for example, an already well established trait for insect resistance.

In summary, priority-setting ultimately comes down to assessing the appropriateness of the technological packages being considered, i.e. their technical feasibility, economic viability, social acceptability, environmental friendliness, relevance to the needs of farmers, consumers etc. – issues that inevitably vary over time and space. Assessing appropriateness requires capacity to identify and make hard choices among the many critical problems facing rural communities that can be addressed better with biotechnologies than by taking other approaches. This, in turn, depends on the quality of the background information available, the methods used, and who participates, and how, in informing decision-making.

Priority-setting therefore requires a comprehensive approach for assessing the technology itself and its transfer to end users, and in so doing takes account of both its functional and institutional dimensions. The results will always be speculative, open to uncertainties and different interpretations and certainly cannot be extrapolated reliably from one country to another or even from one location to another within a country. It is therefore important to review results against studies from other countries with similar and different socio-economic conditions. Rigour can, however, be improved by considering the results of *ex post* impact assessments, and in both cases by comparing the proposed biotechnological with the conventional package.

Given the paucity of information about the long-term costs, benefits and risks associated with essentially all biotechnologies, especially for the rural poor, and particularly the conflicting conclusions reached by different authors concerning GM crops (Smale, Zambrano and Cartel, 2006; Smale *et al.,* 2009; IAASTD, 2009), new approaches are needed to assess (and compare with conventional approaches) the likely impacts – social as well as economic, immediate and long-term, positive and negative – of all major modern biotechnologies used in food and agriculture.

Priorities should be need and demand-driven, and decisions therefore based on national priorities and policies for agricultural and rural development and wider food security. Nevertheless, in most countries research priorities for BFA are still neither examined nor defined systematically, and much still needs to be done to accelerate priority-setting methods at national and institutional levels.

Government policy-makers should encourage the introduction within their NARS of more rigorous and participatory mechanisms and methods to inform decision-making on these matters, including allocation of resources through specific programmes, projects and activities. Possible mechanisms for doing so are presented in Chapter 8.

Regional research organizations and the CGIAR could also foster more systematic priority-setting for BFA by focusing on capacity building and advocacy, possibly through a web portal and community of best practice to promote appropriate methods. Related to this, it is important that methodologies are developed to improve impact assessment practices for biotechnological products based on economic, environmental and social data, particularly for smallholders in disadvantaged areas.

7.6 ANNEX: The processes of developing, approving and overseeing biotechnology policy/strategy frameworks and of providing independent advice in selected developing countries

7.6.1 Development and approval of NBS frameworks

7.6.1.1 National frameworks

Leadership

In some countries, the process was led "from the top", i.e. by the Prime Minister and/or through setting up a "high level" (i.e. interministerial) coordination mechanism (team, council or committee) involving a lead minister or permanent secretary (normally for S&T) with participation of Ministers/Secretaries for Agriculture, Health, Education, Environment, Finance, Trade and, in some cases, Foreign Affairs and Justice. This was done by Brazil, Chile, India, Malaysia and Thailand.

In the other countries, there appeared to be no formal interministerial coordination. Rather, the process was assigned to the Ministry of S&T or similar and from there to one of its constituent entities, e.g. National Council for Science/Research Council. Examples of this approach include Kenya and Uganda.

In most countries, the NBS was prepared only very recently, but some national biotechnology policies go back many years and have been updated as the technology evolved. In the case of China, biotechnology first emerged in 1977 through the declaration of the Four Modernizations as its State policy. Here, biotechnology was a focal point of the country's S&T development programme and agricultural biotechnology perhaps the most important component. The first policy document on the subject (the National Biotechnology Development Policy Outline) was prepared in 1985 and revised in 1986 at the beginning of the "Seventh Five-year Plan" under the leadership of the Ministry of S&T, the State Development and Planning Commission and the State Economic Commission and approved by the State Council in 1988 (Huang and Wang, 2002).

In the case of India (see Chaturvedi, 2005), originally a National Biotechnology Board (NBTB) was set up chaired by a Science Member of the Indian Planning Commission with representation from almost all the S&T agencies in the country. It produced a Long Term Plan in Biotechnology for India in 1983 outlining priorities for achieving national development objectives. Later, the NBTB graduated to the Department of Biotechnology within the Ministry for S&T and together with other agencies it coordinated development of the current National Biotechnology Development Strategy.

Developing the draft policy/strategy

In countries that set up an interministerial mechanism, responsibility for drafting the NBS was assigned to a 10–20 person task force, advisory/steering committee, consultative group or expert panel. This included representatives from key departments within ministries, universities, research institutions, science funding bodies, private foundations, industry and, in some instances, civil society and consumer groups. In some cases, separate working groups were established to lead consultations and report on specific topics (e.g. R&D, communication) and sectors (e.g. agriculture, health, environment, industry). For example, in Thailand, six sub-committees were established under the National Biotechnology Policy Committee to obtain inputs and draft the document, and a further sub-committee dealt specifically with genetic modification and biosafety policy development.

Some countries (e.g. Malaysia, Malawi, South Africa and Zambia) brought in outside consultancy organizations, development partners or individuals to assist the process. Others (e.g. Argentina, Brazil, India and Uganda) provided opportunities for consultations at state, regional or provincial levels, while some countries (notably India) also solicited public comments by placing their draft strategies on the Internet, while Chile sought the views of parliamentarians and experts. In other countries (Jamaica, Kenya, Namibia and Uganda), the tasks of both coordinating inputs and drafting the document were undertaken by the National S&T/Research Council or similar.

NBS scope

While a number of countries (e.g. Jamaica, Kenya, Malawi and Uganda), emphasized that the policy/strategy applied to both conventional and modern biotechnologies, in the majority of cases, and although not specifically stated (except in the case of Namibia and Peru), the thrust was clearly toward modern biotechnology and particularly the governance of R&D and diffusion of GMOs and their products.

NBS content

Despite the wide differences between countries in terms of population, economic strength, scientific and technological capabilities and cultures, there was a remarkable consistency to their vision of biotechnology as contributing to social and economic development by improving productivity, creating jobs, promoting health and a better environment. However, a specific vision statement was provided by only five countries, namely India, Malawi, Malaysia, Thailand and Uganda.

In terms of overarching principles, virtually every country stressed the importance or essentiality of protecting health and sustaining the environment as pre-conditions for success in applying biotechnology, and many stressed public participation. Malaysia stressed the importance of strong IPR protection while the precautionary principle or approach was mentioned as a cornerstone to regulation by many countries as was liability and redress (e.g. Malawi, Namibia, Uganda and Zambia). Many included labelling of GMOs and their products (e.g. Malawi, Thailand), and Namibia put a moratorium on the use of GURTs. Brazil, Kenya, Peru and Uganda mentioned the importance of integrating and protecting indigenous knowledge, resources and practices, and of benefit-sharing. The priority sectors identified by the majority of the countries were health, agriculture, industry (and trade) and the environment.

R&D and communication were cross-cutting themes included by all countries. Many countries included bio-resources (specifically biodiversity in only a few), education (also of the general public), and ethical, cultural and socio-economic issues, although little or no detail was provided by any country as to how exactly such considerations would be included in decision-making and what mechanisms would be set up to address them. Except in the case of Uganda, promoting gender equality was a non-issue in all documents.

With respect to agriculture itself, most countries dealt with it in an integrated "across the board" manner (i.e. covering crops, livestock, forestry, aquaculture), while some emphasized particular areas of interest (e.g. aquaculture, fruits and forestry in Chile), crops resistant or adapted to drought, pests, diseases and climate change (Brazil, India and Kenya), livestock vaccines, diagnostics, feeds, drugs and reproductive technologies (Argentina, Brazil, India and Kenya), biopesticides and biofertilizers (Kenya), and the creation of bio-industries from crop and animal by-products (Argentina, Brazil and India).

Apart from the national BFA strategy documents developed specifically by Argentina and India (see below), the plans outlined by Kenya, Uganda and Malawi are also almost exclusively or heavily directed towards BFA and related issues. Kenya's strategy, for example, covers the crop, livestock and fish/aquaculture sub-sectors, while those of Uganda and Zambia have a heavy bias towards crops and towards micropropagation (and particularly GM crops in Uganda), although both Kenya and Uganda also include the development of industries using biotechnology for capitalizing on their rich resources of biological diversity.

The Zambian document (entitled "National Biotechnology and Biosafety Policy") and particularly the Namibian policy document (entitled "Enabling the Safe Use of Biotechnology") are heavily oriented towards biosafety, while the documents e.g. from Brazil, Chile, Kenya, Malawi and Peru deal equally with "promotion" and "regulation". Documents from China, India, Thailand, South Africa and, particularly, Malaysia are oriented towards "promotion", with limited or no reference to regulation.

Approval of NBS frameworks

Countries took, or intended to take, one of three routes for approving their NBS documents:

- creating new primary legislation that embraced substantial elements of the entire document (including the creation of new financial and/or regulatory institutions and mechanisms and/or additional roles and responsibilities of existing institutions, financing arrangements etc); The legislatures of China, Brazil, Peru and Chile (in progress) passed decrees/laws covering the policy/strategy documents prepared by government authorities;
- obtaining full government approval for the NBS and, separately, creating primary or secondary laws and regulations to cover specific aspects e.g. on biosafety, IPR, establishment of funding instruments etc; This was the path chosen by the vast majority of countries reviewed (see Table 1).

- obtaining approval from the ministry given the lead responsibility for the issue and creating non-binding guidelines for specific matters; Based on available information, this was the path chosen by essentially all countries initially and has been retained by many for particular aspects.

While the advantages of the first of the three options include wider debate, greater political and possibly financial commitment and level of enforcement, and "up front" agreement on the roles and responsibilities of governments and legislatures, one disadvantage would be the significantly longer timeframe between preparation and initiating implementation. The second option would lead to earlier implementation of activities requiring regulatory action and oversight, but in some jurisdictions it may not have the same level of enforcement. The third option would most likely be ineffective and even counter-productive in terms of moving forward, particularly on the many regulatory matters associated with some modern biotechnologies.

7.6.1.2 Strategy frameworks for BFA

Two of the countries (Argentina and India) prepared comprehensive BFA policy/strategy papers although, as described in more detail in Chapter 8, these and most other countries have also developed laws and regulations on GMOs. In Argentina, the strategy was developed under the leadership of the Secretariat of Agriculture, Livestock, Fisheries and Food (SAGPyA). Its development involved many stakeholders including the offices of Senators and Deputies, the Secretariats of Industry, Sustainable Development and S&T, the Ministry of Foreign Affairs, all the main universities, funding bodies, industry and civil society groups and individual companies, including multinationals. In India, the Department of Agriculture and Cooperation within the Ministry of Agriculture set up a Task Force to formulate a draft long-term policy on applications of biotechnology in agriculture, including suggestions to streamline/harmonize decision-making under various ministries/organizations. The strategy covers the crop, livestock, forestry and fish sectors. It also deals with related issues like genetic resource conservation and use, food safety, co-existence of organic, conventional and GM agriculture, regulation, public participation and commercialization. Five working groups were set up to examine, report on and provide recommendations on the various issues, culminating, after eleven meetings and interactions with a wide variety of stakeholders, in a comprehensive report issued in 2004.

7.6.1.3 Sub-national biotechnology policy and strategy frameworks

A comparatively recent development in an increasing number of countries is the initiative taken by sub-national (e.g. state and provincial) governments to develop biotechnology policies and strategies. In India, for example, the Governments of Andhra Pradesh, Maharashtra, Karnataka and Tamil Nadu have each produced their own policy and strategy documents. It is outside the scope of this Chapter to deal further with this subject, but an important policy issue for countries that have moved, or are moving, towards de-centralized decision-making is the extent to which powers are invested in sub-national governments and agencies to make laws or regulations with respect to R&D, technology diffusion, local and international markets and any risks to these markets associated with the introduction of e.g. GMOs. Failure to do so has already lead to inter-jurisdictional competition for investment from both federal and foreign sources, and although they may have the same or similar regulatory approaches to those promulgated by national authorities, sub-national bodies have interpreted these in an inconsistent manner leading e.g. to production and trade inconsistencies within countries.

7.6.2 Oversight

- Brazil established a high level National Biotechnology Ministerial Council/Committee within the Prime Minister/President's office to coordinate implementation of their strategy/law;
- India set up a Department of Biotechnology within its Ministry of S&T to promote and coordinate all aspects of biotechnology development in the country;
- Malaysia established a Biotechnology Corporation overseen by an Implementation Council and advised by an international Advisory Panel, both under the leadership of the Prime Minister;
- Peru established an Interministerial Commission to harmonize sectoral policies, and a National Executive Committee on Biotechnology (CONEBIO) within its National Council for Science, Technology and Innovation Technology (CONCYTEC) to deal specifically with biotechnology;
- In Thailand, the National Biotechnology Policy Committee was chaired by the Prime Minister and assisted by seven sub-committees including one dealing with genetic engineering and biosafety policy development;
- Kenya proposed the setting up of a National Biotechnology Enterprise Programme consisting of a National Commission to oversee implementation of the policy framework and a National Education Centre to coordinate and facilitate training, develop databases and a national culture collection, but whether an interministerial mechanism will be created to oversee these initiatives is unclear.

7.6.3 Independent advice

Among the countries analysed, various mechanisms were used:

- South Africa's Biotechnology Advisory Committee is a sub-committee of the National Advisory Council on Innovation which assists the Minister for S&T;

- Argentina set up a National Advisory Commission on agri-biotechnology to advise its Secretariat on technical and biosafety requirements. Public and private organizations with competencies in BFA are represented;
- Chile established a Commission for the Development of Biotechnology and plans to set up an independent Biotechnology Forum to be consulted on issues and charged with promoting public debate;
- In India, the Department of Biotechnology set up a Scientific Advisory Committee and an international Standing Advisory Committee;
- In the case of Malawi, a National Biotechnology Commission with representatives from academia, R&D, education and commerce is proposed to advise the National Research Council;
- Peru established a National Advisory Committee for Biotechnology R&D within CONEBIO to advise on non-regulatory issues;
- The African Union (AU) and the New Partnership for Africa's Development (NEPAD) put together the High Level African Panel on Modern Biotechnology, whose specific remit was to "provide the AU and NEPAD with independent and strategic advice on developments in modern biotechnology and its implications for agriculture, health and the environment". The Panel, consisting of two co-chairs and 12 panel members assisted by a Secretariat and a Research Team, delivered a comprehensive report about biotechnology and the role it can play for development in Africa (Juma and Serageldin, 2007). The final report was based on many meetings, submissions from various stakeholders, requests for comments on the web and feedback from workshops and conferences in Africa and elsewhere. An Executive Summary of the draft report was submitted to the Ministers' Meeting of the extraordinary conference of the African Ministerial Council on Science and Technology in November 2006 and in their meeting Declaration, the Ministers endorsed the report.

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CHAPTER 8

ENABLING R&D FOR AGRICULTURAL BIOTECHNOLOGIES

SUMMARY

The planning, conduct, financing and organization of research and development (R&D), including its interplay with local traditional and indigenous knowledge, are necessary parts of national development policies and strategies for harnessing the potential of agricultural biotechnologies. Technical options for using biotechnologies in food and agriculture (BFA) – and the accompanying legal and institutional policies to support their implementation – should be founded on inventories and analyses of existing national capacities for science and technology (S&T) and biotechnologies generally, and for agricultural S&T and BFA in particular. Countries considering developing genetically modified organisms (GMOs), or using GMOs and their products developed by others, have to consider also both the S&T and the wider legal and institutional support needed by regulatory agencies before authorizing their marketing. Examples include the capacity to conduct risk assessments for environmental releases, to determine food and feed safety, and to test products for GMO content.

Most developing countries wishing to pursue biotechnology applications in food and agriculture meaningfully need to consider policy options for addressing three inter-related issues. First, the pervasive under-investment in human and infrastructural capacities within public agricultural research organizations and universities – something that can only be remedied by political commitment to raise both awareness and the financial investments needed to build and maintain the human capacities and infrastructure for planning and implementing the kind of R&D appropriate to meet the needs of smallholders. Second, the generally fragmented and uncoordinated manner in which biotechnology R&D is often pursued, reflecting insufficient rigour in priority-setting, and leading to reduced effectiveness and efficiency of the public R&D enterprise. This calls for exploring alternative institutional arrangements for both setting priorities and funding agricultural S&T. Third, policy-makers must determine the appropriate

balance between modern biotechnology and other technical approaches for addressing the constraints faced by smallholders, and in particular the balance between phenotype-based and genotype-based solutions, especially where inadequate capacities already exist for evaluating and improving genetic resources for food and agriculture.

Most options for increasing financial commitments and the efficiency and effectiveness of R&D involve moving away from traditional institutional instruments and arrangements, and the "linear" paradigm of planning and implementing R&D. The options generally involve changing the division of labour in R&D between public and private entities and between national and regional or state entities; improving coordination between academia, public sector institutions, the private sector and non-governmental and civil society organizations (NGOs and CSOs); and putting in place mechanisms or institutions that sit between the funding bodies and beneficiaries of R&D to influence the research agenda and who carries it out. They also put a premium on collective responsibility for funding (e.g. through levies from producers, tax and other concessions for private firms and grants from foundations), and on the areas of early stage capital funding and addressing the commercialization gap.

To illustrate some of the options available to countries, the Chapter provides an analysis of 15 selected developing countries. Examples are provided of national funding policies and initiatives in these countries to achieve these aims, as well as policies to build scientific and technical capacities relevant to the pursuit of agricultural biotechnologies. Admittedly, what remains unclear is whether the inevitable increases in transaction costs and downstream movement of research agendas arising from some of these initiatives will actually improve the efficiency and effectiveness of national R&D enterprises in terms of delivering a more diverse and pro-poor relevant suite of biotechnologies in the years ahead.

A regulatory system responsive to national needs and priorities, consistent with international agreements, and that ensures the safe and efficient development and use of biotechnology methods, processes and products is also part and parcel of a national and international enabling environment for BFA. Indeed, regulation itself should be seen as a positive development – demonstrating responsibility and oversight by governments as well as collaboration between governments and developers of biotechnologies – to ensure that only products that are as safe as their conventional counterparts are released into the environment and consumed. On the other hand, developing and implementing a regulatory framework can be a complex and resource-intensive exercise and, irrespective of the established structures, regulatory "functions" place enormous scientific, technical and administrative demands on national institutions.

This Chapter also covers general principles and specific aspects requiring consideration when developing and implementing a national regulatory system. Before deciding on an appropriate regulatory structure and the legal and political means by which it can be implemented, substantial background data collection and analysis coupled with political negotiating skills are required to deal with the scientific, technical, legal, judicial, economic, trade and logistic aspects involved in regulation of new technologies.

Options for giving legal authority to the regulatory system include using existing primary laws and the delegated legal authorities within these to promulgate regulation, and establishing a new primary law. The pros and cons of these two options are described and examples of each provided by reference to specific developing countries. Also described are options for establishing structures and decision-making responsibilities that promote unified and well-coordinated systems of biotechnology governance. National examples are again used to illustrate different options and, although containing many common elements, they vary considerably between countries.

Essential to any regulatory system is transparency with respect to the criteria and standards used for assessing safety; roles, responsibilities and accountabilities of national committees and existing national institutions; and provision of information to regulators and the public. Ambiguities within some Articles of international agreements coupled with insufficient guidance about the scope of, and discretion available to countries for national action makes interpretation of how to "play by the rules" challenging. Concerns and disagreements within and across countries include: appropriate methodologies for risk assessment – defining the nature of the hazard(s), if any, and the most appropriate approaches and methods to assess potential risks from employing some biotechnologies in the agrifood sector; the roles of substantial equivalence, product- and process-based regulation, and of labelling; and how and at what point precaution and socio-economic considerations can be taken into account when making decisions on risks and their management. Analysis of the information available from the 15 selected developing countries suggests that there remains considerable scope to improve clarity with respect to these and other issues, and again, that while there are many common features, there are clear policy differences between national approaches with respect of risk management. This simply illustrates that decision-making on some biotechnologies is both highly complex and has scientific, social and political dimensions.

Concerning harmonization of biotechnology regulatory oversight, the analyses underpinning this Chapter suggest that considerable scope exists to improve understanding and reduce regulatory costs among developing countries through the pursuit of informal collaborations and mutual recognition of voluntary guidelines, and possible examples are described. Nevertheless, the prospects for comprehensive harmonization within developing country regions do not look promising, because (1) decision-making is essentially about dealing with uncertainty and societal value judgements concerning levels of acceptable risks, and (2) science can only inform but never replace the decisions of policy-makers concerning what they consider to be legitimate and justifiable reasons for particular courses of action. More important, therefore, at this juncture is coordination and harmonization of regulation between the different relevant government ministries within a country.

These and other considerations suggest that developing countries may wish to consider adopting a strategic and integrated biosecurity approach to analysing and managing relevant risks to human, animal and plant life and health and associated risks to the environment from biotechnology. Many developing countries simply cannot afford GMO or other biotechnology-specific approaches and might benefit greatly from a more integrated approach without necessarily creating new or unified structures. This would also provide an opportunity for greater harmonization of terminology and methodology for risk analysis while respecting the need for individual sectors to tailor risk analysis procedures to the characteristics of the risks involved.

8.1 SCIENCE AND TECHNOLOGY SYSTEMS IN DEVELOPING COUNTRIES

"Science, technology and innovation underpin every one of the Millennium Development Goals. It is inconceivable that gains can be made in health and environmental concerns without a focused science, technology and innovation policy" (UN Millennium Project, 2005).

This quotation does not mean that the solution to the world's food insecurity, poverty and other sustainable development challenges lies only in S&T, but that S&T, and particularly the benefits from innovations in its planning, conduct, financing and organization, including its interplay with local traditional and indigenous knowledge, are necessary parts of national development policies and strategies. History shows that technological, institutional, organizational, trade and other innovations relating to the use of natural resources have played a critical role in agricultural productivity growth and reductions in food insecurity and poverty in industrial and some advanced developing countries. Yet, few developing countries have up-scaled overall S&T as a policy focus. The almost total neglect of S&T in the Poverty Reduction Strategy Papers[1] (PRSP) currently available for a number of developing countries emphasizes again the need for more joined-up S&T management.

The same can be said about policy and strategy frameworks for BFA. Although all of the 15 selected developing countries (listed in Table 1 of Chapter 7) put the agrifood sectors among or at the top of their priorities for national development, the overwhelming emphasis to date of most of these countries is on establishing biosafety laws, regulations and "structures". Little consideration has been given either to non-GMO biotechnologies

[1] The PRSP approach was initiated by the International Monetary Fund and the World Bank in 1999. Country PRSP are available at www.imf.org/external/np/prsp/prsp.aspx

or to how the human and infrastructural requirements for successful development and use of any of the biotechnologies would be met. For example, critical aspects like establishing sector or sub-sector wide S&T coordination mechanisms and setting priorities for research; for developing and diffusing products; for building scientific capacity and infrastructure; for strengthening, closing down or establishing new institutions; for introducing new modes of funding and providing incentives for private investment; and for establishing ways of involving stakeholders and the public at large in biotechnology-related S&T decision-making seem to have been neglected in all but a handful of countries.

Pursuing such strategic issues is certainly fraught with many difficulties, but it can also provide new opportunities for innovative approaches to the identification, development and uptake of agricultural biotechnologies. Some of the challenges and opportunities for S&T systems in developing countries will now be considered.

The traditional developers and disseminators of agricultural technology, the national agricultural research systems (NARS), are highly diverse in size, scientific and technical strength, and the way in which they are managed and funded. Over the past 20 years or so, while the central institutional structure has remained relatively intact apart from some internal re-organizations (see e.g. Beintema and Stads, 2008a; Stads *et al.,* 2008; and Stads and Beintema, 2009 for detailed studies of the Asia-Pacific, Central American and Latin American-Caribbean regions respectively), agricultural research is becoming increasingly decentralized with the establishment of autonomous regional and provincial research agencies (see e.g. Hartwich and Jansen, 2007). Also, in some developing countries, and certainly in the most technologically advanced ones, universities play a much stronger role in agricultural research (particularly basic or "curiosity led" and strategic research) and training, including in biotechnology, than do publicly-funded research institutes attached to Ministries of Agriculture or Research Councils attached to particular departments within them which traditionally have engaged in applied or adaptive R&D, as well as providing analytical/diagnostic support services.

In Africa, and particularly in the smaller countries of Latin America, the opposite is generally the case. Universities are largely teaching institutions with limited research and outreach activities. In Asia, the picture is more mixed. In China, R&D for BFA is dominated by the Chinese Academy of Agricultural Sciences (CAAS) which is directly affiliated to the Ministry of Agriculture while extension and education are undertaken elsewhere. In India, the main government agency is the Indian Council for Agricultural Research (ICAR) which comes under the Ministry for Agriculture and has responsibility also for technology transfer and farmer training. However, BFA is also performed within the many State Agricultural Universities and in other institutions supported by the Department of Biotechnology within the Ministry for S&T.

Re-organizations within ministries with mandates that cover particular aspects of biotechnology are a further challenge. Argentina created a new Ministry of Science, Technology & Productive Innovation in 2007 to focus the country's S&T efforts on economic development, including through biotechnology, while at the same time splitting off education into a new ministry from the former Ministry of Education, Science and Technology. Kenya did the opposite. In 2008 it merged the existing Ministry of S&T with the Department of Higher Education in the Ministry of Education to form the Ministry of Higher Education, Science and Technology with the aim of bringing together scientists in universities and mission-oriented research institutions.

Depending on the importance given to biotechnology, changes of this nature can affect positively or negatively the balance between education and research, among research performing institutions (universities, publicly-funded research institutes and private sector research), between basic and applied R&D, and between filling immediate and long-term needs for skilled human resources.

Into this mix must be added the sub-regional and regional organizations that were set up to promote concerted action. Examples include the Association for Strengthening Agricultural Research in Eastern and Central Africa (ASARECA), the Asia Pacific Association of Agricultural Research Institutions (APAARI), the Forum for the Americas on Agricultural Research and Technological Development (FORAGRO), and specifically for biotechnology, the Technological Cooperation Network on Agricultural Biotechnology in Latin America and the Caribbean (REDBIO). Advanced research institutes, mainly in developed countries, are other important players. At international levels, the research centres belonging to the Consultative Group on International Agricultural Research (CGIAR), the International Centre for Genetic Engineering and Biotechnology (ICGEB) and their NARS partners continue to enhance agricultural knowledge, science and technology in many countries to generate high rates of return on investment in terms of productivity.

Investors are changing, with new philanthropic organizations like the Bill and Melinda Gates Foundation beginning to influence the size and nature of development assistance to agricultural knowledge, science and technology, including through BFA. The recent granting of US$3 million to ICGEB to strengthen sub-Saharan African regulatory regimes in biosafety[2] and of US$10.4 million to the New Partnership for Africa's Development (NEPAD) African Biosafety Network of Expertise[3] exemplify this development.

The agricultural R&D agenda has itself become more complex. The issue is no longer simply to produce more food, but to do so in ways that reduce the environmental footprint of intensification and that create greater opportunities for small-scale producers to access national and international input and output markets, thereby improving incomes, reducing

2 www.icgeb.org/~bsafesrv/pdffiles/%20ICGEB_Gates.pdf

3 www.nepadst.org/newsroom/pdfs/news_brs.pdf

poverty and increasing food security. This means expanding indicators of "success" to include the environmental and poverty dimensions of interventions in order to understand the potential trade-offs and complementarities between productivity, environmental and livelihood goals and to set priorities (Hazell, 2008). In other words, the paradigm now is research for sustainable food security.

In addressing that paradigm, it is the demand from markets rather than producers *per se* (whose traditional suppliers of knowledge and technology are research institutes and universities) that is increasingly driving change. Biotechnology clearly illustrates this fact – it has already become an industry itself within some countries and within the agrifood sector it is increasingly moving along that path in developing countries like Argentina, Brazil, China, India and South Africa.

Still, the key social challenge remains in ensuring that the millions of subsistence farmers and landless workers living in less endowed areas are not further marginalized by policies and technologies that favour larger producers and producers with higher levels of land productivity and greater access to inputs and existing markets. The plethora of "pro-poor" agricultural activities underway demonstrates the much greater commitment now being given to this issue in S&T and wider development circles, although it remains to be seen whether the principal beneficiaries of these national and international initiatives are indeed poor farmers and citizens.

As free trade agreements expand and consolidate, agricultural knowledge, science and technology is increasingly globalized and private sector led. On the one hand, this offers both considerable potential to exploit global networks, encourage public-private sector collaboration and improve R&D efficiency. On the other hand, private appropriation threatens the free flow of knowledge and technology. Biotechnology increasingly exemplifies both sides of this coin, with the issues of corporate concentration and patent monopolies, in particular, being raised by many scientists, NGOs and government advisory bodies, e.g. CIPR (2002). In addition, the norms for accessing and sharing the benefits of biodiversity in general have changed, particularly for plant genetic resources in food and agriculture, bringing new challenges to the agricultural R&D agenda.

The new catchwords "innovation" and "knowledge economies" have gained currency to the point of even replacing S&T at times. Both stem from the increasing realization that the standard linear or "vertical" model of generating and transferring knowledge (including the knowledge embedded in technology) in which new ideas only originate from basic and applied scientific research, move on to development and then on to farmers via public extension services (the traditional perspective of NARS) is fast becoming obsolete. The numerous technologies that "sit on the shelf" attest to this reality and to the need to complement traditional with the more horizontal "national innovation system" approaches to achieve desired social and economic outcomes. Innovation systems use all the knowledge assets within the full network of organizations, institutions, policies and individuals involved in the production of goods and services to identify knowledge gaps (including gaps in the knowledge embedded in technology), understand how a country's agrifood sector can make better use of new knowledge, and design alternative interventions that go beyond research system investments (Leeuwis, 2004; Hall *et al.*, 2006; Spielman and Birner, 2008; IAASTD, 2009). It gives greater emphasis to production systems, value chains and farm to table approaches than to individual components. It also recognizes the necessity of connecting and learning from the knowledge of farmers, input suppliers, processors, marketers and their institutions to successfully introduce new and useful products, processes and ways of working through continuous and incremental upgrading.

Like S&T policies in general, national biotechnology policies are framed horizontally. The scope for independent action by Ministries of Agriculture within their traditional portfolios of responsibility for R&D, including biotechnology, has therefore become increasingly limited. While undoubtedly increasing transaction costs, this should nevertheless provide greater impetus to encouraging interministerial and institutional partnerships as well as promoting innovative approaches to planning and implementing R&D and securing the necessary funding.

The agricultural sector must increasingly compete with other sectors in determining the types of courses offered, research conducted and other services provided by universities and technical training institutions, for attracting the trained scientists and technicians that graduate from them, and for the financial resources needed to establish or strengthen the necessary infrastructure and human capacities needed to incorporate biotechnology into on-going R&D efforts. These challenges are made all the more difficult by the substantial array of new opportunities for social and economic development available through other channels within increasing numbers of developing countries.

Other relatively new trends include growing public scepticism about S&T and the public nature of scientific debate, in particular where food and the environment are at stake. GMOs have been at the centre of many of these concerns which demand more complex ways of organizing the interplay between science, decision-making and society to satisfy requirements for public proof about risks and benefits.

All of the above and other related factors have major implications for how countries develop public policies on investments in biotechnology-related infrastructure, human resources training and development, and institutions and organizational arrangements that provide the appropriate enabling environment for creating and diffusing knowledge that meets the requirements of subsistence and commercially oriented producers, the private sector and governments themselves.

At the same time, it is essential to stress yet again that all options for doing so depend for their viability on other "indirect" policy measures, e.g. macroeconomic, fiscal, trade, infrastructure (transport, water, electricity, information and communication technologies), and education from primary through to tertiary levels. The importance of having sound policies and actions in these areas for underpinning technology and small business creation to increase productivity and enhance the livelihoods of poor marginal producers, cannot be overstated. Consideration of such policies is nevertheless outside the scope of this Chapter.

This Chapter covers policies for enabling R&D, including diffusion of agricultural biotechnologies. While relevant to the pursuit of developing, adapting and using new knowledge and technologies for improving the agrifood sector irrespective of discipline and approach, including the more traditional biotechnologies, its coverage focuses on policies for meeting the additional demands – scientific, technical and institutional – for engaging effectively in R&D involving modern biotechnology, including taking some of its products onto farms and into national and international markets. Throughout the Chapter, examples are provided from the same 15 developing countries described in Chapter 7, supplemented by data from a variety of other sources.

In this Chapter, Part 8.2 provides a general overview of the global picture with respect to human and financial investments in agricultural S&T including biotechnology. Part 8.3 describes the funding instruments and options to be considered by countries. Both Parts are supported by examples from individual countries about capacity building and funding for BFA contained in Annex 1. Part 8.4 deals with regulation, describing also how the 15 selected developing countries deal, or intend to deal, with regulation from "farm to fork"– including the scientific research and analytical techniques needed to underpin it – within their national biotechnology policy/strategy (NBS) documents[4]. Also covered are some features of the frameworks they have established, or intend to establish, to deal with the environmental and food/feed safety regulation of GMOs. Annex 2 provides supplementary information concerning these aspects. Part 8.4 also provides options for establishing national biotechnology regulatory frameworks, covering issues like establishing legal authority, structures and decision-making responsibilities. Emphasis is also given to the international dimensions of biotechnology regulation, including international harmonization.

8.2 AGRICULTURAL SCIENCE AND TECHNOLOGY: CAPACITIES AND INVESTMENTS

8.2.1 The global picture

The starting point for countries considering their options for using BFA is to inventory and analyse their existing national capacities for S&T and biotechnology generally, and for agricultural S&T and BFA in particular. Each feeds off the other and consequently they

[4] Most of the NBS documents of the selected developing countries are available at www.fao.org/biotech/country.asp

should not be considered in isolation. Countries considering developing GMOs, or using GMOs developed by others, have to consider also the S&T support that will be needed by regulatory agencies before authorizing their marketing, e.g. the capacity to conduct risk assessments for environmental releases, to determine food and feed safety, and to test products for GMO content (Part 8.4 below).

S&T capacity cannot easily be quantified. It is so multi-faceted and subject- and country-specific that no set of indicators for measuring capacity can cover all circumstances (IAASTD, 2009). Attempting to measure "innovation" adds to the complication. Some countries have weak NARS but show strong innovative capacities in particular areas. For example, some Central American and African countries which lie at the "bottom of the league" in terms of traditional measures of S&T capacity have developed successful fruit, vegetable and flower export markets with the United States and Europe – sometimes with limited or no involvement of their NARS.

Budgets for R&D expressed in absolute terms or research intensities (see below) are both necessary and informative but they also do not tell the full story. Effectiveness and efficiency depend greatly on the quality of coordination, rigour of priority-setting, intensity of networking, to whom budgets are allocated and how they are spent. Despite these and other caveats, one conclusion stands out from all the work done on both overall and agricultural S&T indicators – the vast majority of developing countries have huge deficiencies in S&T capacity compared with economically prosperous countries in the northern hemisphere, and substantial deficiencies relative to countries like Brazil, China, India and South Africa.

For example, Wagner *et al.* (2001) developed four broad categories of countries, namely those that are scientifically advanced, proficient, developing and lagging. While there are a number of caveats to the calculation of these indices, and hence considerable caution is needed in interpreting them, the corresponding agricultural science and technology indicators which deal primarily with investments in R&D suggest a very similar categorization for most countries (Table 1). In almost every case, the highest research intensities are found in those countries classified by Wagner *et al.* (2001) as "scientifically proficient" and "scientifically developing" while the lowest values are associated with countries in the "scientifically lagging" category. Notable exceptions are China and India with relatively low research intensities and where the agricultural GDP (gross domestic product) has increased at a faster rate than R&D spending, although this has also increased dramatically in both countries over the last 10 years.

At the global level, US$23 billion was used for publicly-funded agricultural research in 2000 (Pardey *et al.,* 2006; Beintema and Stads, 2008b). Notably, around 55 percent of this R&D was spent in the 32 high income countries surveyed, the remainder by 108 middle and low income countries. Also, over the past 25 years or so these investments have become

TABLE 1

AGRICULTURAL RESEARCH INTENSITY OF 15 SELECTED DEVELOPING COUNTRIES

Country	Agricultural research intensity
Argentina	1.27 (2006)
Brazil	1.68 (2006)
Chile	1.22 (2006)
China	0.40 (2005)
India	0.36 (2003)
Jamaica	Not available
Kenya	1.23 (2000)
Malawi	0.67 (2001)
Malaysia	1.92 (2002)
Namibia	Not available
Peru	Not available
South Africa	2.81 (2000)
Thailand	Not available
Uganda	0.61 (2000)
Zambia	0.62 (2000)
Developed country average (Beintema and Stads, 2008b)	2.35 (2000)

Source: Agricultural Science and Technology Indicators (ASTI) data tool, www.asti.cgiar.org/data/

Measured as public agricultural R&D spending as a share of agricultural GDP. Year of data is within brackets

increasingly concentrated, with just four industrialized countries (United States, Japan, France and Germany) accounting for around 65 percent of the publicly-funded agricultural R&D conducted in developed countries, and five developing countries (Brazil, China, India, South Africa and Thailand) accounting for half of developing country expenditures.

In 2000, around US$17 billion was spent by private sector entities in agricultural R&D, but developing countries captured only 6 percent of this investment (i.e. less than US$1 billion), most of which was in the Asia-Pacific region where 8 percent of agricultural R&D was private compared with only 2 percent in sub-Saharan Africa, almost two thirds of which was in South Africa. Many developing countries, and particularly the low-income food deficit countries, have failed to increase their investments for decades.

This disparity between advanced and developing countries in their financial commitments to fostering agricultural R&D is starkly illustrated by comparing their research funding intensities. In 2000, developing countries on aggregate spent 56 cents on R&D for every

US$ 100 of agricultural GDP while the developed countries spent on average US$2.35 (Table 1). If the contribution of private sector funding is included, that gap increases to more than eight-fold. In some developing country regions (e.g. in Central America), the aggregate spending is 25 cents and some individual countries are spending less than 10 cents for every US$100 of agricultural GDP (Stads *et al*., 2008; Stads and Beintema, 2009). There is therefore increasing evidence of a growing gap between developed and developing countries and within developing countries themselves in their financial commitment towards agricultural R&D (Pardey *et. al.,* 2006; Alston, Pardey and Piggott, 2006).

As far as international initiatives are concerned, spending trends for the CGIAR show that collectively the CGIAR centres spent US$445 million on agricultural R&D in 2006 (in 2005 US$) compared with US$379 in 2000 (Beintema and Stads, 2008b), but increasingly these funds are earmarked by particular donors to specific projects. In 2006, these "restricted" funds accounted for 58 percent of total funding, compared with less than 40 percent in the early 1990s.

Expenditures for biotechnology research cannot be documented or compared with any precision, but assuming average spending on biotechnology of 5 to 10 percent of total agricultural R&D (Janssen, Falconi and Komen, 2000), developing countries spent US$1.3 billion on biotechnology in 2000. However, in recent years there are some indications of new additional public BFA investments in developing countries. These include in China (US$3 billion over the next 15 years); India (around US$125 million in the Indian Government's ninth 5-Year Plan, plus over US$20 million in grants from bilateral donors and the European Commission [Chaturvedi, 2005; Jayaraman, 2008]); Brazil (where the government announced in 2007 plans to invest about 2.4 billion euros in biotechnology, mainly in health, agriculture, industry and environment, over the next 10 years); Argentina (US$16 million over five years with an unspecified amount for BFA); and Vietnam (US$63 million over nine years).

Together with the data available from the CGIAR and FAO on biotechnology applications in the crop sector, these figures strongly suggest that investments in BFA now constitute a significant and possibly increasing component of agricultural R&D in some developing countries. Despite the limited data, both the figures provided above and the results of Wagner *et al.* (2001) indicate that the categorization of NARS by Byerlee and Fischer (2001) with respect to crop biotechnology as Type 1 (strong capacity), Type 2 (considerable) and Type 3 (fragile) corresponds well with the "scientifically proficient", "scientifically developing" and "scientifically lagging" categories proposed by Wagner *et al.* (2001).

Although again no hard data are available, it is noteworthy that the focus of the new additional public BFA investments in developing countries is overwhelmingly on plants and on plant genomics and GMO technologies, while work on livestock, farmed fish, trees and micro-organisms is attracting substantially less funding although following a similar direction. Support for the less advanced, i.e. non-molecular, biotechnologies and more traditional approaches for developing better tools, practices and products needed by producers and consumers alike is progressively becoming a smaller part of the agricultural R&D "mix". Indeed when people talk about, and science commentators report on "biotechnology", the term is nowadays invariably synonymous with GMOs.

Given the many competing demands on the public purse including for agricultural R&D, the above information raises at least three inter-related strategic policy issues for governments and the international community:

- Despite the increasing awareness of the social, economic and environmental importance of agriculture and if, despite the many caveats, one accepts a figure of 1 percent of agricultural GDP as a reasonable level of investment for agricultural S&T, then it is clear that most developing countries substantially under-invest to reap the unquestionable benefits that can flow from appropriate developments and applications. Awareness of the critical role of agricultural research for addressing food security, poverty reduction and sustainable use of natural resources must therefore be improved to tackle the pervasive under-investment in public agricultural research in developing countries (Echeverria and Beintema, 2009). Political commitment to raise awareness and investments in R&D appropriate to meet the needs of smallholders is therefore a top priority (FAO, 2009a).
- Policy-makers must also find alternative institutional arrangements such as public-private partnerships for both setting priorities and funding agricultural S&T; information given in Part 8.3 illustrates how some countries are attempting to tackle this in relation to BFA.
- In setting priorities, policy-makers must determine the appropriate balance between modern biotechnology and other technical approaches for addressing the constraints faced by smallholders, and in particular the balance between phenotype-based and genotype-based solutions in situations where inadequate capacities already exist for germplasm evaluation and varietal development (FAO, 2006).

8.2.2 Examples of capacity building initiatives

In their national biotechnology planning strategies, all countries surveyed gave top priority to building their indigenous capacities for S&T including infrastructure, recognizing that such capacity is the key to acquiring, absorbing and diffusing biotechnology for development. Surprisingly, a number failed to mention "innovation" and most gave no indication of the instruments in place, or to be introduced, for achieving this goal.

As illustrated by looking at the selected developing countries in Annex 1 (Part 8.5.1), the options and opportunities available are numerous. But policies for capacity building must be accompanied by policies that avoid "brain drain", surely the prime example of extreme policy ineffectiveness because of the huge costs to societies that have paid for the investments but do not enjoy the benefits. While domestic policies alone are insufficient to deal with this issue, improving employment opportunities, salaries and other conditions of employment, and ensuring the availability of the necessary equipment and supplies are part and parcel of an effective capacity-strengthening policy package. Surprisingly again, few developing countries mentioned the issue or how it would be tackled, China and India being notable exceptions.

Also, most countries dealt (or intended to deal) with capacity building at the "top end" (i.e. postgraduate levels), omitting consideration of raising awareness and skills within their secondary and tertiary education systems. Exceptions were Brazil, Chile, India, Kenya and South Africa which specifically emphasized the importance of targeting these groups for long-term growth and sustainability, and documented specific actions for doing so.

Training in biotechnology has also become highly globalized, with nationals from essentially all the countries covered in this Chapter going to institutions in the developed world to study, train and participate in scientific exchanges through workshops, courses etc. under the great variety of programmes associated with inter-governmental and institutional agreements. For example, for African countries, the Biosciences eastern and central Africa (BecA) hub which has been set up on the campus of the International Livestock Research Institute (ILRI) in Nairobi provides a common R&D platform, research services, training and capacity building opportunities with top class facilities. Last year, BecA hosted more than 180 African students and scientists in workshops and bioinformatics courses[5].

In addition to building up PhD and postgraduate training opportunities, Argentina, Brazil, Chile, China, India and South Africa have already moved forcefully into supporting innovation by giving much greater encouragement within their S&T systems to both public-private sector partnerships and to meeting the demands and requirements of private enterprise (examples from selected developing countries are provided in Annex 1, Part 8.5.1). These include:

- "re-engineering" existing university departments and curricula by focusing on areas and approaches that are presently inadequately covered, e.g. degrees in regulatory matters, product development, bioinformatics, technology transfer, entrepreneurship and commercialization;
- creating new institutions and "re-branding" existing institutions for R&D;
- creating institutions specifically for scaling up and commercializing research outputs;
- providing incentives for qualified citizens working abroad to participate in national activities. Brazil, China, Chile, India, Malaysia and Thailand have all introduced instruments for this purpose. The Indian Government's Department of Biotechnology, for example, established the Ramalingaswami re-entry fellowships which offer five-year placements for high calibre nationals working abroad.

[5] http://hub.africabiosciences.org.

8.3 FUNDING: INSTRUMENTS AND OPTIONS

Securing appropriate and consistent levels of funding for agricultural S&T has consistently been hugely problematic for most developing countries. With its additional requirements for infrastructure and organizational, scientific, technical and legal skills, and the challenge of addressing the many other priorities that have surfaced in recent years, introducing biotechnology makes that task all the more daunting.

Even so, a number of options can be considered to both increase levels of funding and to move away from traditional instruments that often involve little if any consideration of priorities or planning (see examples from a number of selected developing countries in Annex 1, Part 8.5.2). Most of these options involve changing the division of labour in R&D between public and private entities and between national and regional or state entities, improving coordination between academia, public sector institutions and the private sector, and putting in place mechanisms or institutions that sit between the funding bodies and beneficiaries of R&D to influence the research agenda and who carries it out. They also put a premium on collective responsibility for funding (e.g. through levies from producers, tax and other concessions for private firms and grants from foundations), and on the areas of early stage capital funding and addressing the commercialization gap. The options include:

- redirecting part of the total public support package for agriculture (e.g. through subsidies and other policy instruments) to innovative technological packages directed to tackling priority constraints to sustainable production within disadvantaged regions with minimum economic potential;
- introducing commodity levies and tax check-offs, and likewise directing a proportion of the income to support "pro-poor" agricultural R&D; The case for special purpose levies to fund agricultural development is reviewed in FAO (2005).
- encouraging commercialization of agricultural R&D; On the other hand, if the goal is to simply increase funding, the tendency of governments to substitute commercial funds for public investments should be noted (see e.g. Rozelle *et al.*, 1999).
- developing much closer partnerships with, and alignment between, policies, programmes, projects and funding mechanisms linked to R&D supported by other ministries and their donor communities (particularly with Ministries of S&T and the Environment);
- moving progressively away from traditional arrangements whereby "block grants" provided by the Ministry of Finance and supplemented by donor contributions are provided individually or collectively through the Ministry of Agriculture to a centrally-based national agricultural research organization; Instead, through progressive decentralization which provides an opportunity to adapt research to local contexts, to grant fiscal autonomy to state or regional governments and legal status to producer

organizations, and to encourage the establishment of national and regional research foundations with "arms length" boards or councils to expand and change the sources and flows of funding, including from donors.

- changing the criteria for priority-setting, procedures for allocating funds and the funding instruments used at national and state levels, basing them in all cases on competitive and often matching grants directed at a variety of entry points including more upstream and applied biotechnology research, technology development and scholarships;
- linking research priorities more explicitly to wider social and economic needs, i.e. poverty reduction and rural development programmes and fund accordingly; With the political spotlight now firmly on the MDGs and the Paris Declaration on Aid Effectiveness, this may increase both national resource levels and encourage donors to step up and coordinate their support for research in rural areas.
- creating formal structures and mechanisms for stakeholder participation in R&D policy, including its inter-related elements of priority-setting, funding and review; Since the remit of most biotechnology advisory committees is wide, one option is to create a R&D sub-committee with expertise in S&T, innovations and socio-economic development, and representatives from NGO and civil society umbrella organizations including those representing the agrifood sector.
- giving increasing priority to research that is jointly formulated and implemented through partnerships within the public sector (research institutes and universities), but more particularly through public-private partnerships (e.g. research institutes, universities and small and medium sized enterprises [SMEs]);
- giving increased priority to research projects that arise from analysis of constraints within local and regional product value chains and production systems;
- establishing S&T and innovation funding windows based on thematic "problem-based" priorities and "value chains" established by a government-level think tank; they often require multidisciplinary approaches and cater less to the scientific interests of researchers in specific disciplines.
- establishing or strengthening intermediate funding structures between government and the national S&T and innovation systems, e.g. a Research Council or Foundation with a board or peer review panel;
- encouraging and enforcing intellectual property protection.

As described in Annex 1 (Part 8.5.2), quite dramatic changes are taking place in some developing countries in terms of the manner in which they plan, fund and organize biotechnology R&D and innovation, with considerable emphasis being placed on public-private sector partnerships. These countries have taken advantage of wider productive development policies and institutions that were set up to encourage both trade and private sector investment (for Latin America and the Caribbean, see Melo and Rodríguez-Clare, 2006), and followed national innovations system approaches. Although not always specific to BFA, these illustrate options to be considered by others.

What is less clear, because of their infancy and the current global economic downturn, is whether, with the inevitable increases in transaction costs involved and downstream movement of research agendas, these changes will actually improve the efficiency and effectiveness of national R&D enterprises and the prospects for a more diverse and pro-poor relevant suite of biotechnologies coming on line in the years ahead.

8.4 REGULATION

8.4.1 Context

Having a regulatory framework or system that ensures the safe and efficient development and use of biotechnology methods, processes and products is part and parcel of a national and international enabling environment for BFA. The objective of such a system is to ensure that any potential risks to human health (e.g. FAO, 2009b) and the environment are identified and that they are properly assessed and managed by identifying and putting in place appropriate mechanisms and measures throughout the processes of research, product development and use as well as through trade, based on the country's stated appropriate level of protection. Since uncertainty is an inescapable reality with any technology and not unique to food and agriculture, designing and enforcing the primary laws, secondary regulations and the many guidelines and standards that constitute regulatory frameworks, while never easy for legislatures, government policy-makers and their regulatory agencies, are nevertheless fundamental elements of sustainable agriculture and rural development and wider development.

The main challenges faced by policy-makers are first of all deciding what should constitute a "trigger" for regulatory action, and then finding the right balance between the potentially important benefits of undertaking a particular activity and the safeguards, if needed, that should be put in place to realize the benefits. In fact, government decision-makers may conclude from the safety review process that there is no new risk from a particular technology and therefore safeguards are not needed. Nevertheless, finding that balance is fraught with difficulties and trade-offs, because (1) the desirability of a particular activity depends on societal values which themselves can vary greatly within and between particular societies, and (2) national regulatory frameworks themselves increasingly have to be adapted both to the "rules of the game" imposed by international, regional and bilateral agreements, as well as to new developments in technology and to other changes at national and global levels, e.g. climate change, emergence of new pests and diseases etc.

Traditionally, laws and regulations covering sanitary (human and animal) and phytosanitary (plant) measures – known collectively as biosecurity measures (FAO, 2007a) – have been used to balance the needs to produce, market and trade food and other agricultural products with the need to ensure, as much as possible, that this is done in ways that protect the life and health of plants and animals and as well as the interests of consumers. These measures are based on both the processes and/or the end products themselves. Additionally, other technical rules such as labelling of products have become an important part of market and trade regulation to protect the wider interests of consumers and promote fair practices, or simply to provide information.

More recently, societies have become increasingly concerned about the potential risks to the environment and the knock-on consequences for their socio-economic development arising from agriculture. They are also increasingly concerned about animal welfare. Indeed, even before the UN Conference on Environment and Development (UNCED) in 1992 and its Rio Declaration and Agenda 21 blueprint for action on sustainable development, the linkages between poverty, food insecurity, human health and environmental degradation and the need to strike more appropriate balances between producing goods, generating incomes and protecting natural resources and processes were becoming increasingly recognized by individual governments and the global community including NGOs and the private sector. Also recognized was the need for cooperative planning between governments and societies to address these interactions for achieving sustainable development.

With intensification remaining the cornerstone of efforts to meet the continuously growing demand for food, and at the same time protect both wild and managed biodiversity, and with human populations expected to reach nine billion by 2050, it is relevant to consider the likely contribution of biotechnologies to increasing production and access to sufficient and safe food supplies through national and international markets. Into that debate, as it has done in the discourse on agriculture over the last half century, come two overarching questions about BFA, namely: without better technologies and supportive policy packages, how many more people would suffer from hunger and severe malnutrition with the same population growth?; and what additional area of forests and other environmentally sensitive lands would be used to produce the greater amounts and/or nutritional quality of food that will be needed?

The debate about what agricultural biotechnologies can and cannot do, have and have not done, and will and will not do for sustainable agriculture and rural development still goes on today and is not entered into further here. Nevertheless, over these last 10–15 years of heightened political and legislative activity, one reality stands out: unlike other biotechnologies (such as tissue culture, artificial insemination and molecular markers), and the plants, animals, feeds and other products developed from them, genetic modification (and to a lesser extent, animal cloning) has been the trigger for regulatory actions across the world.

Biotechnology's continuing high global profile can be attributed to a complex set of often intersecting factors that include their rapid proliferation in a few countries and increasing appearance in international trade; the high dependence of many countries on food and feed imports, including food aid; ever-increasing awareness and concerns about food safety and quality; greater public attention to biodiversity and wider environmental issues, including the impact of agriculture on both; increasing movement of people, pests and diseases across borders and species; legal obligations of countries to implement international agreements; advances in communication and global access to information; often unresolved scientific, legal, philosophical and public debate; and scarcities in technical and financial resources. Together, these and other considerations have raised expectations tempered by uncertainty about the future role of advanced biotechnologies and specifically about genetic modification, in the 21st century.

This Chapter does not discuss the appropriateness of singling out R&D and the products and some derivatives of GMOs for regulation among all the potentially available biotechnologies discussed at ABDC-10. That debate is history and need not be entered into further, although regulation itself should be seen as a positive development – demonstrating responsibility and oversight by governments as well as collaboration between governments and developers of biotechnologies – to ensure that only products that are as safe as their conventional counterparts are released into the environment and consumed. On the other hand, the widespread introduction of artificial insemination for example in some developing countries (a biotechnology which is generally not regulated) has had serious negative repercussions on livestock biodiversity and the livelihoods of many small-scale farmers.

What is significant from a policy perspective is the scope for national regulation of "biotechnology" through the two international legally-binding environmental agreements designed to shape national and international actions, i.e. the Convention on Biological Diversity (CBD) and its Cartagena Protocol on Biosafety (CPB), as well as through the all-embracing World Trade Organization (WTO) Agreements on trade and the standards set by the Codex Alimentarius Commission, International Plant Protection Convention (IPPC) and the World Organisation for Animal Health (OIE). Mackenzie *et al.* (2003) provide a comprehensive explanatory guide to the CPB, including its relationship to the WTO Agreements, while FAO (2007b) describes the WTO Sanitary and Phytosanitary (SPS) Agreement and its relevance to biosafety. Options available to countries for meeting their obligations under these Agreements are therefore not covered here. Nor does this Chapter enter into the legalities of relationships between multilateral environmental agreements and the WTO Agreements or into trade disputes between certain countries on matters relating to GMOs. Both have already been covered comprehensively by Zarrilli (2005).

Instead, it describes how the same selected developing countries surveyed for Chapter 7 intended to deal with regulation within their NBS documents as well as some features of the frameworks that they have established, or intend to establish, to deal with environmental and food/feed safety regulation. Information about these frameworks was obtained from a wide variety of official and UN sources, the most important being: websites of the relevant government authorities (e.g. the Department of Biotechnology [DBT], India and the Secretaría de Agricultura, Ganadería, Pesca y Alimentos [SAGPyA], Argentina); the national biosafety frameworks prepared through the UNEP-GEF (United Nations Environment Programme-Global Environment Facility) project[6]; information provided by countries to the Biosafety Clearing House (BCH)[7]; analyses of biosafety systems of specific developing countries (e.g. Burachik and Traynor, 2002; Sengooba *et al.*, 2006); and fact sheets on national biotechnology developments prepared by the United States Department of Agriculture (USDA) Foreign Agricultural Service[8].

8.4.2 Coverage of regulation within national biotechnology policies/strategies

The importance of developing up-front a collective statement of intentions with respect to biotechnology and how these might be achieved, in effect a comprehensive NBS, was emphasized in Chapter 7. Some principles were also described for preparing such a document and the types of information that could usefully be included, such as linkages with other government policies, e.g. on agriculture, the environment, human health, sustainable development and S&T. Laying out a ground plan about how to balance enthusiasm for agricultural biotechnologies with the need to protect the agrifood sectors, the wider environment and peoples' health, livelihoods and cultures against unforeseen risks should be an integral part of that policy/strategy. This should include general principles and direction to the subsequent process of putting in place a framework or system that is responsive both to national needs and obligations arising from international undertakings. At a minimum, it should describe the objectives of the system and highlight the key public policy issues and options that need to be considered, e.g. the roles of science vis-à-vis social and economic issues in decision-making, and how and where in the regulatory process the public may participate.

Annex 2 (Part 8.6) provides a synthesis of how the selected developing countries deal with regulation in their national policy/strategy documents. In some cases, these go into great detail about intentions for dealing with the safety aspects of GMOs, while others provide little or much less detail. In the former category (e.g. Chile, Kenya, Malawi and

6 www.unep.org/biosafety/
7 http://bch.cbd.int/
8 www.fas.usda.gov/info/factsheets/reports.asp

Zambia), this may be attributed to the fact that new biosafety laws had either recently reached the statutes or were in an advanced stage of preparation for their legislatures at the time of preparing the NBS documents. The lack of detail for other countries may have been because entire systems were already in place and the countries concerned considered it unnecessary to provide details already available elsewhere (e.g. Argentina, China, Brazil and South Africa). In other cases, it appeared that the main intent of the NBS documents was to emphasize promotion (India, Malaysia and Thailand in particular).

Irrespective of the scope and depth of coverage, all countries have established, or intend to establish, a specific legal framework, mostly through one or a number of new laws and/or secondary regulations, to deal with the safety issues surrounding GMOs. While considerable variation was noted in the "institutional constellations" for implementing these legal and regulatory frameworks (see below), certain features were relatively common and indeed were also prominent within the laws subsequently approved by national legislatures. These include requirements for labelling, for liability and redress, for taking social and economic considerations into decision-making, and informing and/or otherwise engaging the public in such decision-making.

8.4.3 Establishing national biotechnology regulatory frameworks

The challenge of putting in place and implementing a comprehensive, multifaceted regulatory system responsive to national needs and priorities, to the various articles of the CBD and CPB and that is consistent with other international obligations (e.g. on trade) requires substantial inter-institutional involvement to: (1) conduct inventories of national and international laws, national regulations, research agendas and institutions directly and indirectly concerned with biotechnology and biosafety, (2) analyse these and identify gaps and overlaps, and compare them with other national systems, (3) assess available human and other capacities, and (4) examine choices among the various policy options and delineate their social and other dimensions and trade-offs (also considering the policies of other countries, particularly with respect to trade). Ideally, this should be done before deciding on an appropriate regulatory structure and the legal and political means by which such a structure can be implemented.

Underpinning all these steps and iterations is the requirement for scientific, technical, legal, judicial, economic, trade, logistic, as well as the political skills needed to negotiate with all relevant ministries with their different priorities and perceptions of the appropriate balance to strike between regulating and encouraging the unrestricted use of new technologies. A further key requirement is inclusiveness and balance – ensuring the appropriate participation of representatives of all groups directly and indirectly affected by biotechnology and its regulation (see Chapter 9). While countries should find the conceptual framework developed by the International Service for National Agricultural Research and FAO in consultation with UNEP-GEF useful for developing their regulatory systems for advanced biotechnology (McLean *et al.,* 2002), they should bear in mind that this is only a guide, and that whatever is decided initially should be constantly evaluated and through experience modified to deal with developments in technology, social attitudes and within other countries.

8.4.3.1 Legal authority

When developing these systems, countries should establish clear legal authorities and responsibilities for implementing them. They have two, but not mutually exclusive options for doing so. The first is using their existing primary laws and the delegated legal authorities within these, to promulgate regulations for dealing with activities involving genetic modification. This provides a basis for regulating GMOs within a short time. At the same time, to create or strengthen inter-institutional linkages voluntarily. The second is to introduce a new primary law. This is a longer-term undertaking, but one that might be justified on several grounds, e.g. many primary laws are very old, lack or provide questionable authority to regulate biotechnology or make such authority weak, and/or are confusing and lack transparency and coordination by being scattered among different ministries. The pros and cons of these options and an analytical tool for assessing wider biosecurity legislation are described by FAO (2007c).

While the majority of developing countries surveyed have introduced new biosafety or GMO acts/laws, Argentina, Chile and China regulate GM applications within the framework of existing general legal authorities and specific regulations that have evolved with experience gained over more than 20 years. Brazil and South Africa are examples of countries that have successfully regulated GM applications through amendments to their original GMO-specific laws, while India does so through rules for implementing its 1986 Environment Protection Act.

In other cases (e.g. Peru and essentially all the African countries covered), the relevant laws are very recent and therefore few of the regulations, and particularly the administrative requirements that flow from them, may have been completed. It is therefore premature for these countries to judge whether their regulatory systems will stand the “test of time” or, as in the case of Brazil, have to be re-negotiated by national legislatures or simply adjusted through changes/additions to the regulations and procedures that are initially put in place.

Jamaica, Thailand and Uganda presently oversee biotechnology through voluntary guidelines developed through their S&T agencies which do not have regulatory mandates except perhaps for laboratory work. Thailand, on the other hand, has amended all its fundamental laws dealing with sanitary and phytosanitary measures, fisheries, food and feed etc. to cover modern biotechnology.

8.4.3.2 Structure and decision-making responsibilities

One of the main justifications for establishing new laws and regulations is to provide a unified, or at least well coordinated, national system for dealing with regulation of BFA applications throughout a chain that may stretch from R&D to use and consumption. The selected developing countries examined for this Chapter have systems in place that are both variable and, in some cases, fairly complex.

In Brazil, a National Biosafety Council under the Office of the President and composed of 11 Cabinet ministers is the top decision-making authority. It provides advice to the President in formulating and implementing the national biosafety policy, establishing principles and directives for administrative actions by the federal agencies involved in preparing and overseeing biotechnology guidelines, and considering "the socio-economic convenience and opportunities and national interest" relating to commercial authorization of GMOs. It is the highest institutional body to make a final decision on release of products for planting. It does not evaluate safety.

In China, the Joint-Ministerial Conference for Biosafety Management of Agricultural Genetically Modified Organisms coordinates actions on major issues in biosafety management of agricultural products. It consists of seven government agencies under the State Council, including the Ministries of Agriculture, Environmental Protection, S&T, Commerce, Health and other bodies.

The structure established by most countries consists of a National Biosafety (or Biotechnology or Genetic Engineering) Authority (or Board, Committee, Commission, Council, or Executive Council) for overseeing regulation. In some cases – notably Argentina and China – responsibilities are restricted to BFA. While varying greatly also in size (from less than 10 to over 70 members), their composition generally includes government officials, technical experts and in some cases, representatives of the private sector and CSOs. In China, there is both large ministerial and scientific representation, while in India three non-ministerial experts together with ministerial representatives constitute the national committee. Argentina, Brazil, Jamaica, Kenya and Uganda have representation from ministry, scientific, industry and civil society sources within their multidisciplinary and inter-institutional bodies. China, Malaysia and South Africa appear to have no civil society representation while Namibia's committee appears to be purely scientific in nature.

The authority entrusted to these committees varies. In some countries they take full responsibility for all major decisions concerning the safety of activities and products, e.g. authorizing imports, contained and non-contained field releases and consumption as food or feeds through to approval of specific guidelines and certification of premises. This appears to be the case in India and South Africa. In other cases, their mandate is restricted. For example, in Argentina, the Comisión Nacional Asesora de Biotecnología Agropecuaria (CONABIA) does not cover food safety and regulation of recombinant products of fermentation such as microbial inoculants and processing enzymes, although it does deal with GM animals (Burachik and Traynor, 2002). In many cases, these committees are advisory only, making recommendations to the Minister for Agriculture in China and South Africa; to the Minister of Environment in Malawi, Malaysia, Peru and Thailand; to the Minister of S&T or similar in Jamaica, Kenya, Namibia and Zambia; and to the Secretaries for Agriculture, Livestock, Fisheries and Food and for Livestock and Agricultural Services in Argentina and Chile respectively, and to the Minister for Finance, Planning and Economic Development in Uganda.

In both Argentina and Brazil, separate procedures are in place for advising the President and Secretary for Agriculture respectively of possible impacts on socio-economics and trade before final approval of commercial releases. One outcome of this procedure is that Argentina does not authorize commercial planting of GM crops that are not approved by its main trading partners. South Africa also appears to include socio-economic considerations in biosafety decision-making (Gruère and Sengupta, 2008).

In some countries, a variety of other committees perform specific scientific and technical functions in support of national committees. Examples are: China's Committee for Standardization of Biosafety Management, India's Review Committee for Genetic Engineering, Malaysia's Genetic Modification Advisory Committee, and South Africa's and Zambia's Biosafety Advisory Committees. These have various functions ranging from preparing guidelines, approving and inspecting research facilities and applications up to the stage of restricted multi-location field trials, through in the case of Argentina to evaluating the commercial impact on export markets by preparing technical reports in order to avoid negative impacts (the National Direction of Agricultural Food Markets, DNMA). Essentially all countries surveyed have also established Institutional Biosafety Committees to oversee R&D activities. Usually these are under the authority of Ministries of S&T or similar.

Decentralization of regulatory authority (i.e. from national to state/regional legislatures, governments and departments and even down to local authorities) is an issue of considerable and increasing importance for the regulation of GMOs in all countries, both developing and developed. It has already caused controversy, confusion and even moratoria on using GMOs in some advanced countries. Developing countries should therefore carefully consider and make appropriate arrangements for handling the interplay between central government and the responsibilities devolved to sub-national jurisdictions.

8.4.3.3 Transparency: Establishing clear criteria and standards for safety - baselines, comparators, thresholds and indicators for environmental and food safety

As Parties to the CBD and CPB and Members of the WTO, most developing countries have to establish and implement (including enforce) regulatory measures to protect human health and the environment while not unnecessarily restricting trade. Establishing assessment criteria, i.e. "comparator conditions" against which any effects, direct and indirect, arising from using and consuming GMOs will be judged, and specifying levels of safety expected should be laid out in regulatory guidelines to developers. These are basic requirements for both pre-release case-by-case environmental and food safety risk assessments, and both specific and general post-release monitoring of potential adverse effects. This ensures that notifiers know and understand the standards to which they will be held accountable and it fosters even-handedness and transparency in their implementation by regulators.

Nevertheless, a combination of ambiguities arising from the wording of some Articles within these agreements and the lack of guidance about the scope of, and discretion available to countries for national action, makes interpretation of how to "play by the rules" challenging to say the least. For example, words like "significant", "potential" and "adverse" when referring to reduction or loss of biological diversity and triggers for action; "sufficient" and "relevant" when referring to scientific information; "prevent", "avoid" and "minimize" in relation to the degree to which risks should be managed; and "appropriate" levels of health protection when dealing with food safety appear throughout the texts of these agreements. They also lack guidance, e.g. on how and at what point, precaution and socio-economic considerations can be taken into account when making decisions on risks and their management, and on the thresholds (spatial or temporal) of adversity.

Much has also been written about using the concept of "substantial equivalence" as the comparator within regulatory approaches for dealing with both the environmental and food safety dimensions of GMOs. This has been criticized for being ill-defined and leading to ambiguities concerning, e.g. the choice of growing conditions, comparator plants and acceptable margins of differences in food and feed composition (Millstone, Brunner and Meyer, 1999). These weaknesses have been recognized by national authorities and at the international level, and it is now generally accepted that, rather than being a substitute, substantial equivalence is the starting point for safety assessment. This issue is not pursued further except to emphasize two things.

The first is that the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants states that "the concept of substantial equivalence is a key step in the safety assessment process. However, it is not a safety assessment in itself; rather it represents the starting point which is used to structure the safety assessment of a new food relative to its conventional counterpart. This concept is used to identify similarities and differences between the new food and its conventional counterpart. It aids in the identification of potential safety and nutritional issues and is considered the most appropriate strategy to date for safety assessment of foods derived from recombinant-DNA plants. The safety assessment carried out in this way does not imply absolute safety of the new product; rather it focuses on assessing the safety of any identified differences so that the new product can be considered relative to its conventional counterpart" (FAO, 2009c). The second is that current regulations have protected the environment and the public from all potential hazards from currently available GMOs and their products, and while new *in vitro* molecular and other techniques are being researched for hazard identification, these are not sufficiently developed for regulatory decision-making (see e.g. Kuiper, Kok and Engel, 2003).

Differences in philosophy and implementation of regulations for environmental release of GMOs between industrialized countries (e.g. between product- and process-based approaches) have also been highlighted by many commentators (see, e.g. COGEM, 2008). In relation to risk assessment this debate is about semantics – transgenesis is *de facto* a regulatory trigger in all countries even if it is the phenotypic characteristics of the organism that are the potential source of environmental risks, and the questions prescribed and the type of information required for permits or authorizations are very similar across national jurisdictions.

While there will always be room for improving understanding between regulatory authorities on how to measure risk in all areas of regulation and to employ the same analytical tools for this purpose, such a common understanding could never rule out policy differences on national approaches with respect of risk management (i.e. decisions concerning the level of acceptable risk in a given regulatory policy or system). Further, with few exceptions, management interventions have been developed for, and applied to, large-scale intensively managed commercial farms supported by owner/manager-supplier contracts that define the conditions for using the GMO and related inputs, and in countries that do not have wild relatives of the (food) crops in question. More research is needed to assess the appropriateness (technical, economical and social) of the management strategies used in temperate regions and large farming operations under the variety of climatic and ecological conditions within which small-scale farming systems exist in developing countries.

Decision-making is both highly complex and has scientific, social and political dimensions. In some countries, socio-economic considerations may not be appropriate in regulatory regimes, leaving the market to respond to non-safety consumer demands. In others, it may not simply be the prerogative of scientists and government regulators – some societies increasingly want a say in how it is done and in the decisions that are made, i.e. regulatory systems designed to assess only health and safety risks do not address the concerns of some people about GMOs. Other concerns influencing farming and food purchasing decisions include the type of agricultural system from which the product originated, and whether the foods are "natural" and "pure". Some consumers also have moral, religious or ethical objections to buying certain products. It seems clear, therefore, that while product safety must be assured by the government, public confidence in modern biotechnologies will increasingly require that socio-economic impacts are evaluated along with potential environmental and human health risks, and that people representing diverse views have the opportunity to participate in judgements about using new technologies. Fostering such approaches will need a significant revamping of the current approaches taken to providing assistance to developing countries for making rational technology choices. At a minimum, these should ensure that the human right to adequate food and to democratic participation in debate and eventual decisions concerning these technologies are respected, as must the right to informed choices (FAO, 2001).

8.4.3.4 Definition of roles, responsibilities and accountabilities

Countries should also define, and make transparent, the roles, responsibilities and accountabilities of their National Committees and of existing national institutions since, in most cases, the roles of existing regulatory agencies remain much better defined for conventional than for biotechnology-related activities. While the ultimate intent of most National Committees is to encourage "collective ministerial decision-making" that is informed by scientific and technical considerations, and it is then the responsibility of the traditional regulatory agencies including their inspectors to implement the regulations, it will take some time before most countries have reached the stage of harmonizing the many processes and practices associated with GMO regulation.

It is particularly noticeable that in some countries the regulation of GM foods is not covered by Biosafety or GM Acts and that full decision-making authority resides with Ministries for Health through existing or proposed new legislation. This divorcing of the "environmental" and "human health" aspects of biotechnology regulation may not be optimal for encouraging the development and implementation of comprehensive, fully integrated and balanced policies and regulatory frameworks for some biotechnologies along entire food chains. It may also lead, e.g. to "asynchronous national approvals" for different uses (see below).

8.4.3.5 Making information available to regulators and the public

One issue of considerable concern about BFA relates to the confidentiality of the information provided to regulators when submitting dossiers seeking authorization for particular activities. Under the CPB, Article 21 requires importing Parties to allow notifiers to identify information that should be treated as confidential, but exactly what kind of information can be kept confidential is not clear. Presumably, as in the Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (1998), the Article refers to commercial and industrial information. However, the Stockholm Convention on Persistent Organic Pollutants, for example, states that information on health and safety of humans and the environment shall not be regarded as confidential and this and other agreements provide for other information being exchanged on a mutually agreed basis.

Policy-makers should be aware that confidentially requirements under the CPB appear to apply only to information connected with the advance informed agreement (AIA) procedure – i.e. it is silent on requirements for national development. This leaves countries with essentially two options for dealing with the issue, namely through intellectual property rights or specific GMO legislation. Apart from Namibia, which deals specifically with confidential information within its Biosafety Act, it appears that most countries have chosen to deal with this matter through IPR legislation (Chapter 9). Options for making information available to the public are also covered in Chapter 9.

8.4.4 International harmonization

Many attempts have been made, and continue to this day, to "harmonize" biotechnology regulations regionally and internationally. Undoubtedly, the biggest success story is the work of the WHO/FAO Codex Alimentarius Commission whose standards are accepted as reference points by the SPS Agreement under the Uruguay Round administered by the WTO. These include the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (2003); Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (2003); Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Micro-organisms (2003); and the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals (2008)[9]. In addition, work is underway to deal with food safety assessments for recombinant DNA plants modified for nutritional and health benefits, and through both Codex and the OIE to deal with the matter of assessing the safety of foods derived from animals treated for diseases through gene therapy and recombinant DNA vaccines.

Also, from the perspective of transboundary movements of GM plants, the international standard for phytosanitary measures (ISPM) No. 11: Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risks and Living Modified Organisms (2004)[10] which was developed under the auspices of the IPPC, is of key importance for environmental risk assessment. The Association of Southeast Asian Nations (ASEAN) has also developed (non-binding) Guidelines on Risk Assessment of Agriculture-Related Genetically Modified Organisms[11].

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9 All four texts are provided in FAO (2009c)

10 https://www.ippc.int/file_uploaded/1146658377367_ISPM11.pdf

11 www.aseansec.org/6226.htm.

Other relevant documentation includes the Organisation for Economic Co-operation and Development (OECD) work on risk/safety assessment of modern biotechnology covering food, feed and environmental safety. The main outputs from this programme are two series of "Consensus Documents", one on the Harmonization of Regulatory Oversight in Biotechnology (OECD, 2005) and the other on the Safety of Novel Foods and Feeds[12]. These tools were developed for helping decision-makers and other stakeholders in conducting biosafety assessments of a number of cultivated plants (including on their basic biology), trees and micro-organisms, as well as providing general information about traits. The documents for assessing the safety of novel foods and feeds include elements on key nutrients, anti-nutrients, toxins and allergens. The OECD information sources are constantly up-dated and although most relevant to developed countries, they contain much that is invaluable for developing countries. Recent examples include documents on bananas and plantains and on compositional considerations for cassava.

Another valuable and practical tool developed by the OECD is the "unique identifier"[13] for global tracing of transformed events and which is currently being used by many GMO developers as well as the BCH and the FAO International Portal on Food Safety, Animal and Plant Health.

While there is clearly no shortage of information or readiness of numerous international and national agencies and private consultants to provide training and capacity building services, and despite expenditures estimated to exceed US$150 million up to 2006 on the topic and a further US$80 million earmarked since by GEF (UNEP-GEF, 2006), few developing countries receiving this support have actually approved a GMO for field use. Furthermore, considerable disagreement continues to exist within and across countries concerning the nature of the hazard(s), if any, and the most appropriate approaches and methods to assess potential risks from employing genetic modification and other biotechnologies in the agrifood sector. There is also much disagreement about how to deal with socio-economic risks and whether there is a need for labelling, and whether regulatory decision-making should directly involve people outside of regulatory agencies.

This global regulatory divide, coupled with current disagreements between countries within the one region of the world that has established regionally-agreed standards for biotechnology regulation, suggests that while considerable scope exists to improve understanding, and reduce regulatory costs, among developing countries through the pursuit of informal collaborations and mutual recognition of voluntary guidelines, prospects for

12 www.oecd.org/biotrack
13 http://www2.oecd.org/biotech/

comprehensive harmonization of biotechnology regulatory oversight within developing country regions do not look promising. This is because: (1) decision-making is essentially about dealing with uncertainty and societal value judgements concerning levels of acceptable risks, (2) within all developing country regions, national policies on GMOs currently range from moratoria to approval of field trials through to commercial field releases, and (3) science can only inform but never replace, the decisions of policy-makers concerning what they consider to be legitimate and justifiable reasons for a particular course of action.

This certainly does not mean that harmonizing science and data requirements cannot be improved. Examples of voluntary guidelines might include: approaches for conducting risk assessments; for dealing with confidential information; on criteria and procedures for authorizing and overseeing confined field trials; on methods for obtaining and reporting molecular characterization data; on methods of analysis and sampling for GMOs in different matrices; approaches for conducting post-release environmental monitoring; and for producing consensus documents on the biology of plants used by smallholders in developing countries.

Hence, while there is general consensus that harmonization of regulatory approaches across countries is important, more important at this juncture is coordination and harmonization of GMO regulation between relevant government ministries within a country. Nevertheless, for countries interested in the options and implications for governance of regional biotechnology regulations, Birner and Linacre (2008) deal with possibilities and challenges in West Africa and provide much food for thought.

All of the above may be sufficient justification for developing countries to consider adopting a biosecurity approach, defined as "a strategic and integrated approach to analysing and managing relevant risks to human, animal and plant life and health and associated risks to the environment" (FAO, 2007a). Traditionally such risks have been dealt with in a sectoral manner by means of food safety laws, and animal and plant quarantine and pesticide regulations which have also been implemented separately, resulting in costly regulatory systems that require high investment and recurrent costs (infrastructure and human resources). Many developing countries simply cannot afford sector- or GMO-specific approaches and might benefit greatly from a more integrated approach without necessarily creating new or unified structures. This would also provide an opportunity for greater harmonization of terminology and methodology for risk analysis while respecting the need for individual sectors to tailor risk analysis procedures to the characteristics of the risks involved.

8.4.5 Final considerations

First, developing a regulatory framework for GMOs can be a complex, resource-intensive and daunting process. Second, irrespective of the established structures, regulatory "functions" place enormous scientific, technical and administrative demands on national institutions.

This is because laws and general/specific regulations relating to S&T, import, export, transit, use under contained and uncontained conditions, and consumption of food and feeds all require the development of standards, technical and procedural guidelines, forms etc. These then have to be implemented by institutes and companies that wish to undertake particular activities and by the structures within the regulatory decision-making authorities themselves. They include, but are certainly not limited to: preparing dossiers for and responding to notifications, preparing guidelines for conducting risk assessments, issuing and refusing permits and specifying conditions, certifying and inspecting facilities and field sites, preparing guidelines for post-release monitoring, establishing methods for testing etc.

Third, while the vast majority of developing countries have ratified or are signatories to the CBD and CPB, and through UNEP-GEF and a multitude of other externally financed projects have drafted national biosafety frameworks or set up systems for governing GMOs and their products, most of these have not been put into practice by the countries concerned. In fact, a recent assessment by Johnston *et al.* (2008) concluded: "in all probability the majority of developing countries, perhaps as many as 100, including most countries of Africa, Central Asia, Oceania and the Caribbean, are unable to manage modern biotechnology and implement their national biosafety frameworks. Indeed, the capacity deficiencies are so pervasive and broad that there is no effective international system of biosafety at the moment. In addition, the volume of resources available to address these needs in the coming years appears insufficient to provide the necessary support for countries to implement their basic obligations under the CPB".

This reality is also borne out by the feedback obtained from recent CPB regional consultations on capacity building and exchange of experiences on risk assessment and risk management of GMOs[14]. It is also probably no exaggeration to state that the financial commitments made by the international community over the last 5–7 years to support the setting up of national biosafety systems has exceeded the investments made in partnering with countries to foster R&D in agricultural biotechnologies and their applications. This has both skewed external investments and diverted significant internal investments including human resources into the specific, technically much more demanding and costly area of GMOs at the expense of possibly more easily developed, applied and profitable biotechnological approaches not requiring regulation, e.g. use of molecular markers and possibly genomics for characterizing genetic resources and speeding up selection and breeding programmes. This is a significant issue for reflection among national policy-makers and the international community. On the other hand, a few developing countries have reaped substantial rewards from their investments in biosafety systems.

[14] Information documents from Africa, Latin America and Asia are available at www.cbd.int/doc/?meeting=MOP-04

Another noteworthy issue is the growing trend among researchers engaged in risk assessments of measuring everything that can be measured. Drivers include developments in genomics that make it possible to measure gene expression at the level of proteins and specific metabolites, advocacy groups, regulators themselves and risk researchers. These are constantly pushing up the costs of regulation and barriers to investments in genetic modification compared with, for example, producing new cultivars through traditional breeding. As discussed in Chapter 7, the costs of GMO regulation are already substantial. Developing countries are therefore becoming increasingly challenged to keep up with an ever-widening and constantly evolving battery of scientific skills and analytical tools imposed on developers of GMOs by their regulatory authorities as a result of developments in the industrialized world. From a regulatory perspective, one must ask: are these measurements really needed to measure safety or risk?

A related issue is the mass of information, guidelines and other "decision-support" materials available through the BCH and elsewhere for conducting risk assessments and, on the other hand, the palpable struggle of authorities in most developing countries to actually do the job. This gap between information on, and practical knowledge and experience of, risk assessment is certainly one of the many constraints to successful implementation of the CPB and an Ad Hoc Technical Expert Group on Risk Assessment and Risk Management was established to address, *inter alia*, the need for further guidance on specific aspects of risk assessment. The report of its first meeting (CBD, 2009) suggests that specific case guidance (i.e. a roadmap/decision tree approach) on how to actually apply the methodology for real cases should be developed coupled with extensive hands-on training of practitioners using "real-life" cases. This seems long overdue.

Given this background, developing countries clearly have to make very careful choices concerning what biotechnology activities they propose to pursue and how. In particular, they need to decide whether their S&T efforts should be directed solely at non-GMO biotechnologies including tissue culture, molecular markers, molecular and immuno-diagnostics, and reproductive biotechnologies like artificial insemination and embryo transfer etc. These would not require any or significant regulatory oversight and all other things being equal in terms, for example, of yields, quality and/or efficacy, they would not have the same potential to affect: (1) existing farming practices in national landscapes, (2) arrangements for product harvesting, storage and shipment within and between national borders, and (3) regional and international trade through one or a combination of scenarios such as outright bans on acceptance of GM products; "zero tolerance" of unapproved events present in non-GMO shipments of the same product by a trading partner; and asynchronous approvals by different potential importing countries (see, e.g. Stein and Rodríguez-Cerezo, 2009). In the case of animals, a decision has to be made as to whether cloning should be regulated.

If a GMO is believed to offer potential for addressing an important constraint to agricultural production, decisions have to be made concerning what kind of regulations should be put in place to authorize its use(s), and how and by whom they should be enforced. The decisions made will have a profound bearing on the S&T expertise required and on the scope of any laws, regulations and associated administrative, inspection and judicial procedures that need to be put in place, and hence on costs. This requires taking a total chain approach to decision-making, linking the S&T demands of R&D with those of regulating the environmental and human health aspects of the technology, and ensuring the establishment and operation of a regulatory system that works in the best interests of the country while respecting its international obligations. Unfortunately, many countries have not considered regulatory demands outside of the laboratory and other strictly contained environments before investing in GMOs for developing products that will be used by both farmers and consumers.

8.5 ANNEX 1: Building and funding biotechnology R&D and innovation capacities in selected developing countries

8.5.1 Training and capacity building

India now directly supports institutions providing undergraduate training in life science and biotechnology to achieve the status of "Star Colleges"[15] by improving teacher skills and knowledge and providing equipment and reagents and running summer schools that expose students to platform biotechnologies. It has also established a United Nations Educational, Scientific and Cultural Organization (UNESCO) Regional Training Centre for school and university teachers and researchers. The REDBIO Foundation in the Latin America and Caribbean region has designed interactive and multimedia course materials for educating schoolchildren specifically on BFA.

In order to fulfil their complementary mission of knowledge production and training of skilled human resources for biotechnology, all of the selected countries reviewed increased, or intended to increase, PhD and postgraduate training opportunities, particularly in relation to R&D. How much of that effort has been, or will be, directed to BFA is unclear since national statistics are unavailable or imprecise. Nevertheless, Argentina, China, India and Malaysia are examples of countries that have shown considerable commitment to increasing both the number and quality of research staff working on BFA, with the share of researchers having a PhD increasing in China from 2 percent in 1986 to more than 20 percent in 2000

[15] http://www.dbtindia.nic.in/proposals/Areas/HRD/Star/star_colleges_in_life_sciences.htm

(Huang and Wang, 2002). India is currently offering 18 MSc courses in BFA at various universities and over 30 universities and higher education institutions in Argentina offer undergraduate and graduate training in biotechnology (ProsperAr, 2008).

There are now numerous opportunities for training through programmes associated with inter-governmental and institutional agreements. One example is the Centro Argentino-Brasileño de Biotecnología (CABBIO), which coordinates public-private research teams from Argentina and Brazil that work on specific biotechnology research projects having an industrial application. This centre runs the Escuela Argentino-Brasileña de Biotecnología (EABBIO), which promotes scientific exchange within the Latin American region in biotechnology, including BFA, through courses, conferences and seminars promoted by scientific and academic institutions of both countries, and through the financing of scholarships in Argentinian and Brazilian research centres (da Silveira and de Carvalho Borges, 2005). Another is the agreement reached in 2006 between the Argentinian Ministry of Science, Technology and Productive Innovation and the Spanish Ministry of Education and Science to expand and strengthen exchange between research groups in plant genomics. Similar arrangements now exist also between the more advanced developing countries surveyed (Argentina, Brazil, China, India, South Africa) and those that are less advanced, e.g. in sub-Saharan Africa, South Asia and Central America.

Developing countries in all regions also benefit from the numerous meetings, workshops and courses that are held under the auspices of international and regional organizations, banks and development agencies. These address needs ranging from national and agricultural development, S&T and legal and regulatory policy-making, through to implementing specific projects and using specific techniques.

For countries in all developing regions, a further important option to build knowledge and know-how concerning BFA is through partnerships with the CGIAR centres, most of which have significant capabilities for specific training and wider capacity building. These partnerships continue to be highly valued by even the most advanced developing countries and their continuing pursuit and strengthening should be a cornerstone of BFA policy for the technologically weaker countries, particularly in areas like crop and livestock improvement and genetic resource characterization. An overview of the wide range of capacity building activities that have been organized over the past years by FAO, other UN agencies/bodies and the CGIAR centres regarding BFA in developing countries is available from FAO-BiotechNews[16].

Countries that have created new institutions or "re-branded" existing institutions for biotechnology R&D include:

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[16] www.fao.org/biotech/

- Argentina, which set up INDEAR, the National Institute for Agro-biotechnology, and CEBIGEVE, a new centre for plant genomics resulting from Spanish-Argentinian scientific cooperation (ProperAr, 2008);
- Brazil, which set up ONSA (Organization for Nucleotide Sequencing and Analysis), a virtual genomic research institute initially encompassing 30 laboratories located at several research institutions within the State of São Paulo (da Silveira and de Carvalho Borges, 2005); also, the Centre for Molecular Biology and Genetics of the State University of Campinas (CBMEG);
- China, which established 12 National Key Laboratories (NKLs) specifically working on BFA (Huang and Wang, 2002);
- India, which established seven Centres for Plant Molecular Biology (CPMB) and a National Centre for Plant Genome Research (Sharma, Charak and Ramanaiah, 2003), and a National Agri-food Biotechnology Institute (NABI);
- Malaysia, which created a National Institute of Agrobiotechnology at its Agricultural Research and Development Institute (MARDI);
- Thailand, which set up a National Centre for Genetic Engineering and Biotechnology with units for plant and microbial genetic engineering.

Several countries have also established "biotechnology incubators", "technology parks" or "clusters", the key goals of which are commercialization, employment and economic development through facilitated interaction between government, universities and industry. While many leading universities in the countries concerned now offer entrepreneurial education to support new venture creation, incubation goes a step further by co-locating the resources and capabilities needed for the support of new ventures helping them to navigate the challenges of funding, management and identifying market needs. Though incubator models vary widely, most have some degree of government involvement and many are "spin-offs" from, or affiliated to, universities and research institutions and receive a large part of their support from the parent university, national and state governments, industry and foundations.

While the "core business" of these incubators is S&T based, their potential to provide "added value" comes from the intangible "soft services" they provide such as networking, grouping competencies, learning and promoting synergies. This approach has been given high priority for BFA by governments like those in Brazil (Chandra, 2007), e.g. through Cietec in São Paulo and Biominas in Belo Horizonte; India, e.g. the Biotechnology Park at Lucknow for tissue culture and Knowledge City at Mohali, Punjab for bioprocessing; Malaysia (BioValley); and Thailand (the Thailand Science Park at Rangsit which emphasizes genetic engineering and other biotechnologies).

8.5.2 National funding policies and initiatives

Argentina: Through reforms to its S&T system, Argentina established a National Agency for Scientific and Technological Promotion (ANPCyT) in 1996 with a board to encourage and finance cooperative agreements with national, provincial and municipal governments, corporations and foundations. It administers two funds, the Fund for Scientific and Technological Research (FONCyT) and the Argentine Technology Fund (FONTAR), which finance projects on a competitive basis ranging from basic research to improving competitiveness through technological innovation. A major part of these funds is directed at biotechnology (ProsperAr, 2008).

Biotechnology also benefits from a Law 26,270 published in 2007 for the promotion of the development and production of "modern biotechnology" managed by the Ministry of Economy which is valid for 15 years. This law created a fund for the stimulation of new entrepreneurs in modern biotechnology which finances (at a subsidized cost) the start-up capital for new SMEs, including training of human resources. Interesting aspects include providing leave of absence to employees in public sector institutions to work in the private sector, and a requirement to register new innovations arising from the projects with the National Registry of Industrial Property. Significant also are the sources of finance for this fund which include the State budget; income from legacies and donations; non-repayable funds provided by multilateral agencies, foreign governments or NGOs; and funds repaid by entrepreneurs benefiting from the incentives afforded by the law to individuals, institutions and firms which include:

- accelerated amortization (for income tax purposes) of capital goods and special equipment purchased specifically to be used in the projects;
- early reimbursement of the value-added tax on the purchase of these capital goods;
- transforming 50 percent of payroll taxes into fiscal credit bonds;
- transforming 50 percent of the cost of hired R&D services into fiscal credit bonds;
- special access to the "ANR PATENTES PyMEs", a call through which FONTAR finances the costs faced by SMEs to obtain patents for innovations in the area of biotechnology.

Brazil: Federal funds for financing S&T, including BFA, come from the Ministry for S&T's National Fund for Scientific and Technological Development (FNDCT) which is channelled through its National Council of Scientific and Technological Development (CNPq), whose main goals are to support human resource training and research infrastructure, and a specialized public company FINEP which addresses innovation. In 2001, the government introduced Sectoral Funds as a way of targeting research at particular sectors, with agrifood and biotechnology being two of the beneficiaries. As in Argentina, funding is competitive, not restricted to public sector institutions and promotes public-private sector partnerships.

Funds do not flow directly to the company but to the university, public research institute or foundation to finance a project within a company. Many projects of the Brazilian Agricultural Research Corporation (EMBRAPA) and universities have been funded to develop the Brazilian agricultural system. FINEP also has a venture capital programme called Inovar, as well as a seed capital programme that provides funding for early stage growth. The Brazilian Development Bank (BNDES) which used to finance only large companies now has a support programme also for micro-enterprises.

The State of São Paulo also has an autonomous research foundation (FAPESP) linked to the Secretary for Higher Education in that State which serves essentially the same purposes – competitive grants and both public and private sector involvement. Its funds are guaranteed by the Constitution of the State of São Paulo which ensures it a 1 percent share of the total tax revenue of the State.

Another option available is to secure a loan from a development bank. This was done by a biotechnology incubator in Belo Horizonte which started a programme with the Inter-American Development Bank (IDB) to finance new companies. The IDB provides grant money of US$200 000 – US$1 million for the incubator to invest in promising new firms, subject to the recipient providing matching financing. The programme allows the incubator to invest money in the company and the return on investment is then reinvested in other companies. This particular incubator has financed 12 companies through the IDB programme and it has also started a US$4 million seed capital programme in partnership with FINEP and FAPEMIG (the State Agency for Science and Technology) to invest in early stage biotechnology ventures, with the incubator taking a 25–30 percent stake in the venture in return for its investment.

Additionally, the Brazilian Congress approved a new Innovation Law in 2004 aiming to encourage researchers in public institutions to establish partnerships aiming at developing new technologies. For example, it gives researchers the possibility to work in other S&T institutions for the time necessary to conclude joint projects or they can request special leave without pay if they decide to become involved with a "start-up" company to further develop their new technologies[17].

India: The Biotechnology Industry Partnership Program (BIPP) introduced by the Department of Biotechnology (DBT) supports cost-sharing research between public and private sector entities according to four categories:

- areas of high relevance with no assured market, e.g. new crops against drought, salinity and major diseases and orphan crops of regional interest;

[17] www.wipo.int/sme/en/documents/brazil_innovation.htm

- cutting-edge technology for second generation biofuels and for increasing global competitiveness and leading to high value products, e.g. bio-based energy, genomics, proteomics and metabolomics;
- evaluation and validation of products already developed by SMEs with high national importance, e.g. through field trials of new cultivars provided there is an Indian innovation involved;
- shared major facilities for platform technologies, e.g. large animal and transgenic facilities, genomic technology sectors and good manufacturing practice (GMP) facilities for vaccines.

Different financing and management models are foreseen for these facilities including, for example, government supported (100 percent grant-in-aid), joint ownership, located in an existing national laboratory managed by a consortia of industries; public-private partnership (50 percent grant-in-aid), shared profits, and differential fees for public and private use, specialized facility for discovery and innovation, soft loan, differential fee for public and private users, and certain percent of time devoted to education and training of DBT-identified people for capacity building. Intellectual property, technology transfer and licensing arrangements would vary with the model of partnership and cost-sharing.

Kenya, **Tanzania** and **Uganda**: With joint funding from the Rockefeller Foundation and the Gatsby Charitable Foundation, the Maendeleo Agricultural Technology Fund was established in 2002 and since then it has helped different organizations and institutions in Kenya, Tanzania and Uganda to move innovative agricultural technologies from research into farmers' fields. With an advisory panel of local experts from these three countries and donor representatives, and supported by the Ministries for Agriculture and local governments and NARS, this Trust provides grants on a competitive basis to projects identified through value chain priority-setting. In Kenya and Uganda, tissue culture derived banana planting materials were acquired by large numbers of small farmers through a micro-credit scheme. FARM Africa, a UK charity, provides support and strategic direction to the management of the fund. In Uganda, supplies of plantlets come from a large commercial laboratory which has also set up nurseries and demonstration gardens in different parts of the country to distribute plantlets and train farmers.

Malaysia: Various initiatives and mechanisms have been introduced by the government to promote the development of biotechnology. These include:

- grants to support both R&D and commercialization of research findings in specific areas of national importance to the Malaysian industry, BFA being a high priority. There is a range of schemes available which have a fund allocation to biotechnology and these are administrated by various governmental bodies such as the National Biotechnology Directorate (NBD) and the Malaysian Technology Development Corporation (MTDC);

- venture capital to support companies and enterprises in exchange for a percentage of ownership in the firm. A government-owned company, Malaysia Venture Capital Management Berhad (Mavcap)[18], was set up to manage an approximately US$135 million fund in 2001. Out of this, US$25 million was allocated to biotechnology in the form of direct investment, and outsourced to smaller fund managers;
- companies approved by the Malaysian Biotechnology Corporation are eligible for income, investment and import tax or duty exemptions as well as other financial inducements.

South Africa: An Innovation Fund was set up to promote technological innovations and South Africans seeking IP protection, with the aim of establishing new enterprises and expanding existing industrial sectors, including biotechnology. The main funding instruments are:

- a Technology Advancement Programme (TAP) which offers public venture capital support for projects in the late stages of R&D (i.e. where proof-of-science already exists) and which is open to higher education institutions, science councils, SMEs and consortia of these entities;
- a Missions in Technology (MiTech) TAP which invests in public-private partnerships aiming to develop technological platforms that will improve entrepreneurial competitiveness, and where the co-investments are with industry players on projects identified and driven by that industry;
- a seed fund which supports early commercialization or business start-ups in order to take a novel and inventive technology that is at the prototype stage through to the market. The Commercialization Office administering this fund also engages in strategy formulation, development of commercial routes to market, due diligence and deal-structuring;
- Patent Support Funds which are instruments targeted at SMEs and techno-entrepreneurs to assist with the costs associated with IP support and protection, and supported by an IP office.

8.6 ANNEX 2: Coverage of regulation within national biotechnology policy/strategy frameworks in selected developing countries

Argentina: One of only two developing countries to develop a specific BFA strategy, Argentina mentioned as priorities the need to strengthen the legal and institutional framework through laws on regulation and development of a communication plan and

18 www.mavcap.com/v2/

system for engaging the public. As part of its strategy, it proposed to establish an Office of Biotechnology within SAGPyA to advise and assist in the management of biotechnology and to act as the secretariat of the National Advisory Commission on Agricultural Biotechnology (CONABIA) which had been established in 1991 to regulate the introduction and release of GMOs into the environment.

Brazil would ensure safety to human health and the environment in compliance with obligations under the CBD and CPB, and specifically strengthen implementation of legislation related to research, production and marketing of GMOs and promote training in risk assessment, management and communication. It would also promote monitoring of GMOs released into the environment and strengthen institutional biosafety management.

Chile's NBS gives high importance to the environmental and food safety aspects of GMOs and the need to take protective measures. Of the 23 actions outlined in the policy, nearly half relate to an overall goal of establishing a regulatory framework that guarantees a safe, sustainable and responsible development of biotechnology. These include recommendations to draft a framework law on biotechnology; provide training of staff in public institutions; develop regulations for foods derived from GMOs; labelling; procedures for release into the environment; certification of GMO products for export, including mechanisms of traceability; reviewing, and where necessary amending, legislation on the environment, agriculture, aquaculture and health as well as CONICYT's (Comision Nacional de Investigación Científica y Tecnológica) Manual on Biosecurity Standards which includes technical standards for laboratory safety. Other recommendations include the creation of a Committee on Biotechnological Regulations to ensure appropriate coordination between public regulatory authorities and review proposals for regulation from different agencies, and a Biotechnology Forum for public participation and information allowing for the development of informed public opinion.

India would reinforce its regulatory framework, create a National Biotechnology Regulatory Authority (now called the Biotechnology Regulatory Authority of India) within the DBT which would be set up as an independent, autonomous and professionally led body to provide a single window mechanism for safety clearance of GM products and processes.

Jamaica's biotechnology policy includes addressing the environmental and food safety aspects of GMOs through promoting research on risk assessment and management. The NBS notes that prior to beginning GM trials in 1997, a National Biosafety Committee was legislated [through the Plants (Importation) Control Regulations, under the Plants (Quarantine) Act] to monitor importation of GMOs for experimental use (transgenic papaya and more recently, GM cotton). The Committee has also been involved in sensitizing the public on biosafety issues, and other tasks include preparing guidelines, and codes of conduct for relevant users of GMOs. Through UNEP-GEF funding, a national biosafety framework project was implemented which produced a draft biosafety policy and act which are expected to form the basis for the establishment of requisite legislation prior to ratification of the CPB.

Kenya: Ensuring safety is one of the key objectives in its biotechnology strategy, a critical requirement being to enhance mechanisms to adequately assess safety and to develop and identify appropriate management practices to minimize potential risks to human health and the environment. The Government intended to institutionalize risk assessment and management at the stages of research, field trials and commercialization, as well as introduce an efficient monitoring system. Any non-science issues would be separated from the risk assessment process, and a precautionary approach would be taken to ensure the safe transfer, handling and use of GMOs. All activities would be subject to approval by an assigned authority in addition to fulfilling requirements of the 1999 Environmental Management and Coordination Act, and other existing laws and standards governing the environment, phytosanitary and sanitary measures. The need was expressed for new legislation to address all aspects of modern biotechnology, and therefore the statutory mandates of existing institutions would be reviewed with a view to enhancing implementation of the policy. New legislation on biosafety would take into account international regulations and treaties, and it would apply to all experiments, field trials and commercial activities involving GMOs. The law would also define a liability regime. Flexibility would be achieved by investing relevant authorities with regulatory powers to promulgate subsidiary legislation addressing specific issues. A National Biosafety Authority would be established as a central coordinating and implementing body, working together with the relevant government regulatory institutions to ensure adherence to laws and regulations and provide guidance on biosafety and related legal matters. It would establish linkages with institutions and institutional biosafety committees according to guiding principles and it would work closely with the National Commission on Biotechnology.

Malawi: Biosafety is one of the key issues covered in the country's biotechnology policy document which includes descriptions of: (1) a clear goal, i.e. "promote and ensure the safe transfer, development, handling and use of biotechnology and products that may have adverse effects on the environment and human and animal health", (2) an objective – to provide safety measures for the above and establish acceptable standards for risk assessment and management, and (3) a series of six strategies including establishing facilities for testing and monitoring GM products, instituting a system of risk assessment, monitoring and enforcement, and developing bioethics capacity. Implementation would be through a National Biosafety Regulatory Committee under the Ministry of Environment with representation from 14 ministries and other institutions. Responsibilities would include developing and publishing regulations, guidelines and standard operating procedures (SOPs) for contained experiments, confined field trials, commercial releases, food safety, storage, labelling and transportation; reviewing GMO applications based on expert advice to make recommendations for final approval to the Minister; reviewing risk assessment reports; referring licenses or permits to appropriate reviewers for assessment and recommendation; and mobilizing resources for biosafety programmes. Food safety is a separate policy area/theme with a separate goal, i.e. "promoting quality of life through food security in accordance with local and international safety standards" through establishing effective regulatory mechanisms for importation, exportation, development, labelling, use and disposal of products; and ensuring proper storage and handling of biotechnology products to protect the environment and the safety and health of workers; protecting human rights by guaranteeing consumer choice by: establishing thresholds for acceptance levels of specific biotechnology products; ensuring adherence to safety requirements and appropriate labelling of products; and disseminating information on food products derived from modern biotechnology.

The preamble to **Namibia**'s national biotechnology policy reaffirms its commitment to the principles of the Rio Declaration and especially to those on liability and compensation for damage and precaution. It then describes overarching principles for biosafety, including controlling applications which could harm its biological diversity and the health of its citizens; that the use, import, export, sale and transit of applications and products must conform to its existing laws; and that regulation will be through a competent body advised by a technical body independent of both government and industry. This body would be transparent in its decision-making and take full account of environmental, public health, social, economic and cultural concerns. All costs in the decision-making process including field trials would be met by the applicant; there would be cooperation with other States to ensure safe use within its borders; and pending the outcome of global and regional assessments of the severe potential social, economic and environmental risks associated with genetic use restriction technologies (GURTs), the country would impose a five-year moratorium on the use of any material using this technology. Its policy provides for the establishment of a permanent participatory planning process to feed into regulatory decision-making; for the development of regulatory capacity to assess, test, monitor and control applications in accordance with agreed biosafety guidelines; support for research to safely apply biotechnology techniques; and an institutional framework for national decision-making and international cooperation.

The regulatory framework is described in some detail in the NBS including, *inter alia*, its scope, i.e. all GMOs and their products, and all existing laboratory and field applications; the regulatory process, which would include notification, risk assessment, occupational safety, labelling of food and feed sold in, or imported to or through the country, monitoring and enforcement measures relating to import and export of products, laboratory and field use including handling, disposal, containment, control, monitoring and release. The implementation strategy outlines a national institutional framework for regulatory, administrative and R&D activities which includes the Ministry of Higher Education, Vocational Training, Science and Technology (MHEVTST) as the competent authority and a National Biosafety Advisory Council to receive and process applications, convey decisions and supporting materials to the Minister for MHEVTST who formally makes decisions. This Council will consult international and/or local expert to reach sound decisions and applications can be dealt with on a fast track or full review basis, the former being subject to review by one specialist and the latter by three specialist advisors plus agreement with neighbouring countries in cases where they could be impacted.

Malaysia: Its national biotechnology policy is underpinned by nine policy thrusts, one of which is dedicated to legislative and regulatory framework development, i.e. to "create an enabling environment through continuous reviews of the country's regulatory framework and procedures in line with global standards and best practices".

Peru's stated principles for national regulations regarding biosafety include: guaranteeing an adequate level of protection of human health, the environment, biological diversity and its sustainable use during R&D, production, transport, storage, conservation, exchange, commercialization, confined use and intentional release into the environment of GMOs and products derived from them; their application on a case-by-case and step-by-step basis; labelling decided by a Competent National Authority; but enforcement should not limit the development of modern biotechnology or act as a technical obstacle or concealed restriction to its commercialization; the concept of reserves with high agro-biodiversity to be promoted as a way to minimize the erosion of agro-biodiversity and related cultural diversity; research directed towards defining the potential risks associated with gene flow to be promoted; the evaluation, management and communication of potential risks to be based on scientific and technical knowledge, the characteristics of the biological entity, its environment, non-target biological entities, food safety and cultural, social and economic considerations; in risk analysis and management, the Competent National Authority would consider the harmony and co-existence between traditional, conventional, organic and transgenic agriculture; and oversight and risk assessment would focus on the characteristics of the GMO or its product rather than the techniques used for its production.

South Africa: The policy document was published in June 2001 before the country became a Party to the CPB (in 2003). The document mentions the GMO Act (1997) and subsidiary regulations which govern biosafety and comprehensively address measures to promote responsible development, production, use and application of GMOs. Together with the National Environment Management Act, it provides the principles for environmental responsibilities and liabilities. There would be a review of existing legislation with implications for biotechnology and, based on this and gap analysis, necessary consolidation and amendments of new legislation would be brought forward to remove duplication or areas of conflict. It notes that there are already several Acts on the statute book that provide conflicting legislation with respect to biotechnology, e.g. its GMO and Agricultural Pests Acts both of which cover cross-border movement of genetic material and could conflict with new legislation on indigenous knowledge, technology transfer and biodiversity.

Thailand's policy contains little on safety, stating only that a key strategy will be introducing a law on the protection of biological resources and policies for the development of safe GMOs. On detail, it states only that it: will develop and use the potential of biotechnology for quick, precise, and specific detection and diagnosis in managing food and seed safety by setting up a biotechnology laboratory to certify quality and standards for export products, as well as for inspection of imported products; and it will conduct research to collect scientific data needed for risk assessment of food and agricultural products for export.

Uganda's policy on Biotechnology and Biosafety gives safety high priority within its vision and all its proposed strategic actions for pursuing the subject (e.g. human resources and infrastructure development, R&D, public awareness and participation, commercialization, biodiversity conservation and utilization, and bioethics and biosafety), and that strategies for pursuing these would be placed in the context of the CPB and the African Model Law on Biosafety. It records that the Uganda National Council for Science and Technology (UNCST) established a National Biosafety Committee in 1996 to provide technical advice to the Government and that it developed guidelines for conducting research into genetic modification at laboratory and confined field trial levels, as well as guidelines for containment of GMOs and microbes. Also, institutional biosafety committees have been established in some institutes. All the same, it notes that the UNCST Act is inadequate to regulate the overall development of biotechnology and commercialization of its products, and that legally binding instruments to regulate applications relevant to the conservation and sustainable utilization of genetic resources are scattered in the provisions of several sectoral laws. There was therefore a need for an explicit policy and law on biotechnology/biosafety. No new structures are proposed to implement the policy, but a National Biosafety Act would be introduced to regulate applications, and to legally formalize the establishment of the institutional mandates, functions and administrative roles provided for under this policy. In addition, a monitoring and evaluation framework for biotechnology and biosafety development would be set up to assess performance.

Zambia: The policy is biosafety-focused and aims to guide the "judicious use and regulation of modern biotechnology for the sustainable development of the nation, with minimum risks to human and animal health, as well as the environment, including Zambia's biological diversity". It describes how the country would implement obligations under the CPB and contains guiding principles that include precaution, working through an advance informed agreement (AIA) system, use of risk assessment, inclusion of socio-economic impacts in decision-making, public participation and a scheme for liability and redress. It envisages the formulation of a biosafety regulatory legal framework that includes creating a National Biosafety Authority (NBA), a Biosafety Advisory Committee to advise the NBA and government and institutional biosafety committees for local and national decision-making and international cooperation. The NBA would be responsible for formulating and later implementing and enforcing the legislation and guidelines to be drawn up, and would prescribe laboratory facilities capable of verifying the presence of GMOs and products. The Biosafety Advisory Committee would advise the NBA on prohibition, authorization and the exercise of necessary control of imports, on authorization or notification of contained uses, authorization of trials or general releases, and on control measures to be taken where an intentional release of GMOs may occur.

There would be strengthening of human and infrastructural capacities to support the development of regulations to assess, test, monitor and control research, development, application and commercialization of biotechnology in accordance with agreed legislation and guidelines, and to ensure effective control of transboundary movements of GMOs or products thereof through the exchange of information and risk assessment as well as a transparent AIA system.

Transfer, use and release of GMOs would be on the basis that there is firm and sufficient evidence that the GMOs or their products pose no risk to human and animal health, biological diversity or the environment. There should be no research, development, application, release and commercialization of GMOs or combinations of GMOs and their products without a risk assessment report and the prior approval of the NBA. The risk assessment should include the direct or indirect effects to the economy, social and cultural practices, livelihoods, indigenous knowledge systems, or indigenous technologies as a result of the import, contained use, deliberate release or placing on the market of GMOs or products thereof. Also, the NBA would provide the public with information about applications for the research, development, use and commercialization of GMOs and products, and there might be opportunity for the public to comment. Further, if there is a conflict between issues pertaining to the conservation of biological diversity and trade, the conservation of biological diversity would prevail.

The policy would apply to the research, development, application, release and commercialization of GMOs, combinations of GMOs and their products; occupational safety at workplaces where biotechnology procedures are used or products handled; and labelling of GMOs or products developed in or imported into Zambia. The Ministry responsible for S&T is charged with formulating and ensuring adoption of the policy. Other key stakeholders are the line ministries and the statutory boards responsible for agriculture, health, commerce, trade and industry, legal affairs, finance, home affairs, information and broadcasting, local government and housing, transport and communications, institutions of higher learning, research institutions, civil society, industry, and traditional administration authorities.

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CHAPTER 9

ENSURING ACCESS TO THE BENEFITS OF R&D

SUMMARY

This Chapter covers three subjects of importance to applications of biotechnologies in food and agriculture (BFA): intellectual property rights (IPR) and genetic resources; public awareness and participation; and agricultural extension. Like its two companion Chapters 7 and 8, the Chapter also provides an analysis of 15 selected developing countries to illustrate some of the options available to countries.

Analysis of the national biotechnology policy/strategy (NBS) documents of these 15 countries indicates that most countries mentioned IPR and the importance of their genetic resources. However, very few (1) indicated the need to change their existing, or introduce new, intellectual property (IP) legislation, regulations and other polices to cater for the specific challenges posed in particular by modern biotechnology, (2) described how their research institutions intended to go about accessing, or sharing with others, the research tools, gene constructs or genetic resources needed for research and development (R&D) or any end products arising from such efforts nationally or in other countries. None mentioned the role of research funding bodies in influencing the policies and behaviour of their national research communities.

IP protection systems in developing countries must consider both the structure and multifunctional roles of the agrifood sector and be consistent with the minimum requirements laid down in a number of international IP agreements, which differ in terms of eligibility and scope of protection. Other factors to be considered include: the inter-relationships between these IP agreements and the goal of national food security as well as the core aims of the Convention on Biological Diversity (CBD) and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). Costs and benefits of implementing

national IP legislation for BFA innovations consistent with international rules are further considerations. No single IP system will suit the needs and goals of all countries or serve all agricultural systems within an individual country. Consequently, in the process of designing IP legislation and related policies, countries wishing to use IP as an "enabler" of BFA should make realistic projections about the future role of biotechnologies in helping to meet their national agricultural and wider food security and poverty reduction goals, and make maximum use of the flexibility inherent in internationally agreed rules. Countries should also be aware that there are options outside of IPR instruments to protect developers and suppliers of plant, animal and microbial materials.

Requirements and mechanisms for establishing IP laws, and responsibilities for undertaking the related regulatory and administrative tasks assigned to particular institutions, raise daunting technical, legal, judicial, administrative and financial challenges. The needs for training and capacity building to deal with the wide scope, complexity and interplay between all the issues involved in ways that ensure public sector R&D remains focused on the social needs of the many, rather than the financial interests of the few, must remain paramount if BFA is to deliver on a pro-poor agenda. Consultative mechanisms therefore need to be established to reach agreement and strike compromises between groups both within and outside the agrifood sector on a number of fundamental issues. These include the extent to which, and in what forms, IP protection should be available; ownership of agreed IPR; institutions to identify and manage technologies and knowledge to be accessed and protected; and enforcement of legislation.

In response to changes in their laws that allow commercialization of inventions from publicly-funded R&D, a few agricultural ministries and research organizations in developing countries have established technology transfer offices (TTOs), working under various levels of decentralized authority. Policy-makers should be aware of the pros and cons of establishing such offices for BFA and, in general, of the potential issues regarding commercializing IP assets within the public sector. They should also not dismiss the option of exploiting the IP of their research institutes by publicly disclosing details of innovations though "defensive publication".

The IP and tangible property rights (e.g. germplasm, clones, expression vectors, computer software, and equipment) surrounding BFA can be highly complex. Unravelling this complexity by deconstructing each component and method followed by identifying all the potential patents, plant breeders' rights and licenses relating to each for conducting a product clearance analysis and determining freedom to operate (FTO) requires considerable IP management skills. The strategic IP management choices open to public organizations to access biotechnology tools and technologies for research, development and diffusion will depend on factors such as R&D capacity, objectives, cost, conditions and public acceptance.

Research institutes in developing countries can access them without seeking the owner's permission using gaps in patent and protected variety jurisdictions or using research and experimental use exemptions in national legislation, although both options have potential drawbacks. They can also access them with the owner's permission and several options are available, including material transfer agreements (MTAs), licensing agreements, purchasing outright, patent pools, open source licensing, public sector partnerships and public-private partnerships (PPPs). The pros and cons of each are described. Particular consideration is given to PPPs since such instruments are features of government policy in an increasing number of developing countries, supported in many cases by the donor community. Options to promote partnerships between public entities and the private sector in both research and commercial undertakings on pro-poor BFA without, or with limited, complications arising from IPR, include negotiating royalty-free access to proprietary genes, genetic constructs and germplasm, and using the services of third party brokers. Although promising, convincing evidence is still generally lacking about the success of such PPPs in BFA in terms of products in widespread field or commercial use.

Policy options are provided for consideration by national and international research funding and development agencies when dealing with technology and knowledge transfer. They include encouraging the free exchange of materials and data; ensuring that grant applicants include in their proposals an explanation of their stewardship plans, as well as plans for the sharing and dissemination of research results; and encouraging non-exclusive licensing.

The current plethora of "participatory" planning and implementation of R&D projects and extension services attests to how policies have been transformed within many governments and funding bodies for organizing these services. Nevertheless, such policies have not replaced the more traditional "top-down" (and often "supply-driven") option and both approaches are needed to provide balance, objectivity and transparency to government, ministerial or institutional decision-making. Challenges to participatory "bottom-up" approaches to biotechnology R&D are described, and examples from Kenya and Bolivia illustrate options for priority-setting which can be suitably adapted to include biotechnology.

Although rarely articulated in the NBS documents and not mentioned in any national biosafety or regulatory framework examined for the 15 selected developing countries, participation – as well as awareness and education – are important dimensions in national policy-making on biotechnology. They also carry the weight of law in countries acceding to international environmental instruments which either require or encourage inclusion in national laws and regulations. The Chapter outlines the many challenges involved and the instruments and options available to countries for dealing with information-sharing, education and communication between the public and national planning and implementing agencies with respect to BFA decision-making and regulation. What is essential is that poor people have a voice, that decisions on biotechnology do not further marginalize those already marginalized, and that citizens of developing countries are able to make their own choices rather than having these defined for them by donors.

The role of agricultural extension in enabling access to the products of biotechnology R&D and necessary policy changes to facilitate that role, are almost totally neglected in the NBS documents of the 15 countries. Despite reforms, government policy remains significant within agricultural extension services. The changes to extension systems and the new opportunities from BFA call for policies to bring researchers, extension agents, and smallholder producers and their organizations closer together. They also call for upgrading the skills of extension staff so they are both more capable of understanding the implications of BFA and of facilitating interactions between farmers and others involved in the agricultural knowledge information system.

9.1 INTRODUCTION

Other Chapters of this book clearly demonstrate the significant and ever-increasing interest shown by the scientific and research communities in developing and developed countries alike in using biotechnologies to both understand and improve how biophysical resources are transformed into food and other products to enhance agricultural productivity and the quality and safety of products. As also noted earlier, the success of these efforts clearly depends on having a solid scientific and technical skills base and infrastructure as well as a wider "enabling environment" that includes a sound regulatory framework. Clear and transparent policies for accessing and using both the necessary research tools and tangible end products is also an essential component of the enabling environment for fostering biotechnology innovation and diffusion. Increasingly, these materials and associated information have become the subject matter of grants of intellectual property (IP) protection. Consequently, a further critical dimension of a national biotechnology policy/strategy (NBS) is that it describes how the country intends to deal with the associated IP issues. Policies for accessing genetic resources for food and agriculture (GRFA) and sharing the benefits from using biotechnology to develop useful products from these resources have likewise become increasingly important.

Against this background, it is instructive to examine how the same 15 developing countries surveyed in the companion Chapters 7 and 8 intended to deal with the IP and (related or unrelated) genetic resources/biodiversity issues associated with BFA. It is also useful to highlight the principal considerations that need to be taken into account by countries in designing and managing IP policies that balance their needs to generate and access biotechnology tools and techniques and the genetic materials for research and producing tangible products, while promoting the diffusion of these products to small-scale and resource-poor farmers. Topics covered here include: establishment of laws and institutions, and IP policy options and mechanisms for accessing biotechnology tools and products by research institutes and national and international research funding and development agencies. These issues are covered in Part 9.2 of the Chapter.

A further, and not entirely unrelated, route to ensuring access to the benefits of biotechnology R&D is through improving public awareness and opportunities for participating in decision-making, and this topic is covered in Part 9.3. Decision-making about technology still remains largely in the hands of national agricultural research systems (NARS) working with their specific society groups – farmers, farmer cooperatives etc. However, there is increasing realization that agricultural biotechnologies (traditional and modern) will only fulfil their full potential if all relevant stakeholders have the opportunity to provide input to decision-making processes concerning their use. To make choices, societies have to be informed and educated about the pros and cons of particular decisions, and they will only accept biotechnologies if they consider they are "good" for them.

In addition to IPR and GRFA, this Chapter covers the issue of public awareness and participation from the standpoints of engaging wider society (1) in planning, implementing and assessing biotechnology R&D and extension, and (2) in the regulation of biotechnology. It provides options for dealing with both, including for implementing commitments laid down in international agreements and by international standard-setting bodies in relation to regulation. In common with other strategic policy issues relating to BFA, it describes how the 15 selected developing countries (see Table 1 of Chapter 7) proposed to deal with participation in their NBS documents[1] and/or regulatory frameworks.

The third topic, covered in Part 9.4, is agricultural extension. National agricultural extension systems have been in transition worldwide for some time, and reforms have already impacted, and will continue to impact, the agriculture knowledge information sub-system and thereby access to the fruits of BFA. Since the role of government and government policy in agricultural extension remains significant, it is relevant here to highlight the potential roles of extension in enabling access to BFA.

9.2 INTELLECTUAL PROPERTY RIGHTS AND GENETIC RESOURCES

9.2.1 Coverage in national biotechnology policy/strategy documents

From an analysis of selected developing countries in the Annex (Part 9.5), it is noteworthy that while most countries did indeed mention IPR and the importance of their genetic resources, very few indicated the existence of a national IP strategy or the need to change

[1] Most of the NBS documents of the selected developing countries are available at www.fao.org/biotech/country.asp

their existing, or introduce new, IP legislation, regulations and other policies to cater for the specific challenges posed in particular by modern biotechnologies and how these would be harmonized with the global IP and genetic resources/biodiversity legislative architecture. Also, few described how their research institutions intended to go about accessing, or sharing with others, the research tools, gene constructs or genetic resources needed for R&D or any end products arising from such efforts nationally or in other countries. None of them mentioned the role of their research funding bodies in influencing the related policies and behaviour of their national research communities.

9.2.2 The global context

National policies on IPR and genetic resources seek to optimize the balance between the interests of creators (e.g. scientists, breeders) and investors on the one hand, and those of wider society (farmers and consumers) who wish to use directly and indirectly innovations that are protected by IPR. Finding that balance has become increasingly challenging with the progressive advances of modern plant and animal breeding and other methods in agricultural production and processing. These advances have been accompanied by increasing involvement of private sector companies in both R&D and the placing of innovations into national and international markets; and, in the case of crops, IP being granted to plant breeders for such innovations usually in the forms of plant breeders' rights (PBR) (e.g. in Chile, India, Kenya, Malaysia, Thailand and South Africa), variety or community variety rights holder (China) or a plant variety protection (PVP) certificate (e.g. Brazil).

It has proven to be even more challenging since the arrival on the scene of BFA, particularly advanced biotechnologies which, supported by relatively recent policies within some national and regional jurisdictions, extended patent grant from innovative selection and breeding processes for genetic improvement to cover "life forms" (e.g. plant transformation tools, gene markers, DNA sequences, and improved germplasm and varieties). This stimulated major R&D investments in the biosciences by the private sector and encouraged company mergers and the establishment of "biotechnology industries" in industrialized countries.

Multinational corporations (MNCs) and small and medium enterprises (SMEs) that provide seeds and other agricultural inputs as well as biotechnological reagents and diagnostic, genetic profiling and other services form the backbone of this "privatization and industrialization of biotechnology". These entities, for example, hold proprietary claims in the form of patents on many of the basic research tools, e.g. molecular markers and trait-specific genetic constructs (most noticeably for insect resistance and herbicide tolerance, but more recently also for resistance to abiotic stresses like drought and salinity), transformation and marker-assisted selection technologies and tangible products in the form of plant varieties and breeding lines (FAO, 2007).

However, driven by reduced or stagnant levels of core funding and increasing demands for both cost-recovery and partnerships with private sector entities, many public research institutions in most developed and some developing countries also now commercialize their IP which can be in the form of patents, seeds and related biotechnological services. For example, with respect to the widely used *Agrobacterium*–mediated transformation system, the share of patents held by the private sector fell from 71 percent in 1996 to 49 percent in 2004, while the share of public sector patents increased from 19 percent to 30 percent over the same period (Michiels and Koo, 2008). The Brazilian Agricultural Research Corporation (EMBRAPA), for example, currently holds 206 patents, 290 protected cultivars and other forms of IP protection on books, software, videos etc., and reputedly earns around US$7 million in royalties or about 1 percent of its operating budget from these assets (Texeira, 2008).

With animals, the advent of new reproductive technologies (particularly cloning involving nuclear transfer), molecular biology and sequencing of genomes, e.g. that recently announced for cattle (Bovine HAPMAP Consortium, 2009) has likewise stimulated considerable expansion in both the scope and number of technologies applied to cells, tissues, organs and whole animals that are now protected though patents. Relating to animal breeding, these include DNA markers for improved milk production, superior milk products and litter size, transgenic and cloned animals and methods to produce them, new methods to measure traits, methods to identify animals, and methods for assessing milk and beef characteristics (Rothschild, Plastow and Newman, 2003). There are, nevertheless, some uncertainties at the international level regarding the ownership and patentability of the basic processes of animal cloning through nuclear transfer, the patentability of the animals created and the derived products (Gamborg *et al.,* 2006).

The introduction of *sui generis* systems of PVP and more particularly of patenting into BFA, coupled with computer software and database rights legislation and the use of copyrights to restrict or withhold access to genomic and other biological information (“bioinformatics”) held in private databases, have become increasingly controversial. These trends have generated much debate in developed and developing countries alike about the ethical and moral dimensions of biotechnology, the links between IP and the efficiency of R&D, and the prospects of biotechnology contributing to sustainable agricultural and wider national development.

Fundamental questions raised include the criteria for patentability of gene fragments or mutations (e.g. in some jurisdictions, expressed sequence tags [ESTs] and single nucleotide polymorphisms [SNPs] may be patentable subject matters even in the absence of proven utility/industrial application, although the rules on this have recently been tightened in industrialized countries); the role of IP protection in stimulating agricultural R&D and bringing new innovations to market, and in fostering the transfer and diffusion of techniques, processes, products and information within and between the public and private sectors and between developed and developing countries. The feeling often expressed by the scientific community is that access to key platform technologies and even research tools and data has become increasingly limited and threatens to slow progress in both the fundamental and applied biosciences (e.g. Chapter 6 in FAO, 2001a).

Against this background, all countries should develop IP policies that carefully balance their needs to generate and access the basic tools, techniques, breeding lines and varieties for both research and the production of seeds and other tangible products, while promoting diffusion of these products to small-scale and particularly resource-poor farmers. These are particularly important for those developing countries where the entire agricultural "value chain" running from R&D through to the production, distribution and oversight in using biological inputs remains largely a public responsibility rather than a series of commercial operations.

A further critical consideration is that irrespective of where national responsibilities lie for breeding, and despite the emphasis given to seed industry development through, e.g. policies encouraging the development of local seed companies and the entry of regional and global players, in virtually all developing countries where small-scale farming predominates it is farmers' systems of selection, improvement, multiplication and diffusion that provide by far most of the crop seeds (and animal types) used by farmers. For example, only about 7 percent of wheat seed and 13 percent of rice seed in India are sourced from the formal (public and/or private) sector, and in many parts of Africa and Asia it is estimated that over 80 percent of total farmers' seed requirements are met from outside the formal sector (Rangnekar, 2002). These systems are also the only way that farmers' varieties of plants and animals can be maintained and evolve *in situ,* thereby contributing to both national and global agro-biodiversity and food security.

IP protection systems must consider both the structure and multifunctional roles of the agrifood sector in developing countries and be consistent with the minimum requirements laid down in international IP agreements, the most important from a BFA perspective being:

- the 1961 International Convention for the Protection of New Varieties of Plants (the "UPOV Convention") and its revised Acts of 1972, 1978 and 1991. There are currently 68 country members, mostly from the Northern hemisphere but increasingly also from Latin America;
- the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) which had 153 members as of July 2008. Particularly relevant here is Article 27.3(b). Although not referring specifically to biotechnology, this contains provisions concerning patentability that are relevant to it and offers countries three options for protecting plant and animal inventions, i.e. (1) through patents, the

criteria for which are novelty, involve an inventive step and usefulness/capable of industrial application (2) a system created specifically for the purpose ("*sui generis*") which may or may not conform with one of the UPOV Acts but must be "effective" or (3) a combination of the two. Such flexibility is also available for essentially biological processes for producing new germplasm and varieties of plants and animals.

These Agreements differ in terms of eligibility and scope of protection, and it is beyond the scope of this Chapter to deal with these differences in detail or to dwell on the many "creative interpretations" by individuals concerning definitions, commitments (or lack thereof) and inter-relationships. See Tansey and Rajotte (2008) for more details.

In designing and managing national IPR systems, countries should be aware of a number of key issues. One is that the core assumptions of the TRIPS Agreement, and indeed of the UPOV Acts, are that IPR will stimulate international transfer of technology and therefore (bio) technology-related R&D in developing countries as well as the wider exchange of improved breeding lines and varieties. However, the relationship between the strength of IP protection and all these factors is highly complex and, as noted by FAO (2003a) and others in relation to biotechnology, IP is only one factor influencing technological innovation, transfer and diffusion. Others include S&T capacity and wider infrastructure, structure of the agricultural sector, potential market size, ecological similarities between countries, the subject matter of protection (e.g. hybrid or open pollinated crops; poultry, pigs or cattle), national policies concerning foreign direct investment, trade, and the macroeconomic environment.

Another issue is the inter-relationships between international IP agreements (specifically the UPOV Acts and TRIPS Agreement) and (1) the core aims of the CBD and the ITPGRFA – namely, access to and fair and equitable sharing of benefits from using genetic resources, conservation and sustainable use of GRFA, and preservation of and respect for knowledge, innovations and practices of indigenous and local communities/farmers' rights and (2) the goal of national food security.

Each of these has been, and remains, the subject of much contentious debate within and between countries (see, e.g. Gehl Sampath and Tarasofsky, 2002; FAO, 2002a; UNCTAD-ICSTD, 2003; Gepts, 2004). This only serves to emphasize the need for further empirical work to clarify the relationship between IPR, the protection of agricultural biodiversity and wider biodiversity and food security at national and global levels.

A further issue concerns inclusions and exclusions to patentable subject matter – namely, standards of patentability, rights granted, conditions of disclosure, what constitutes an "invention", "novelty", "an essential biological process" and a "variety". Also, what constitutes an "effective" *sui generis* system and the procedures in place for enforcement of both patenting and UPOV or UPOV-type PVP laws. National patent and *sui generis* PVP laws and regional rules contain the same or similar terminology and incorporate similar principles with respect to IP through patents, variety, product and process technology protection. However, there is considerable diversity in how countries interpret their meaning and in the specifics of their implementation for protecting plant, animal and microbial innovations irrespective of how these are achieved. It is therefore not surprising that the global community holds widely differing views on many of the underlying technicalities and the validity of different systems. Modern biotechnology has served to widen these differences further.

A fourth issue is the costs and benefits of implementing national IP legislation for BFA innovations consistent with international rules. These are simply unknown, but will certainly be country-specific and depend, for example, on the status of current legislation, technical and administrative capacities, and subject matter eligibility criteria such as the number of plant species protected. Costs of implementing patent administrative systems will certainly be higher than for *sui generis* PVP systems, while potential benefits (with many underlying caveats) include contributions to greater productivity, trade, incomes and food security. Developing countries intent on building strong breeding capacity involving biotechnology should nevertheless be aware that granting patents for gene constructs and genetically modified organisms (GMOs) will increase the price of seeds, propagating materials and other products because of the IP-related "technology fees" charged by patent owners. On the other hand, higher input prices must be balanced against potential yield, quality and other benefits and costs, all of which have to be factored in when assessing uptake and distribution of economic and social benefits (see Chapter 7).

The principal policy goal of these international agreements is to provide incentives to biotechnologists and breeders to develop new products that are useful to the agrifood sector and for seed, breed/brood stock and food and other input supply companies and government support services to market or use these nationally and/or through international trade. One complication is that they cover what might be termed "conventional" IPR. Since the main driver for developing IPR policies and using IP systems is the strength of the domestic science and (bio) technology capacities within the public and private sectors of a country, where these capacities are weak the IP system will be used primarily to protect imported technologies. This reality is clearly illustrated with respect to modern BFA applications in both Brazil and Argentina where non-residents are responsible for about 90 percent of BFA patents (Biotecsur, 2008). In South Africa, almost 60 percent of the protected plant varieties are not owned by South Africans (Van der Walt and Koster, 2005).

Another consideration is that these agreements do not have provisions for rewarding farmers, local communities and indigenous peoples for their roles in conserving and providing the genetic resources used by scientists and breeders to develop the new IP-protected varieties and other products using agricultural biotechnologies or other means. Neither do they protect farmer-bred varieties (i.e. "traditional" and more informal communal systems of innovation by farmers and indigenous communities). These are concepts covered under multilateral biodiversity agreements (the CBD, particularly Articles 12 and 16, and the ITPGRFA), and which countries have to address in ways that are both consistent with international trade agreements and between different pieces of legislation. How they do this – through biodiversity or PVP laws or other instruments – is also a matter of some controversy, but is outside the scope of this Chapter. Details are provided by Bragdon (2004) and Stannard *et al.* (2004).

This Chapter also does not cover the options open to countries for organizing their national IP systems (and their systems for managing access to, and sharing the benefits of, applying biotechnology to GRFA) in ways that are consistent with their obligations under international, regional and bilateral treaties and arrangements. However, given the importance of IP and access/benefit-sharing issues it would be essential for countries to formulate a national strategy outlining the measures to be taken by government and other stakeholders to foster the creation, development and management of IP for serving national objectives. Excellent guidance on the legal and technical options available for developing strategies consistent with the UPOV Acts and the TRIPS Agreement is available from the IPGRI (1999) and FAO (2002a). These should be consistent with strategies for managing GRFA, guidance on the formulation of which is available from Spillane *et al.* (1999).

Inevitably, no single IP system will suit the needs and goals of all countries or serve all agricultural systems within an individual country. Consequently, in the process of designing IP legislation and related policies, countries wishing to use IP as an "enabler" of BFA should (1) make realistic projections about the future role of biotechnologies in helping to meet their national agricultural and wider food security and poverty reduction goals, and (2) make maximum use of the flexibility inherent in internationally agreed rules. Because of the "minimum standards" framework of both the UPOV Acts and the TRIPS Agreement, national governments have considerable discretion in interpreting and applying their provisions. For example, the discretion offered by the TRIPS Agreement to protect plant varieties through three distinct approaches allows its members to balance the protection offered to breeders against other important (and possibly competing) development goals, including those found, e.g. in the CBD and the ITPGRFA.

Nevertheless, in pursuing biotechnology, an important consideration is how to avoid overlaps and contradictions between national patent and *sui generis* PVP systems, and thereby balance incentives for plant breeding using biotechnology and traditional breeding. Here, it should be borne in mind that the TRIPS Agreement does not prevent patent laws being modified or *sui generis* systems being created to include exemptions for farmers and/or breeders, and it does not define the scope of protection of patents for biological material and biotechnology processes. In other words, countries, for example, can include genes but not the plant in which the gene is contained, i.e. limit the scope of protection of a gene patent so that it does not "carry through" to plants into which the gene has been inserted.

Countries should also be aware that there are options outside of IPR instruments to protect developers and suppliers of plant, animal and microbial materials, e.g. biologically, through seed, contract and biosafety laws, material transfer agreements and trade secrets. These options are well covered by the World Bank (2004).

9.2.3 Establishing laws and institutions

Principles, requirements and mechanisms for reviewing, updating and possibly introducing legislation to meet international obligations and establish complementary policies, and mechanisms and responsibilities for undertaking the related regulatory and administrative tasks assigned to particular institutions were described earlier in relation to agricultural and biosafety policies (Chapter 8). These apply equally to coverage of IPR and related biodiversity issues and are therefore not repeated here.

Nevertheless, the daunting technical, legal, judicial, administrative and financial challenges in doing so should not be under-estimated. Few developing countries have amended or introduced legislation that describes the scope of biotechnology-type patent subject matter, often because of the complex technical, social and ethical questions it raises. For example, should inventions from publicly-funded research be patentable and who should benefit from IPR, considering the various social groups that may have contributed to the development of the final product (FAO, 2002b). Similar comments apply to IP protection of animals and micro-organisms and related inventions, all of which are highly relevant to BFA and potentially relevant to biotechnology applications in other sectors.

Additionally, few public research institutions and funding bodies in developing countries have established and implemented ground rules, principles and guidelines for managing biotechnology IP and knowledge transfer, e.g. by concluding agreements concerning research cooperation with third parties which may be public, private, national or foreign. These are also highly complex and inter-connected tasks, the outcomes of which may be influenced significantly by national and international developments, research funding and commercial considerations.

Using the principles outlined earlier, consultative mechanisms therefore need to be established to reach agreement and strike compromises between groups, within and outside the agrifood sector, which invariably will have widely different perspectives on a number of fundamental questions (particularly with respect to patents) concerning legislation, its implementation and enforcement. These include to what extent, and in what forms, should IP protection be available? who can, or should, own those agreed property rights?; how will legislation be enforced?; and what institutions will be put in place and how will they be resourced (staffed, equipped) to identify and manage technologies to be accessed and protected? Graff (2007) provides an excellent account of the laws and institutions established by Argentina, Brazil, Chile, China, India, Kenya, Malaysia, South Africa and Uganda at central and decentralized levels to deal with IPR issues.

The economic and social consequences of GM crops grown from illegally obtained seeds are described by Giannakas (2003), and these may be relevant for other agricultural biotechnologies. Unlicensed copying, particularly when combined with systems allowing use of farmer-saved seed, reduces the economic rents that come to the innovator. Also, the price of the new technology to all farmers who purchase GM seed legally will likely increase. Countries should also bear in mind that weak enforcement of IP laws may reduce incentives for further innovation, negatively impact bilateral and multilateral relationships, open the possibility of trade sanctions and restrict the inflow of foreign direct investment and technologies needed by other sectors of the economy.

9.2.4 Intellectual property management: Options for research institutes

9.2.4.1 Accessing proprietary biotechnology tools and products

IPR allow holders to exclude others from making, using, selling and distributing their technology. However, this right is not absolute. One restriction is the national jurisdiction of protection. Another, present in all UPOV Acts and many national patent laws, is the so-called "research" or "experimental use exemption". Article 30 of the TRIPS Agreement also describes exceptions to the rights conferred, i.e. "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties".

The strategic IP management choices open to public organizations to access biotechnology tools and technologies for research, development and diffusion are described by Byerlee and Fischer (2001) and Nottenburg, Pardey and Wright (2001). The option(s) chosen will depend on R&D capacity, objectives, cost, conditions, public acceptance etc.

The IP and tangible property rights (e.g. germplasm, clones, expression vectors, computer software, equipment) surrounding BFA can be highly complex, involving products, processes and components, and knowledge of variables such as owners, who controls them, how they were obtained, and whether they were purchased or licensed (Kowalski *et al.,* 2002). Other aspects like where the product will be produced, whether it will be used for national production and consumption and/or enter international trade must also be evaluated, as must the IP laws of all the potential countries concerned.

Unravelling this complexity by deconstructing each component and method followed by identifying all the potential patents, PBR and licenses relating to each in order to conduct a product clearance analysis and determine freedom to operate (FTO) requires considerable IP management skills and access to patent, PVP and other databases as well as the scientific literature. For individual scientific tools, the task is relatively straightforward; for single gene expression systems it is arduous; for stacked or multi-gene systems, it becomes an enormous task – made all the more difficult by the "time lag" between what is contained in a patent or PVP database and what is actually protected through filing. Disentangling the complexity of product clearance for FTO in relation to Golden Rice exemplifies that challenge (Kryder, Kowalski and Krattiger, 2000).

In conducting a product clearance analysis for a GMO, breeders must also clarify the IPR in the germplasm used to produce transgenic materials. The plant cells used for genetic modification are often from lines or varieties that are not suitable for growing in the intended location and therefore the transgenes have to be backcrossed into agronomically more suitable germplasm.

To use proprietary tools and products, research institutes in developing countries may or may not request the permission of the owner. For each of these alternatives, they can use different options.

a) Without seeking the owner's permission

Using gaps in patent and protected variety jurisdictions

Patents are only valid in countries in which they are registered. Under *sui generis* laws, plant varieties are only protected in the country issuing the PVP certificate or PBR and in other countries that are members of the same UPOV Act. One option therefore is to use the research tool or technology (e.g. a transformation or selection tool, specific transgene, molecular marker or novel variety) without seeking the owner's permission. This option is legal in those countries where the particular patent or plant variety is not registered. Many current and important biotechnologies (both research tools and finished technologies) appear to be unprotected in all but a relatively small number of developing countries. Major exceptions in the countries covered here would be large producers and/or exporters of cotton, maize and soybeans and derived products, such as Argentina, Brazil, China, India and South Africa, i.e. countries with Type I NARS, but also some of those with Type II NARS (Byerlee and Fischer, 2001).

There are, however, legal and technical caveats to this option. First, that the use of the material in laboratory, greenhouse and/or field settings and/or products derived from biotechnology (plant, animal or micro-organism, food and feed products) is not covered by other relevant national laws (e.g. seed, environmental/biosafety/plant protection, animal health and/or food safety). Second, that any product derived from the proprietary technology is not exported to a country where the invention is protected (i.e. establishing "freedom to trade" is also important). This would require systems to segregate production and these may be logistically impossible in many situations. Third, that even where a technology is not legally protected in a particular jurisdiction, if a patent or PBR has been granted on a tool, technology or variety that means it is under IP protection in the owner's country.

Research institutes should therefore consider seriously the option of requesting permission. Most likely the owner would be prepared to make it available (subject, for example, to agreement on liability issues and/or a stewardship plan), particularly for developing countries with Type II and Type III NARS working on staple or orphan crops, and possibly also for use within small/subsistence production systems. The advantage of this approach is that it encourages partnership and access to the "know-how" needed for facilitating adaptation of the technology to the laboratory or field conditions of the requester.

There have been several cases of IP-protected GMOs entering, being used and exported from countries that lacked biosafety or other relevant (e.g. seed) legislation. Also, while public research institutes in some developing countries are increasingly engaging in crop transformation activities using genetic constructs developed nationally or by multinational companies (Cohen, 2005), the FTO status of these materials is unclear, i.e. whether their use for research is itself legal, restricted to research, and/or may be extended to commercialization and trade activities.

From Cohen (2005), it is also clear that few transformation events have moved out of laboratories or greenhouses into farmers' fields. Whether this is due to concerns about potential litigation for patent infringement, weak scientific, research and breeding capacity, lack of partnerships for delivery to end users, biosafety and/or related trade issues is a matter of speculation. Cohen and Paarlberg (2002) believe that commercial fears are the main constraint to the approval and availability of GM crops in developing countries. The reasons, however, are both more complex and context-specific than that – an additional factor being the general lack of a clear strategy and expertise for moving products from laboratories to farmers at the domestic level and from there, to marketing and export of commodities (FAO, 2002b).

Regarding the trade dimension, Binenbaum *et al.* (2000) examined the production and trade patterns between 168 developing countries and 29 developed countries for the 15 staple crops that are most important for food security in the developing world. Their analysis revealed that exports from developing to developed countries constituted less than 5 percent of the total production and consumption in developing countries. Also, it showed that the value of these exports was concentrated in only four crops, i.e. bananas, soybeans, rice and coconuts, and that these came from very few countries (Costa Rica and Ecuador for dessert bananas, Brazil and Argentina for soybeans, Thailand for rice, and the Philippines for coconuts). Further, the bulk of these exports was to Western Europe (64 percent) followed by the United States (16 percent) and Japan (11 percent). The data also showed that for other crops covered by the CGIAR centres, the share of developed country imports originating from developing countries varied from around 90 percent (in the case of cassava, chickpeas and groundnuts) to figures ranging from 5–40 percent for wheat, maize, barley, sorghum, millet, lentils and beans.

The implication of these findings is that for now, and at least with respect to food/feed crops, constraints to FTO in developing countries are most likely to occur with soybeans and their processed products. However, these could well become more serious if, and when, additional staples and products produced through or derived from advanced biotechnologies in developing countries enter international trade. They also indicate that IPR established in foreign countries should not be a major stumbling block to pursuing either R&D or commercialization of BFA in most developing countries.

Using the research and experimental use exemption within national legislation

The generality of the criteria and the vagueness regarding the scope and nature of exceptions in IP laws for using other peoples' proprietary technologies, make it difficult to interpret rights and obligations. For example, defining the scope of a "research tool" or the cut-off between "basic" and "applied" research or between "research" and "development" is fraught with difficulties. A rice line with resistance to a bacterial pathogen is a research tool. It can be used as a breeding tool by some, but to biotechnologists it is source material for mapping, sequencing and cloning the gene coding for the resistance trait, and subsequently for the grant of a patent on the gene sequence. Through an exclusive license negotiated with the patent owner to a company it then becomes a research tool for a commercial company to develop pest-resistant GM crops (and to gain access to the gene, the developers of the original rice-resistant line would have to negotiate conditions for using the gene sequence for furthering their own applied research).

In some jurisdictions, the present position is that experimental use exception to patent rights is very narrow and that even projects undertaken without direct commercial application may be perceived in law as furthering an institute's legitimate business interests through undertaking projects that, by using proprietary IP, serve to increase its status and thereby attract research grants and students. Most national laws permit private, non-commercial/industry and experimental uses, although there is lack of clarity about whether experimental uses include work done for commercial and industrial purposes.

In short, the situation with respect to the experimental use exemption within both national and regional arenas is far from clear. Researchers and breeders therefore tend to assume that they need not worry about the IPR of others when carrying out research with no direct commercial goal, because research done for purely academic or experimental purposes or under a government contract is thought to be protected from infringement due to an experimental use exemption.

Of course – and perhaps also because of the plethora of patents surrounding both upstream and downstream biotechnology discoveries – some scientists and their organizations simply "turn a blind eye" towards respecting other peoples' IPR. In practice, both they and those who invoke the research exemption probably expose themselves to little risk of being pursued in the courts by doing so. This is because patents and PBR on research tools are rarely enforced; infringement is hard, if not impossible, to detect; private companies are generally loathe to pursue non-profit research institutes for infringement; and, as described earlier and below, there are solutions to directly using or acquiring the rights to practise proprietary biotechnology innovations (Walsh, Arora and Cohen, 2003).

Appropriate courses of action to follow for building and retaining trust (as well as funding) within national scientific, breeding and commercial establishments could therefore include 1) for governments to ensure an appropriate exemption for research directed towards providing public goods (e.g. for crops, micro-organisms and traits important to small-scale subsistence farmers) 2) for research funding organizations and implementing institutions to be aware of their legal rights and to develop general and specific policies, strategies and operating procedures that set the conditions and obligations for both protecting (and sharing) their own IP and for using technologies and resources developed by others and 3) as a "rule of thumb", for those working in the BFA arena at both R&D and commercial levels, to determine whether the permission of the owner is needed to use the material in question, i.e. whether there is FTO.

b) With the owner's permission

A number of different options are available to the public sector wishing to access proprietary tools and technologies with the owner's permission (Byerlee and Fischer, 2001). Seven potential options are considered here.

Material transfer agreements (MTAs)

These are likely to remain the main mechanism for accessing (and providing) BFA for non-commercial uses. Nevertheless, researchers seeking access to genetic resources in another country (and sometimes also in their own country) may have to contact the National Biodiversity Authority to obtain the agreement of the provider on the transfer, and clarify the conditions under which the transfer and use are authorized. The MTA may include provisions on whether IPR can be sought and under what conditions, i.e. joint ownership of rights arising from inventions derived from the resources, preferential access to any technology developed, or monetary or non-monetary benefit-sharing arising from their use.

Licensing agreements

The main difference between licensing agreements and MTAs is that usually the recipient (licensee) is granted the right to make, use and/or sell the technology in question. However, they are also widely used for obtaining access rights to bioinformatics databases and for using computer software. Like MTAs, these agreements define the property to be licensed, field(s), and sometimes the territories of use. They can also define use within regions of countries, type of farms by size, products and income levels and therefore (in theory at least) provide access or preferential access to small-scale and subsistence farmers. If the technology is covered by a patent, the subject matter of the licence can be for the product (e.g. a new micro-organism) and/or for the method of using it to manufacture/process something, e.g. an enzyme, biopesticide etc. Although access to public bioinformatics databases may be free or based on a modest subscription, payment of royalties to the licensor is the norm, the cost of which varies enormously depending on the status of the licensee (public, SME, MNC), and the perceived value of the invention or data.

Purchasing outright

This needs skills in technology valuation. Although there are models available for valuing some BFA (Nadolnyak and Sheldon, 2003), the high volatility in returns from marketing many biotechnologies renders this option less appropriate than MTAs and licensing agreements for obtaining tools and products, especially for smallholder farming situations.

Patent pools

These are agreements between two or more patent owners to license one or more of their patents to one another or to third parties. They can reduce problems caused by "blocking" patents, and lower significantly the transaction costs associated with licensing, e.g. by providing a "one-stop-shop" for obtaining licenses essential to a core technology. At present, patent pools are of greatest relevance to commercial organizations holding bundles of patents. Nevertheless, it would be surprising if there were not greater opportunities for public sector organizations to pool or combine their IP portfolios (proprietary and non-proprietary) based on mutually complementary assets, with a start being made by the CGIAR and by some groups of developing countries.

Open source licensing

The Biological Innovation for Open Society (BIOS)[2] initiative developed by the Centre for the Application of Molecular Biology to International Agriculture (CAMBIA) provides open source licensing. It is based on the idea of a protected commons for making and using improvements to licensed technology for research or commercial purposes through a web-based meeting place for scientists. Anyone can obtain a free license to the technology, but they have to agree to put any improvements back into the licensing pool. Examples of technologies developed through this approach are Trans-Bacter, a technique for transferring genes to plants using a plasmid containing a new T-DNA sequence that allows gene transfer into bacterial strains other than *Agrobacterium tumefaciens*, and GUSPlus, a new reporter gene for sensitive visualization of gene transfer events.

While there certainly appears to be a great need for this kind of model, one constraint is the sheer number of patents to circumvent if an end product is to be brought to market. For researchers interested in more upstream knowledge generation and making more options available, the approach has many merits although, as noted earlier, patents are not an issue because most large biotechnology companies do not enforce their patents for research purposes and increasing numbers appear unlikely to do so when these are used for humanitarian uses.

Potentially useful as all the modalities described above may be, it should be emphasized that it is not simply patent information or access to an IP-protected tool or product that is important for successful technology transfer. The associated "know-how" is also essential, which many owners of IP continue to guard carefully, and which can only be accessed through an appropriate MTA or licensing agreement.

Public sector partnerships

There are numerous examples of BFA partnerships between public sector entities involving different combinations of actors. These can include partnerships between national institutes, partnerships involving one (or a number of) NARS and individual or teams of CGIAR centres, sometimes also involving advanced research institutes in developed countries.

Possibly the best example of a purely national effort leading to commercialization of products is the Bt cotton varieties developed using a modified Bt fusion gene (Cry 1ab and Cry 1Ac) by the Chinese Academy of Agricultural Sciences. This organization has also now developed Bt hybrid cotton which is distributed through state-owned county, prefectural and provincial seed companies and has also recently been approved for cultivation in India.

2 www.bios.net/daisy/bios/home.html

The second type of institutional constellation is best illustrated by the CGIAR's Generation Challenge Programme[3], which brings traditional and advanced biotechnologies to bear on 12 target crops and seven crop-trait combinations (with a major focus on drought tolerance) for developing tools and technologies that help plant breeders in the developing world to produce better crop varieties for resource-poor farmers. It uses a network of over 170 institutes in all regions of the world, and a cornerstone of the Consortium Agreement and project contracts is the provisions on IP requiring outputs to be released as public goods, enabling scientists in developing countries to readily use elite genetic stocks and new marker technologies in their breeding programmes. However, a recent review of the programme has shown that these terms are not always respected, and that ways need to be found to compel compliance to the contractual documents, including ultimately requiring reimbursement of funds from partners who fail to live up to their obligations (Woolley *et al.,* 2009).

The CGIAR's Harvest Plus Challenge Programme[4] operates along similar lines, but different IP arrangements. It involves a consortium of donors and over 200 agricultural and nutrition scientists in the task of developing (through conventional breeding) staple crops like beans, cassava, maize, pearl millet, rice and sweet potato which are biofortified with vitamin A, zinc and iron. In this programme, individual research partners can take out patents on their own discoveries, but they must make their results freely available in the public domain for use in developing countries.

The FAO/IAEA coordinated research projects[5], organized and funded through FAO's Joint Programme with the IAEA, are other examples of public sector partnerships. They bring together public sector research institutes in developing and industrialized countries to develop and validate BFA tools and products needed to improve understanding or solve particular constraints to agricultural development. Prominent examples of technologies developed or validated and subsequently widely applied in developing countries include mutations, using radiation and targeting induced local lesions in genomes (TILLING), combined with molecular markers to develop new varieties of food and industrial crops, and immunoassay and molecular diagnostic tests for rinderpest, foot-and-mouth disease and brucellosis. Here again, contributors to these projects agreed to release products and other information without IPR restrictions.

In line with its mandate, the International Centre for Genetic Engineering and Biotechnology (ICGEB) has adopted IP policy guidelines. These state that "access to IPR concerning the results emanating from the research work of the Centre shall be granted to members and to developing countries that are not members of the Centre in accordance with

3 www.generationcp.org/
4 www.harvestplus.org/content/about-harvestplus
5 www-naweb.iaea.org/nafa/index.html

applicable international conventions" with the objectives of (1) promoting the development, production and wide application of biotechnology in the interests of developing countries, (2) promoting the transfer of technology and know-how to its member countries, and (3) overcoming the difficulties encountered by developing countries in fostering innovation, ownership and in-house application.

With Brazil, China, India and, to a lesser extent, South Africa now heavily engaged in front-line fundamental and applied R&D and commercialization, and increasing numbers of developing countries beginning to enter the scene in specific niches, the scope for further globalization of partnerships between public sector institutes in BFA at all levels of activity is likely to increase substantially in the years ahead. Also, irrespective of their institutional makeup, with ever-increasing pressure on public budgets, partnerships are the way to maintain and even increase support for key public goods programmes.

Public-private partnerships (PPPs)

As noted earlier, there is increasing recognition in developing regions of the importance of collaboration between public institutions and private firms for applying biotechnologies to improve fundamental biological knowledge, agricultural productivity and the livelihoods of farming communities. Government policy in both developed and developing countries has therefore moved (decisively in some instances) to bring biotechnology R&D closer to filling perceived market failures, resulting in a diverse set of institutional arrangements for fostering partnerships between the public and private sectors and within the public sector itself at both national and international levels. These include university and NARS-industry collaborations, government grants to support technology development and commercialization, and global partnerships in BFA.

For governments, the motivations include increasing the competitiveness and social welfare benefits of the agricultural sector, reducing market failures in both knowledge (through basic S&T research which is risky and long-term) and consumer surplus spillovers (product and process development where profits will not be sufficient to cover the costs of R&D), and improving the mission orientation of their research and innovation systems by sharing costs and risks. For the private sector, motivations can range from gaining access to knowledge, technology and markets that would otherwise be difficult to tap, to showing that the company can deliver something useful or is simply a good corporate citizen. Potential risks to participants include conflict of interest, losing public trust or control of proprietary technology, compromising missions etc. There are also context-specific challenges concerning governance.

A flavour of the wide range of relevant ongoing PPPs is available from presentations at the recent Crawford Fund Annual Conference[6] that explored ways in which the private sector

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6 www.crawfordfund.org/conference/2009.html

can engage in international agricultural research, development and extension to the benefit of the rural poor. One of these is dedicated to the Hybrid Parents Research Consortium (HPRC) that was initiated in 2000 by the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) and private sector seed companies as a R&D partnership for improving the availability of seeds of high yielding cultivars. It was the first PPP arrangement in the CGIAR system, and ICRISAT has now partnered with many private sector seed companies in India, Indonesia, Egypt and Mexico through the HPRC to deliver its improved sorghum, pearl millet and pigeonpea hybrids to poor farmers. As a member of the CGIAR, ICRISAT adheres to policies concerning the transfer of germplasm in line with the CBD and with the agreement between the CGIAR centres and FAO by which designated germplasm held in-trust for the world community is made freely available through the standard MTA under the ITPGRFA (Gowda *et al.,* 2004).

A variety of options are available to promote partnerships with the private sector and with other public entities in both research and commercial undertakings on pro-poor BFA without, or with limited, complications arising from IPR. These could be more actively explored by research institutions and funding bodies in industrialized and advanced developing countries committed to assisting countries that do not have strong scientific capacities, by the CGIAR centres, and by countries where small-scale and subsistence farming involve primarily staple and non-export crops. The options include:

(a) Negotiating royalty-free access to proprietary genes, genetic constructs, and germplasm

There is increasing evidence of the willingness of MNCs to donate proprietary biotechnology with no, or limited, restrictions on FTO. This should be recognized as a step in the right direction. Recent examples include Syngenta, which has committed to provide its technology royalty-free to benefit subsistence farmers in developing countries. It has also stated that it will not pursue patent protection for any plant biotechnology or seeds invention for private and non-commercial use in least developed countries. Furthermore, IPR related to the rice genome will not be enforced in least developed countries for non-commercial use by subsistence farmers[7]. Monsanto and Syngenta have also provided royalty-free licenses to the Golden Rice Humanitarian Board for technologies that can help further the development of pro-vitamin A (beta carotene) enhanced rice.

In addition, Monsanto and BASF are partners in a large project on water efficient maize for Africa (WEMA), funded by the Bill and Melinda Gates and Howard Buffet Foundations, with the participation of the International Maize and Wheat Improvement Center (CIMMYT) and a number of NARS in Africa[8]. These companies will provide

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7 www2.syngenta.com/en/media/positionstatements_full.html#ip

8 www.aatf-africa.org/wema

proprietary germplasm, transgenes and advanced breeding tools without royalties for research, and any products developed will likewise be made available to small-scale farmers without royalties. The agricultural biotechnology company Arcadia Biosciences Inc. has also agreed to provide compensation-free technology for the development of nitrogen use efficient and salt tolerant rice for Africa.

(b) Using the services of third party brokers

A number of organizations and advanced research institutions work to facilitate the transfer of proprietary tools and technologies and related knowledge from private companies to public sector institutes with a focus on Africa, pro-poor crops and livestock diseases. Well known examples include the African Agricultural Technology Foundation (AATF), based in Kenya, which was set up to facilitate and promote PPPs for accessing and delivering appropriate proprietary agricultural technologies for use by resource-poor smallholder farmers in sub-Saharan Africa[9]. It is a "one-stop-shop" that provides expertise and know-how to facilitate the identification, access, development, delivery and use of proprietary agricultural technologies. It is backed by a number of donors, including the Rockefeller Foundation, the UK Department for International Development (DFID), the United States Agency for International Development, the Bill and Melinda Gates Foundation and the Buffett Foundation. It engages actively with CGIAR centres, NARS, local and international seed and biotechnology companies, and is involved in most of the African initiatives on PPPs described above.

Another example is the International Service for the Acquisition of Agri-biotech Applications (ISAAA), which was established to deliver the benefits of new agricultural biotechnologies to the poor in developing countries[10]. Best known for its annual report on the global status of commercialized GM crops, this organization also facilitates the transfer of proprietary technologies from the private sector in industrial countries for the benefit of subsistence farmers and the poor. It has been particularly active in the area of tissue culture for bananas and cassava in East Africa.

The Public Intellectual Property Resource for Agriculture (PIPRA)[11] also assists developing countries to access new technologies by reducing IP barriers to cooperation among public sector institutes for improving staple and speciality crops, and facilitating the transfer and adoption of their technologies by resource-poor farmers. A final example is GALVmed[12], an alliance of public, private and government partners, which was established

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9 http://aatf-africa.org/
10 www.isaaa.org/
11 www.pipra.org/
12 www.galvmed.org/

in 2005 to make livestock vaccines, diagnostics and medicines accessible and affordable to developing countries, primarily in Africa, funded by the Bill and Melinda Gates Foundation and DFID. It is part of a task force led by the African Union-Interafrican Bureau for Animal Resources (AU-IBAR) to facilitate the registration and commercialization of a tissue culture-derived vaccine for East Coast fever that is presently produced by the International Livestock Research Institute (ILRI) and to transfer vaccine manufacture and distribution to the private sector.

Given the limited understanding within NARS of IPR and how to access proprietary tools and technologies, these organizations clearly have considerable potential for filling important gaps. They have also been successful in brokering royalty-free licenses for particular technologies (gene constructs and varieties), and thereby provided opportunities for R&D training and capacity building in many essential aspects of project planning and implementation that otherwise would not have been available. Some technologies have moved from the laboratory to the field but, due to a combination of regulatory delays (biosafety and seed certification) and some other work being early-stage research, the contributions of these projects to technology development, improved productivity and poverty reduction remain to be determined. One significant up-coming challenge for all these projects will be ensuring dissemination of the products according to the humanitarian use requirements of the tool and technology providers.

Other issues surrounding PPPs are covered in more detail by Hartwich, Gonzalez and Vieira (2005) who studied 124 cases of PPPs in Latin America including a number dealing with basic and applied plant breeding. Their analysis indicated that when entering into these partnerships, public sector priorities and goals are not sufficiently addressed. Hence, while there can be no question that PPPs in BFA are an interesting approach to development and there are many promising initiatives, outside of India and Brazil convincing evidence is still lacking about the success of such partnerships in terms of products in widespread field use or application within government or other support services, e.g. by plant and animal health authorities.

9.2.4.2 Establishing legal or institutional structures and intellectual property and knowledge transfer policies

Virtually all research institutes and universities in industrialized countries dealing with BFA have established technology transfer offices (TTOs). These are staffed by people trained in advising on, and processing, IP applications and with the negotiation and business skills for securing agreements with third parties seeking access to the products in question or holding IP on products considered relevant to furthering the research or commercial interests of the institution housing the TTO. These offices also deal with non-proprietary assets, e.g. textbooks, training manuals, software, audio-visual material etc. In some cases, public institutions have allowed/encouraged their staff to engage in the creation of spin-off companies.

Typically, a well-functioning TTO provides support to institutes and their scientists on all aspects of IP. These include creating awareness of IPR-related issues through seminars and individual contacts; providing access to PVP and patent literature; assessing the market potential of an invention and the best way of protecting it; drafting and filing patent applications and managing the financial arrangements; negotiating the terms and conditions of MTAs, licensing and confidentiality agreements; and finding commercial partners.

In response to changes in their laws that allow commercialization of inventions from publicly-funded R&D, a few agricultural ministries and research organizations in developing countries have followed suit. Notable examples include the Chinese Department of Agriculture and the Indian Council of Agricultural Research (ICAR), the Instituto Nacional de Tecnología Agropecuaria (INTA) in Argentina and EMBRAPA in Brazil, and the Agricultural Research Council (ARC) in South Africa. These are all large organizations operating many centres, and they have made substantial investments in biotechnologies, breeding (of crops and animals) and seed production and distribution.

Both EMBRAPA and ICAR have legal authority to manage their own IP portfolios and technology transfers (relating mainly to both patents and *sui generis* PVP and copyrights) in conformity with existing national IP laws and other related laws/rules. ICAR even registers its own patents and PVP certificates. In the case of the ARC, IP is managed through its Intellectual Property Management Office (IPMO) which works under the umbrella of a National IPMO which was set up to harmonize IP management across all institutes supported through public funds and which deals with patent applications from these institutes.

At the international level, the CGIAR has a Central Advisory Service on Intellectual Property (CAS-IP) to assist its centres and their partners (primarily the NARS) in managing intellectual assets as public goods. Individual centres also have staff responsible for negotiating agreements that are within overall CGIAR policy guidelines.

Irrespective of the above, policy-makers should be aware of the following potential issues regarding commercializing IP assets within the public sector. First, there is the risk that the focus of BFA research shifts to private research interests at the expense of tackling issues with a predominant "public goods" value (i.e. from more upstream to near-market, and from species and traits important to small-scale and resource-poor farmers to those of interest to export and commercially-oriented operations). It is important, therefore, that the principles for seeking protection and for managing biotechnology IP and wider assets further the mission of the institute, i.e. foster access to, and diffusion of, their proprietary and non-proprietary assets to the poor and food insecure.

Second, the ability to obtain royalties from licenses to third parties for protected varieties and other biotechnology materials, and from outright selling of other intellectual assets, contracts, consultancy fees etc. can potentially raise revenue for the institute and/or the scientists involved. Many commentators mention this second possibility. However, except in the highly unlikely event of a "blockbuster", licensing protected assets will not be sufficient to cover the costs of seeking, maintaining and licensing patents relating to BFA. Figures from the United States Department of Agriculture (USDA) illustrate this point (Day Rubenstein and Heisey, 2005). Of the 270 active licenses negotiated by this organization in 2003, only 56 generated royalty income which had a median value of US$3 102. The widely quoted example of EMBRAPA which reputedly earns several million US$ annually in royalties (mainly through licensing its crop cultivars to local and multinational or joint venture owned seed companies, including for the production of GM seeds) is clearly an exception. This derives mainly from its direct and indirect involvement in seed production and the fact that its income is generated overwhelmingly from seeds of the country's dominant agricultural export (soybeans). Few other developing countries have agricultural research organizations holding such key roles in R&D, outreach and (indirectly) global commodity trade.

Less clear also is whether the earnings from EMBRAPA, and indeed for all other TTOs, are net of the costs of running their operations, and whether – as has happened elsewhere (Rozelle *et al*., 1999) – success in raising money through commercial activities leads to reduced funding by government on agricultural R&D.

Third, the main benefits of licensing proprietary technology are (1) the potential to facilitate technology transfer when a private partner is needed, while reserving the rights of the public sector to deliver that technology to farmers who otherwise could not afford it, i.e. as a means of market segmentation, (2) as a "bargaining chip" to access technologies owned by others, and (3) as an entry point into global or regional research consortia, often involving the sharing of research tools for non-commercial purposes.

Countries, large and small, industrialized and developing should not dismiss the option of exploiting the IP of their research institutes by publicly disclosing details of innovations though "defensive publication" (Adams and Henson-Apollonio, 2002). Defensive publication and patenting share the requirement for novelty but since a published description of the research product is available, it can no longer be called new and therefore patent-worthy. Defensive publication effectively prevents competitors, and possibly even the originating scientist, from patenting an identical or similar innovation. This strategy is especially useful for innovations that do not warrant the high legal costs and fees for patent applications, for public sector agricultural research institutes working on pro-poor issues, and for keeping innovations in the public domain free from fear of patent infringement.

Before embarking on the complex and expensive business of applying for IP protection in the first place and establishing TTOs for managing such protection and accessing the proprietary assets of others, developing countries and their public sector institutes should therefore be clear about both the underlying rationale and the policies they will follow in implementing these tasks. Making such decisions should be underpinned by conducting and maintaining an inventory of the assets within both the public and private sectors irrespective of whether these are or may be covered by IPR. Only in this way, can governments and institutes determine how best to use these assets to achieve their mission and goals and to develop partnerships for R&D and commercialization even if the national legislation excludes IP protection of life forms.

In some (albeit very few) developing countries, these complementary assets are substantial. They extend from capacity to develop new research tools and gene constructs through to producing, multiplying and distributing GMOs, considerable capacity in structural and functional genomics, strong characterization and breeding programmes and an active private sector etc. In some others, the assets may be knowledge about local germplasm, breeds and diseases; technical expertise and facilities for applied breeding and running evaluation trials; cell culture for vaccine production and running vaccination campaigns; and seed multiplication and delivery through extension services and/or local companies. Nevertheless, in the majority of developing countries, particularly where potential private sector partners are essentially non-existent, discussion of IPR in relation to BFA is largely irrelevant to the design of national research programmes.

Institutes with significant R&D activities and other complementary assets should therefore develop IP/knowledge transfer policies as part of their long-term strategy and mission, publicize it internally and externally and establish a single contact point. The IP policy will require guidelines on aspects like the assets to be made freely available and those which need IP protection to keep them in the public domain; clear rules for staff and students regarding, in particular, the disclosure of new ideas with potential commercial value; the ownership of research results; record-keeping; the management of conflicts of interest and engagement with third parties.

For knowledge transfer, policies are required for licensing, including the financial and non-financial aspects of compensation; on the creation of spin-offs, making clear the management of relationships between the research institute, the spin-off company and the staff involved; and policies for sharing the financial returns from knowledge transfer income between the research institute (and/or relevant department) and the scientist(s) involved.

Principles also have to be developed for engaging in collaborative and contract research compatible with the mission of each party. In the case of PPPs, they should take account of the level of private funding and maximize the commercial and socio-economic impact of the research, maintaining an IP position that allows further academic and collaborative research and avoids impeding the dissemination of the R&D results.

For public sector research institutes whose mission is pro-poor agricultural development, the policy statements published by some of the CGIAR centres are good guides for informing their own scientists, stakeholders and the public at large on their position concerning the protection and use of their intellectual assets[13].

Few developing countries have scientists, patent attorneys or agents who are sufficiently knowledgeable to bring the required depth and breadth of understanding in biotechnology, agriculture and law to the complexity and variety of tasks required for effective filing and management of modern biotechnology-related patents. Most do so by contracting this work out to third party management companies and centres, especially for the needed specialized legal and business skills. For example, the biotechnology incubators and parks described in Chapter 8 have established technology transfer and commercialization offices which take on consultancy work for public sector institutions, in addition to undertaking IP work for companies situated within the hub.

9.2.5 Options for national and international research funding and development agencies

National and international S&T funding agencies and donors are essential catalysts of agricultural R&D and development. With the advent of the genomics and proteomics era in BFA, the policies adopted by these organizations, including the question of disposition of rights to IP arising from the R&D supported by them, play a critical role in determining the policies, practices and behaviour of the research institutes and individual scientists that rely on them for funding. Some of these organizations have also proven to be highly influential in intervening on behalf of the public sector to obtain tools, technologies and data of value or potential value to developing countries either free or on preferential terms from MNCs and other private sector entities.

At the national level, funding bodies have different roles in R&D. For example, through their "in-house" programme they can be leading producers and suppliers of new tools as well as users. Also, as sponsors of research in external institutes they have interests in how the recipients of their grants and their contractors obtain research tools from others and how they disseminate the tools developed through the work they support. As government agencies, they may also have unique legal authorities over how they manage their own IPR and what agreements they enter into to obtain research tools for their own programmes.

Administrators in many funding agencies, research institutes and universities and many scientists themselves have noted the increasing complexity of the patent landscape and the burden that this is placing on the scientific endeavour in the fields of structural and

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[13] For example, for CIMMYT at www.cimmyt.org/en/about-us/policies/cimmyt-intellectual-property-policy

functional genomics (proteomics, metabolomics etc.) through patents on gene sequences, their protein products and methods to detect, produce, study or manipulate genes or proteins (Royal Society, 2003).

This has raised concerns about the freedom of publicly-funded national and international agricultural research institutions to employ proprietary tools and technologies on reasonable terms for conducting both fundamental research and more applied R&D leading to products that benefit the agrifood sector because of a patent or, more likely, an exclusive or other restrictive license on a patent. These institutions have also warned of the likelihood that as more knowledge is created and more patent applications are filed, impediments to the exchange of research materials may become more severe. While they also recognize that IP protection (patents in particular) may be a valuable tool to provide incentives for the translation of research results into products that benefit society, their own general policies and advice to the scientists and institutions they support both directly and indirectly through grants and contracts and to other government funding agencies, is to encourage sharing, believing this to be in the best interest of all science, both basic and applied.

A number of principles and practices are now presented as options for consideration by the scientific and development communities of all countries including private sector entities when developing and implementing policies, programmes and projects that incorporate advanced biotechnologies into agricultural R&D and development to benefit small-scale and subsistence farmers.

- encourage the free exchange of materials and data; Nucleic acid sequences, including ESTs and SNPs, are fundamental for describing and understanding the structure, function, and development of agriculturally important plants, animals and micro-organisms. Although private industry retains sequence data relating to many agriculturally important organisms in proprietary databases, these firms should be encouraged, and public sector institutions required, to place such sequences in public data banks.
- ensure that grant applicants include in their proposals an explanation of their stewardship plans, as well as plans for the sharing and dissemination of research results;
- monitor the actions of grantees and contractors with regard to data and material sharing and, if necessary, require grantees and contractors to comply with their approved IP and data sharing plans;
- extend the "Bermuda Rules" that were agreed for the human genome project to the sequencing of genomes of organisms that are essential for agricultural production in developing countries. This means releasing within 24 hours all DNA sequences longer than say 1 000 base pairs to a public database and issuing a directive against patenting newly discovered DNA;

- foster responsible patenting and licensing strategies. Whenever possible, non-exclusive licensing should be used when technologies owned or funded by public sector institutions are transferred to the commercial sector. This facilitates making broad enabling technologies and research uses of inventions widely available and accessible to the scientific community. Options include:
- ensure that proprietary or exclusive means of dissemination are pursued by recipients of grants and contracts only when there is a compelling need. Also, whenever possible, licenses should be limited to relatively narrow and specific commercial application rather than as blanket exclusive licenses for uses that cannot be anticipated at the moment;
- because of the complexity in determining FTO and the fact that most developing countries have little experience in managing IP, industrialized countries donating proprietary technology should conscientiously supply products that are "clean" with respect to intellectual and tangible property (Kowalski *et al.*, 2002);
- introduce explicit reservations of rights in commercial technology licenses to protect their own institutional objectives and support humanitarian applications (Bennett, 2007).

9.2.6 Final considerations

The formulation of appropriate IP legislation to deal with BFA, and the establishment of institutions to administer and make rational decisions about how to use it successfully as part of the "enabling environment" for biotechnology transfer, development and diffusion are huge challenges and still very much "work in progress" for developing economies. The needs for training and capacity building to deal with the wide scope, complexity and interplay between all the issues involved in ways that ensure public sector research remains focused on the social needs of the many rather than the financial interests of the few must remain paramount if biotechnologies are to deliver on a pro-poor agenda.

9.3 PUBLIC AWARENESS AND PARTICIPATION

9.3.1 Participatory biotechnology R&D and extension

The farmer and technology development "participatory" paradigm of planning and, in some cases, implementing and assessing the benefits of particular courses of action came from the recognition that those targeted as potential beneficiaries of R&D projects should have a say in, and influence, priorities and strategies. Other terms used are "bottom-up" and "demand-driven". Combined with similar approaches to providing extension services, these were designed to encourage scientists and extension agents to work with small-scale farmers when defining problems and finding solutions – in effect to make R&D and extension more responsive to their needs and priorities. The current plethora of "participatory" planning and implementation of R&D projects and extension services (which now cover topics ranging from plant breeding, integrated pest management, soil and water management, gender planning, assessment of organic agriculture, risk assessment for animal diseases like bird flu etc.), attests to how policies within many governments and funding bodies for organizing these services have been transformed.

Such policies have not, of course, replaced the more traditional "top-down" (and often "supply-driven") option. Here, a committee (chaired perhaps by the Permanent Secretary of the Ministry of Agriculture) is normally set up composed of senior ministry officials, research leaders within NARS and relevant universities including those located regionally, and key private sector bodies and non-governmental organizations (NGOs). Other ministries (particularly of S&T, Rural Development and Economic Planning) would also be appropriate participants, the aim being to optimize the match between technical and wider policy considerations. Ideally, both approaches are needed (and in fact, are usually practised) to provide balance, objectivity and transparency to government, ministerial or institutional decision-making.

Several constellations are possible for "participatory/bottom-up" approaches (see e.g. Boerse, Bunders and Loeber, 1995 and Cohen, Falconi and Komen, 1998). Puente-Rodríguez (2007) presents a notable example of a "participatory" and self-organized "bottom-up" approach within the context of subsistence agriculture, for the control of the castor semilooper (*Achea janata*) pest in Andhra Pradesh, India. Their common features are that they involve farmers, extension services, scientists, local or national policy-makers and NGOs in identifying and prioritizing problems and finding solutions at the grassroots level that are amenable to R&D. Critical challenges include:

- establishing a multidisciplinary coordination team/steering committee with a wide policy, scientific and cultural background to support the process, which involves substantial dialogue to reach common ground;
- supporting the process with "evidence-based" data and information obtained through one or a combination of the methods described in Chapter 7;
- ensuring that the process goes beyond diagnosis and priority-setting by involving the communities concerned, e.g. in farm or village experiments to test new technology.

Another challenge with all these approaches is deciding who participates and the manner and extent of their involvement. In setting up participatory priority-setting, decision-makers have to establish criteria. These should be guided by research objectives and proposed target groups which, in turn, will depend on whether the exercise is purely national or part of a wider regional or global programme with involvement of one or a number of regional research organizations, CGIAR centres, bilateral donors, banks and philanthropic organizations. In such cases, agreement has to be reached between the government or responsible ministry on participatory principles and administrative arrangements. It is important here to retain national ownership and identity.

In addition, focusing on applications of biotechnologies through participatory approaches raises both opportunities and restrictions for all concerned. For farmers and their communities, if the programme being considered has to include a biotechnology, this limits enormously the scope for prioritization of problems and possible solutions. The same applies to scientists and policy-makers who have the additional dilemma of deciding on the geographic or production system focus of operations (i.e. which poor farmers?).

Kenya (World Bank, 2008) and Bolivia (Hartwich and Jansen, 2007) provide examples of options for pursuing priority-setting which can be suitably adapted to include biotechnology. In the case of Kenya, the Kenyan Agricultural Research Institute (KARI) has an Annual Research Forum to set the national strategic research agenda and a number of Research Coordination Committees to approve proposals, as well as Centre Research Advisory Committees to screen proposals at the national and regional research centres. The KARI Biennial Science Conference is where agricultural policy-makers, researchers and the private sector participate and provide feedback on on-going research activities and identify emerging issues. The national and regional research centres identify research topics in consultation with various stakeholders in their districts, including district agricultural officers, farmer groups and scientists in local universities and, after technical review meetings, their recommendations are submitted to KARI headquarters. KARI is also now establishing a monitoring and evaluation system.

Bolivia, on the other hand, introduced the Bolivian Agricultural Technology System (SIBTA) by which government support to agricultural research and extension was partly delegated to regional semi-autonomous foundations with advisory boards. These foundations work with organized farmer groups with legal status, e.g. producer associations, community-based organizations or indigenous groups, and have been able to effectively identify and prioritize the demands of small farmers and provide transparency and accountability on decision-making and funding. The government's roles through the Ministry for Rural and Agricultural Development are to provide strategic direction, develop national level priorities through inputs from regional foundations, regulations for funding mechanisms, and in general to acts as a "one-stop-shop" for linkages to international R&D agencies.

9.3.2 Participatory policies for regulation of biotechnology

Extending participation into the realms of national and international policy-making on biotechnology is more complex since it involves a much broader range of relevant stakeholders with more diverse and conflicting positions.

The importance of public participation in decision-making was recognized by policy-makers through Principle 10 of the Rio Declaration on Environment and Development, adopted by over 170 countries in 1992. It states that: "Environmental issues are best handled with the participation of all concerned citizens, at the relevant level. At the national level, each individual shall have appropriate access to information concerning the environment that is held by public authorities, including information on hazardous materials and activities in their communities, and the opportunity to participate in decision-making processes. States shall facilitate and encourage public awareness and participation by making information widely available. Effective access to judicial and administrative proceedings, including redress and remedy, shall be provided".

The Rio Declaration is not legally binding. A number of legally binding international instruments have, however, been adopted that are relevant to public participation and awareness in biotechnology matters (see Mackenzie *et al.,* 2003 for more details). One is the CBD, which through Article 14.1 promotes notification, exchange of information and consultation on activities that are likely to have significant adverse effects on biological diversity. The Cartagena Protocol on Biosafety (CPB), a supplementary agreement to the CBD, deals specifically with public awareness and participation regarding living modified organisms (LMOs) in Article 23. This Article states that Parties to the CPB shall promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of LMOs in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health; endeavour to ensure that public awareness and education encompass access to information on LMOs identified in accordance with this Protocol that may be imported; in accordance with their respective laws and regulations, consult the public in the decision-making process regarding LMOs and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21; endeavour to inform its public about the means of public access to the Biosafety Clearing-House.

The Aarhus Convention[14] is the most recent and comprehensive international agreement relating to public participation, adding much "meat" to government obligations. Its full title is the United Nations Economic Commission for Europe's (UNECE) Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (where the UNECE is one of five regional commissions of the UN, with 55 Member countries from North America, Western, Central and Eastern Europe and Central Asia). Although a UNECE Convention, it has a global significance as it is also open to all non-UNECE States that are members of the UN.

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14 www.unece.org/env/pp/treatytext.htm

At their 2nd Meeting in Kazakhstan in 2005, Parties to the Convention adopted an amendment aiming to strengthen the rights of the public to participate in decision-making on GMOs. This amendment enters into force when it has been ratified by three fourths of the Parties and would require the Parties to inform and consult the public in decision-making on the deliberate release and placing on the market of GMOs. The public would have the right to submit comments and the public authorities would be expected to take these into account in the decision-making process. Once made, the decision taken should be publicly available together with the reasons and considerations upon which it is based. Except for cases of commercial confidentiality, information associated with GMO decisions would be made available to the public i.e. Parties could not withhold as confidential, information on the intended uses of the release or on the assessment of environmental risk[15]. The amendment requires that the provisions made by Parties be complementary and mutually supportive with their approaches for meeting the objectives of the CPB.

From the aspect of food safety, the Codex Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (2003) appear particularly relevant from the standpoint of public awareness and participation. On risk communication, they state that: "Effective risk communication is essential at all phases of risk assessment and risk management. It is an interactive process involving all interested parties, including government, industry, academia, media and consumers. Risk communication should include transparent safety assessment and risk management decision-making processes. These processes should be fully documented at all stages and open to public scrutiny whilst respecting legitimate concerns to safeguard the confidentiality of commercial and industrial information. In particular, reports prepared on the safety assessments and other aspects of the decision-making process should be made available to all interested parties. Effective risk communication should include responsive consultation processes. Consultation processes should be interactive. The views of all interested parties should be sought and relevant food safety and nutritional issues that are raised during consultation should be addressed during the risk analysis process". Since Codex standards and guidelines are reference points for national implementation of the Sanitary and Phytosanitary (SPS) Agreement, this suggests a clear linkage between public awareness and participation and this WTO agreement.

As noted in Chapter 7, governments have two roles: (1) fostering community understanding/awareness about biotechnology including by improving access to understandable information, and (2) providing means by which citizens can express their views. This doesn't mean that they should "go it alone", but rather that they create the environment/provide the incentives for others, e.g. schools, universities, extension services, farmer and business

15 www.unece.org/press/pr2005/05env_p06e.htm

organizations, NGOs, civil society organizations (CSOs) etc. to take initiatives. Because biotechnology needs horizontal governance, this should include developing a "top level" strategy to which all ministries commit through a shared programme of work that includes agreement on the combination of mechanisms that can realistically be applied and financed in the light of national circumstances.

Since biotechnology is also a very broad topic with intersecting thematic areas that include biosafety, food and feed safety, consumer protection, intellectual property, seed certification, bio-ethics, as well as access to genetic resources and benefit-sharing, national capacity for fostering public awareness needs to extend to these topics. In the resource-constrained environments within which all developing countries operate, and given the reality that resources for enhancing public empowerment need to compete for scarce funding, decisions may have to be made as to whether communicating, e.g. to small-scale farmers about the merits of using biotechnology to improve crop or animal productivity should take priority over communicating to urban consumers about the merits of consuming food derived from these crops.

International agreements do not provide guidance on how the public should be informed, educated or engaged in decision-making processes, or how any decisions about GMOs would be communicated. For providing information, obvious channels of communication include the internet, publications, radio, television, newspapers, workshops, public hearings, official bulletins, and even labelling of products, whereas education would be through public educational systems. Concerning public participation, this would depend on whether participation is "passive" (i.e. meaning that information would be posted, e.g. on the Government Gazette and a public register maintained by the Competent Authority and "feedback" required within say 30 days) or "active" (i.e. involves sharing and communicating information and views through public consultations and hearings), the results of which would then be fed into decision-making and regulatory processes. Since most rural communities do not have access to the Internet or understand the main international languages used in much print media, governments and their agencies, NGOs, CSOs and others will need to rise to the challenge of creating spaces for activities that foster public participation by these communities.

9.3.3 Coverage in national biotechnology policy/strategy documents and regulatory frameworks

9.3.3.1 In NBS documents

The survey of NBS documents of selected developing countries showed that scientific and technical capacity building in biotechnology from undergraduate through to PhD levels was a key element of essentially all national plans, and that in a few countries efforts would be made to initiate awareness-building among schoolchildren. But apart from that, more than half of the NBS surveyed were either silent on public education/awareness and participation, or made only short generic statements to the effect that "civil society would be engaged", "public information/ education programmes would be set up" etc.

It is noteworthy that all NBS documents that raised the issue of public awareness/participation were either vague or silent on the rationale for involving the public at all. Also, none defined whether such involvement would be (1) used for developing wider policies, (2) confined to regulatory aspects, (3) purely advisory or entail involvement in decision-making, and (4) if the latter, whether this would be "arms reach" participation, e.g. providing comments in writing or verbally which would then be fed into decision-making by people traditionally considered to be better qualified to make judgements, e.g. scientists, regulators etc., or actually sitting at "the top table" and being directly involved.

Only three countries were more specific. Chile made public participation one of its "Flagship Initiatives" with thrusts to include ensuring dissemination of accurate and reliable information, particularly on regulatory matters, decisions based on ethical values as well as scientific principles, and a commitment to respect the value of considering different societal options. South Africa, in recognizing the critical importance of public understanding of biotechnology, outlined a number of specific initiatives. First, the government would articulate a single vision of biotechnology so that it is not confronted with different opinions from different ministries and departments. Second, public education campaigns on biotechnology would be initiated to give accurate information based on the inputs of various ministries/public sector agencies. Third, biotechnology issues would be included in high school curricula to encourage debate on potential benefits, risks, and ethical and environmental issues. Also, the media would be provided with information representing all sides of debates and encouraged to convey biotechnology issues to the public in a responsible manner. Only Peru provided any insight into the government or public sector structures that would be involved in leading or coordinating national initiatives in these areas. In this case, a National Forum on Biotechnology (FONABIO) would be established to connect citizens with up-to-date information on biotechnology, receive and respond to feedback and thereby create an environment of consultation and educated opinion. There would also be a Committee on Ethics to discuss, review and make recommendations to its regulatory authority on all aspects related to the promotion and development of modern biotechnology.

9.3.3.2 In national regulatory frameworks

Analysis of national regulatory frameworks provided little further insight on these issues. As noted in Chapter 8, in the majority of countries the main link between public awareness/information and biosafety lies in the reference by many countries to labelling of GMOs and products. Given the considerable practical difficulties and cost of labelling (let alone of implementing the necessary systems of co-existence between GMO and non-GMO production and harvesting), making the public aware of the full implications of such a policy is a legitimate part of information sharing and awareness building about modern biotechnology. Other frequently quoted mechanisms were through the BCH or national nodes of the BCH; providing information and requesting feedback through the Government Gazette and national newspapers (e.g. Kenya and Zambia) on proposed releases into the environment (and in some cases even on laboratory/greenhouse research activities); and, in one case (Namibia), by holding public hearings, the outcomes of which would be fed into higher level decision-making. Of the 15 countries surveyed, only five appeared to have consumer or farmer organization representatives on their national biosafety committees, and only two appeared to have civil society representation.

Noteworthy also were the confidentiality provisions in most of the national instruments (see Chapter 8) but again, these were stated in generic terms and it was not possible to determine how countries would use them and whether they would restrict the public's access to relevant information for policy or regulatory decision-making.

Some Biosafety Laws/Acts did not cover food safety, raising questions as to whether opportunities for pubic participation of any form existed on this important issue in the countries concerned. On the other hand, as pointed out by FAO (2003b), the lack of specific public participation provisions in a Biosafety Law does not necessarily mean that the public is barred from participation. Relevant environmental, consumer protection and other laws on public participation may already exist in a country and the criteria established in these would also be applicable for addressing modern biotechnology.

Concerning the BCH, the type of information envisaged includes applicable laws, regulations, guidelines, agreements with other countries, results of risk assessments, decisions on imports and releases of GMOs as well as information on scientific and technical issues concerning dealings with GMOs. Currently, the BCH contains relatively little information from developing countries, indicating that it may be some time before regulatory information could be shared electronically between countries to foster transparency. In addition, it would seem appropriate for countries to use their national BCH nodes not just as a conduit for documentation and one-way dissemination of information on biosafety, but to extend this both to biotechnology as a whole and to encouraging feedback, discussion and debate amongst their citizens.

Finally, making laws and regulations is one thing – implementing them is quite another. The extent to which public awareness and participation are actually facilitated or exist in a country is impossible to determine from a simple review of the country's biotechnology-related legislative instruments. Fine legally-expressed words may not translate into actual participation if, as is clear for many of the national instruments examined, additional criteria are not provided on the form public participation may take. Also, the best public participation provisions may not be used if the public does not have the capacity to participate effectively.

As pointed out by Glover (2003), and demonstrated through case studies of public participatory processes in a number of countries surveyed for that paper (Glover *et al.,* 2003) and others (Fransen *et al.,* 2005; CBD, 2009), the way in which participation is practised in different countries depends on local contexts, perspectives and public concerns. These determine when and how transparency and public participation are demanded or considered politically necessary for decision-making, as well as what participatory mechanisms are possible in different circumstances. In effect, because the issue of choice arises differently in different countries, there is no "one size fits all" or "toolkit" approach that can be applied everywhere.

Similar conclusions were reached through an e-mail conference organized by FAO on public participation in decision-making regarding GMOs in developing countries, which focused on how to effectively involve rural people (FAO, 2005). While there was broad agreement that citizens including rural people should be involved in decision-making when it is likely to impact on them, opinions on the degree and nature of the suggested participation differed, although many contributors felt that in many cases participation of the rural people could usually be indirect, i.e. through their chosen representatives. It was also felt that effective participation depended on access to unbiased and comprehensive information on the nature and consequences of GMOs, and that this information would have to be adapted to the needs and capacities of different groups of rural people and their representatives in order for it to be helpful, and that it would have to be communicated effectively, e.g. through extension services and radio. Use of local languages was particularly emphasized. Many participants complained that misinformation abounded (both for and against GMOs) and some were quite sceptical that a real public participation exercise might take place on this issue and, if it did, that its outcomes would have any impact. Interestingly, international agreements were regarded as being useful, but concern was expressed that commitments to these agreements might compromise the outcomes of an eventual national debate on GMOs – a point that also emerged from the analysis of Glover (2003).

From the perspective of this Chapter, the "take home message" is that it is essential that poor people have a voice, that decisions on biotechnology do not further marginalize those already marginalized, and that citizens of developing countries are able to make their own choices rather than having these defined for them by donors. Also, as concluded by FAO's independent Panel of Eminent Experts (FAO, 2001b): "The right to food carries with it obligations on the part of States to protect individuals' autonomy and capacity to participate in public decision-making fora, especially when other participants are more powerful, assertive or aggressive. These obligations can include the provision of public resources to ensure that those fora take place in a spirit of fairness and justice".

9.4 AGRICULTURAL EXTENSION

The term "agricultural extension" covers public and private sector activities relating to technology transfer, education, attitude change, human resource development, and dissemination and collection of information (FAO, 2009). Over the last two decades, national agricultural extension systems have undergone dramatic changes, driven by forces such as the growth of the commercial farm sector, particularly in developed countries; trade liberalization, contributing to a rapidly developing global food system; as well as the perceived lack of success of public agricultural extension systems in many countries. National agricultural extension systems have therefore been in transition worldwide, with the major trends including the movement from single main public systems to pluralistic systems involving the private sector, public sector and CSOs; from centralized top-down systems to decentralized systems where decision-making is delegated to the district or field level; from systems that are entirely publicly funded to those in which an increasing amount of the financial support comes from the farmers themselves and where specific advisory activities/services are effectively privatized (FAO, 2008). Further, extension systems are now focusing on being demand-driven and market-oriented. In practice, this means that farmers are not passive recipients of technology developed by researchers. Rather, it is the farmers' demand that should partially drive the research agenda and the educational and organizational work of the extension agents (Neuchatel Group, 2007). Similarly, research and extension interventions should respond to market conditions and market signals (Neuchatel Group, 2008).

In this dynamic situation, a shift of power may take place in some countries, but the role of government and government policy still remain significant. When and if the decision is made to reform agricultural extension, the government is faced with significant policy and strategy choices that will also indirectly impact the issue of farmers' access to the fruits of biotechnology R&D. As highlighted in Chapter 7, the paradigm now in vogue for describing the process of agriculture development is that of an agricultural "innovation system". It calls for rethinking the respective roles of those intimately involved in the agriculture knowledge information sub-system, namely research, extension, education and training. Fundamental questions raised by this evolving context include: how do farmers' specific demands for agricultural assistance impact biotechnology research and delivery?; what should be the goal of the extension services (e.g. production, transfer of new technologies, linking farmers to markets or helping farmers organize themselves into special interest groups around marketable products)?; and what should the government do to coordinate institutions that provide extension services (FAO, 2009).

Specific national agricultural extension policies have been drawn up in a number of developing countries in recent years. China and India are two countries where major extension policy changes have occurred (FAO, 2008 and 2009). Common features of the extension changes in these and other countries are:

- progressive transition from public technology transfer to the private sector;
- enabling problem solving skills of farmers through an inter-disciplinary approach;
- public funds for private extension;
- providing for cost recovery and co-financing of extension via farmers' organizations;
- reducing the number of village level workers;
- using para-extension workers and farmer interest groups for extension;
- employing more subject matter specialists;
- preparing strategic research extension plans;
- improving the research-extension-farmer interface;
- skill development of extension agents;
- improving women's access to technology;
- linking with agro-processors; and
- government as a facilitator and creator of an enabling environment.

The changes to extension systems and the new opportunities from biotechnology call for bringing researchers, extension agents, smallholder producers and their organizations closer together. They also call for upgrading the skills of extension staff so they are both more capable of understanding the implications of biotechnology and of facilitating interactions between farmers and others involved in the agricultural knowledge information system. Yet, the role of agricultural extension in enabling access to the products of biotechnology and necessary policy changes to facilitate that role is almost totally neglected in the biotechnology policy/strategy documents of the 15 selected developing countries consulted.

Lack of information and skills is one of the main reasons for the gap between potential and actual productivity/profitability of smallholder farmer systems, constraining the adoption of available technologies and practices and reducing their efficiency if eventually adopted (World Bank, 2007). For example, Guei, Somado and Larinde (2008) noted that farmers in sub-Saharan Africa do not use improved seed because very often it is not available to them or they are not aware of its advantages. Good quality seed is also not accessible to smallholders because there is often a weak linkage between farmers, extension systems, research institutions and the market. In the e-mail conference organized as part of the build up to ABDC-10 (see Chapter 6), the weakness of the extension system was identified by participants as one of the reasons for the failure in adoption of biotechnologies like artificial insemination in developing countries. Indeed, one of the four main suggestions for increasing the success of agricultural biotechnologies in the future that emerged from cross-sectoral discussions during the e-mail conference was that extension systems should be strengthened, as they can ensure that relevant R&D results actually reach the farmer.

Once biotechnology products are commercially available, extension services also play an important role in providing impartial information about them, as illustrated by Stone's (2007) analysis of the adoption of Bt cotton in the Warangal district in India. Farmers there had difficulties in accessing reliable independent information about the new cotton seed as government-sponsored extension programmes were virtually non-existent and the most common source of information on cotton seed was corporate promotional material. An equally important role that a strong functioning extension service plays is channelling farmer needs into practical demands. By helping farmers to frame their demands (for improved seeds, for example) and then to organize the demand into an effective strategy (demands to governments, seed suppliers, others), extension personnel can play a vital role in ensuring that products that are demanded are eventually supplied.

9.5 ANNEX: Coverage of IPR and genetic resources issues in national biotechnology policy/strategy frameworks of selected developing countries

The following summarizes the coverage given to these issues in NBS documents:

Brazil gave considerable attention to access to genetic resources, benefit-sharing and guaranteeing the rights of traditional communities and indigenous peoples. It intended therefore to improve its legislation concerning these aspects. At the same time, it would promote the strategic use of IP to make national biotechnology more competitive; increase the number of Brazilian-owned patents in Brazil and abroad; improve IP management capabilities within research, industry and the judiciary; harmonize IP practices within agencies that promote R&D; harmonize IP practices for recovery of traditional knowledge; review and strengthen national legislation for the protection of plant cultivars; strengthen breeders rights; and adopt mechanisms for protecting lines derived from animal breeding.

Chile intended to update and upgrade its IP system, design and implement a programme to train decision-makers on biotechnology-related IP issues, and encourage patenting in national research institutes.

India's National Biotechnology Development Strategy notes that a new bill on protection, utilization and regulation of IP for public funded R&D has been prepared through inter-ministerial consultation, its aim being to optimize the potential of public R&D, encourage innovation in SMEs, promote collaboration between government and non-government organizations and catalyze commercialization of IP generated through public R&D. The strategy also includes building capacity in technology transfer and IPR by having national and regional centres linked to university departments for training personnel which would also be done overseas.

Jamaica's NBS included a number of key strategies, one of which was to protect IP. Here, the government would play a proactive role in creating awareness of the importance of IPR issues in research and innovation, and through the development of databases and assistance to scientists and entrepreneurs through the national IP Office.

Kenya's biotechnology policy document stated that biotechnology would be developed in cognizance with international agreements (TRIPS and UPOV), and noted that the country's rich species diversity and the traditional knowledge associated with it offered great opportunities for industrialization through biotechnology. It therefore intended to set up a database on species in different ecosystems and the knowledge associated with them, develop capacity for effective management of IP including training scientists, improve the accessibility of IP services and establish a government fund to support filing of patents from public research. It would also review its policies and legislation on protection of traditional knowledge and resources and align these with policies on royalties, patenting, access to information and benefit-sharing on products resulting from biotechnology.

Malawi proposed to use biotechnology to conserve and sustain the use of its biological diversity by enacting legislation to regulate access and benefit-sharing, setting up a national database on, and clearing house for, facilitating access and sharing of benefits, facilitating adherence to the terms of technology transfer agreements, providing copyright and patent protection in respect of all conventions to which it is a signatory. It noted that it did not have an IPR policy and that its present legislation dating back to 1948 did not address biotechnology and community rights. It intended therefore to establish an IPR policy and legislation that would conform to its international legal obligations without undermining national development opportunities, to strengthen domestic legislation to ensure that IPR protected indigenous knowledge systems and genetic resources while at the same time attracting investment and development in biotechnology. It would formulate regulations that protected biotechnology innovations through IPR by harmonizing national implementation of biotechnology, trade and IPR agreements, and it would develop *sui generis* legislation to protect farmers and community rights. It would also develop appropriate guidelines for accessing and sharing the benefits from the products of biotechnology and establish mechanisms to facilitate access by Malawians to IPR-protected products of modern biotechnology.

In the Foreword to **Malaysia**'s biotechnology policy, the Prime Minister highlighted the potential of the country to be a key player in biotechnology because of its wealth of biodiversity. Regarding IPR, the policy states that the country will develop a strong IP protection regime to support R&D and commercialization efforts.

Namibia stated that national legislation relating to community or individual IPR will include contractual arrangements to share financial and other benefits arising from biotechnology, and that the State would facilitate community access to advice for negotiating such agreements. No details were provided on roles, responsibilities or mechanisms.

Peru specifically provided for the granting of patents except for whole organisms or parts thereof that exist naturally or have been modified by modern biotechnology, and for IP certificates for plant varieties developed with or without modern biotechnology. It also expressly recognizes and protects the rights of indigenous peoples and local communities in furthering biotechnology.

South Africa noted that it had many Acts relevant to biotechnology but since these provide conflicting legislation they would be reviewed and harmonized. It intended to update its Plant Breeders Right Act to include DNA fingerprinting to distinguish between phenotypes and it would consider introducing legislation for animal breeders. It would also introduce a search and examination capacity into its IP Office and develop standard guidelines on IPR of inventors for science councils and universities.

Thailand stated its intention to strengthen IP management including competency in international negotiations for fair benefit-sharing and technology transfer. It also intended to establish "community business networks" to promote the conservation and use of indigenous resources and thereby provide incomes for local communities. Further details were not provided.

Uganda made no specific mention of IPR, but intended to integrate indigenous knowledge with modern biotechnology to develop a vibrant biotechnology-based industry while promoting equitable access and benefit-sharing of indigenous knowledge.

Zambia described the need to ensure fair and equitable access and benefit-sharing from using genetic resources and by transfer of technologies, taking account of all rights over these resources and technologies. The NBS document did not elaborate further on how this would be achieved.

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CHAPTER 10

AGRICULTURAL BIOTECHNOLOGIES FOR FOOD SECURITY AND SUSTAINABLE DEVELOPMENT: OPTIONS FOR DEVELOPING COUNTRIES AND PRIORITIES FOR ACTION FOR THE INTERNATIONAL COMMUNITY

CONTEXT

Agricultural biotechnologies[1] provide opportunities to address the significant challenges of ensuring food security without damaging the environmental resource base. Because most of the world's poor live in rural areas, there is a need to facilitate greater access for poor rural producers to technologies that can increase the productivity of smallholder agriculture and help reduce rural poverty. This Chapter highlights lessons learned and options for the future for developing countries in relation to harnessing agricultural biotechnologies for food security and agricultural sustainability. In addition, the document provides a series of Priorities for Action for consideration by the international community that focus on both policy and capacity development. These priorities can be related to the following overarching goals or principles:

Policy goals or principles

- To facilitate the development and adoption of agricultural biotechnologies that address the needs of poor rural producers and preserve the natural resource base.

1 Agricultural biotechnologies encompass any technological applications that use biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use in food and agriculture. There is a wide range of agricultural biotechnologies available, one of which is genetic modification. For the purpose of this document, the term agriculture includes the crop, livestock, fisheries and aquaculture, forestry and food processing sectors.

- To develop and deploy biotechnologies for food security and poverty reduction in rural areas.
- To promote public and private sector investment in agricultural biotechnologies for greater impact on food security and rural livelihoods.
- To develop science-based policies, regulation and standards which promote sustainability and enable the positive impacts of agricultural biotechnologies on food security.
- To develop national capacities for generating, adapting and adopting agricultural biotechnologies that address the needs of poor rural producers and contribute to agricultural sustainability.
- To facilitate the access of smallholder farmers to agricultural biotechnologies that can contribute to food security and agricultural sustainability.
- To foster improved communication, information sharing and public participation practices regarding agricultural biotechnologies for food security.

Capacity development goals or principles

- To facilitate regional and national policy-setting that enables biotechnologies for sustainable development, including food security and agricultural sustainability.
- To support the strengthening of national and international cooperation programmes and action plans for agricultural biotechnologies for food security and agricultural sustainability.
- To facilitate multi-stakeholder approaches to policy planning and development for biotechnologies for sustainable development, including food security.
- To facilitate training and education for pro-poor agricultural biotechnology development and implementation, for food security and agricultural sustainability.
- To facilitate the uptake of agricultural biotechnologies that address food security and agricultural sustainability.
- To promote linkages between agricultural biotechnologies to other sectors in support of food security and poverty reduction.

10.1 INTRODUCTION

1. The FAO international technical conference on Agricultural Biotechnologies in Developing Countries (ABDC-10) takes place against the backdrop of a series of global food, energy, environmental and financial crises. There are a range of alarming statistics and negative trends concerning rural poverty, hunger and food insecurity, food and energy demand, the carbon footprint of agriculture, climate change, and degradation of natural resources (such as land, water and biodiversity) that present serious challenges to societies.

2. Over recent years, there has been a steady succession of authoritative high-profile reports and intergovernmental declarations[2] detailing the immense challenge of sustainably feeding the world's growing population without destroying the environmental resource base. The urgency of the challenges highlighted in such declarations, reports and statements raises serious concerns about the adequacy of "business-as-usual" approaches to meeting these challenges, in particular if countries are to make more rapid advances to meet the targets of the Millennium Development Goals and other internationally agreed policies.

3. The vast majority of the world's hungry lives and works in rural areas. Three of every four poor people in developing countries live in rural areas; 2.6 billion live on less than US$2 a day and 880 million on less than US$1 a day. Most of the poor rural producers depend on agriculture for their livelihood, either directly or indirectly through rural off-farm activities. Meeting the challenges ahead will require significant increases in investment in agricultural research in developing countries and major refocusing of agricultural research activities towards strengthening the food security of the rural poor. In particular, addressing food insecurity will require policies, strategies and programmes, including the generation and dissemination of knowledge and technologies, that can: (a) stimulate widespread and long-term increases in the production and value of staple foods and income-generating rural products through enhanced productivity; (b) develop sustainable agricultural systems that do not degrade the environmental resource base; (c) ensure food safety and nutritional quality to protect the health of consumers; and (d) promote improved access to, and engagement with, markets for smallholders.

4. Technologies and knowledge that increase agricultural productivity, facilitate diversification and the marketing of agrifood products, and improve natural resource management can be powerful forces for reducing poverty, hunger, food insecurity and environmental degradation. The five sector-specific papers prepared by FAO for ABDC-10 (in Chapters 1-5 of this book) document the current status and options regarding the wide range of agricultural biotechnologies currently used in crops, livestock, fisheries/aquaculture, forestry and food processing/safety in developing countries, *inter alia*, to increase production, diagnose and manage diseases and conserve genetic resources for food and agriculture.

5. The sector-specific papers highlight that while there have been some notable agricultural biotechnology successes with demonstrated impacts on the livelihoods of poor rural producers in developing countries, many agricultural biotechnologies (especially newer

[2] For example, the G8 L'Aquila Joint Statement on Global Food Security (2008) stated that "Effective food security actions must be coupled with adaptation and mitigation measures in relation to climate change, sustainable management of water, land, soil and other natural resources, including the protection of biodiversity". It was further highlighted that sustained and predictable funding and increased targeted investments are urgently required to enhance world food production capacity if sustainable global food security is to be achieved. See also the 2009 Declaration of the World Summit on Food Security (ftp://ftp.fao.org/docrep/fao/Meeting/018/k6050e.pdf).

technologies developed within the past decade) have, as yet, had little impact in most developing countries or, with few exceptions, on the farming systems and incomes of the rural poor. Such a lack of access by poor rural producers to advanced technologies exists within a broader context of lack of access to more basic science and technology (S&T) innovations, including electricity, healthcare and sanitation.

6. Building on the five sector-specific documents, and a sixth FAO document prepared for ABDC-10 on policy options (presented in three separate chapters, 7 to 9, of this book), this FAO document synthesizes the lessons learned and options available to developing countries for making informed decisions regarding adoption of agricultural biotechnologies within their national food security and rural development plans and policies. It also presents a set of Priorities for Action for the international community regarding agricultural biotechnologies for food security in developing countries, organized in three categories covering policy, capacity development and coordination.

10.2 LESSONS LEARNED AND OPTIONS FOR DEVELOPING COUNTRIES

10.2.1 Current status of impact of agricultural biotechnologies on food security

7. ***Recent scientific and technological advances have developed products and techniques that can contribute to improving food security and agriculture sustainability.*** Some agricultural biotechnologies are already benefiting smallholder farmers in some developing countries. Available or pipeline products and techniques developed through biotechnology can potentially contribute to addressing present and emerging challenges facing poor rural producers.

8. ***Application of agricultural biotechnologies is not yet widespread in developing countries.*** Many existing agricultural biotechnologies (and other technologies) have not yet been adopted or adapted for the benefit of the majority of poor rural producers. Some developing countries remain excluded from biotechnology developments and benefits.

9. ***Spillovers of proprietary agricultural biotechnologies for the benefit of smallholders have to date been minimal.*** Technology spillovers from research innovations in agricultural biotechnologies have so far had limited impact on the livelihoods of the majority of the rural poor in developing countries. Most poor rural producers have limited access to technological advances and other inputs in all areas of agricultural research, including lack of access to basic S&T innovations across many areas.

10. ***Public sector research has developed some agricultural biotechnologies that address food security and agriculture sustainability, but has not always been sufficiently focused on the needs of poor rural producers.*** The most enduring successes to date have come from long-term national and international (e.g. the Consultative Group on International Agricultural Research,

CGIAR) public sector agricultural improvement programmes addressing farmer-relevant problems. However, even where there was strong development of agricultural biotechnologies within the public sector in developing countries, these have not always been directed at, or made available for, improving the livelihoods of poor rural producers.

11. ***Some sectors of relevance to food security remain relatively neglected in terms of agricultural biotechnologies.*** The application of biotechnologies in developing countries seems relatively more widespread in crops, livestock and food processing than in forestry and fisheries/aquaculture. These important areas tend to be somewhat neglected, although it should be noted that applications of biotechnologies are of much greater significance in planted forests than in naturally regenerated tropical forests, and in aquaculture than in capture fisheries. This is also reflected in terms of private sector investment, where there are e.g. fewer companies involved in forestry and aquaculture biotechnologies than in crop biotechnologies. Also, within each sector, investments in biotechnology research and development focus more on products and techniques relevant to large-scale, commercial agriculture, while insufficient attention is paid to biotechnology products and techniques that can address the problems of poor rural producers.

10.2.2 Development of integrated and coordinated national plans on agricultural biotechnologies for food security

12. ***Need for a clear vision for the role of agricultural biotechnologies in relation to national development needs, including food security***. It is important for governments to clarify and decide what role they envisage for agricultural biotechnologies in helping to meet national needs (both short- and long-term).

13. ***Planning for agricultural biotechnologies is of cross-cutting relevance to national development plans and strategies.*** It is essential that policies and plans regarding agricultural biotechnologies are coherent with other national policies and plans, and also support agreed international policies and targets. Some goals and objectives of National Development Plans (including long-term visions and 10-year plans), Poverty Reduction Strategies and sector programmes (e.g. in Agriculture, Health, Education) can be supported by harnessing agricultural biotechnologies for national needs.

14. ***Promote biotechnologies as a common platform to leverage cross-sectoral innovations that meet national needs, including food security needs.*** To maximize the impacts of using existing biotechnology capacity across all sectors, planning for the development and utilization of biotechnologies should be integrated across all planning processes leading to national development plans as well as processes leading to sector-specific plans for agriculture, food/nutrition, health, education, economic development, poverty reduction and the environment.

15. ***Establish a National Biotechnology Policy/Strategy Framework.*** A National Biotechnology Strategy should provide a shared long-term vision and a coherent integrated framework describing clear principles, priorities, objectives and actions. Objectives should be specific, measurable, achievable, realistic and time-bound, with performance indicators against which progress can be measured. All sectors should be represented in the National Biotechnology Strategy, including the crop, livestock, fish, forestry and food sectors. In some instances, regional frameworks may be an appropriate option to harmonize biotechnology strategies and maximize the utilization of capacity, particularly in poorer or resource-limited regions.

16. ***National S&T policies/strategies which include biotechnology must also address the food and agriculture sector.*** There is a tendency for biotechnology to be narrowly equated with the biomedical (pharmaceutical) and industrial sectors. Where biotechnology is a component of an overall national S&T strategy, it is important that all sectors and subsectors (for which biotechnology innovations are a cross-cutting issue) are represented in terms of their needs.

17. ***Ensure that agricultural biotechnologies are not considered in isolation from broader agricultural advancement efforts.*** Agricultural biotechnologies need to be built upon existing agricultural research systems and capacities. Biotechnologies in any sector (including agriculture) are typically not "stand-alone" alternatives to existing research, and cannot substitute existing agricultural research programmes. To deliver positive food security impacts for poor rural producers and consumers, agricultural biotechnologies need to be integrated within well-functioning agricultural research and innovation systems.

10.2.3 Priority-setting to enable agricultural biotechnologies to better meet national needs regarding food security

18. ***Priority-setting and monitoring mechanisms are needed for the development, adoption and impact of agricultural biotechnologies.*** Priority-setting mechanisms are necessary to identify areas of focus where interventions involving agricultural biotechnologies could have maximum impact. Decision-making regarding research and innovation priorities should be based on needs (demand-driven), be transparent and evidence-based. Regular foresight and horizon-scanning systems regarding agricultural biotechnologies should be used to inform national strategies, plans and sector-specific plans, along with frequent consultations with intended beneficiaries.

19. ***Clear targets and performance indicators are required to measure uptake and the impact of agricultural biotechnologies on meeting food security needs.*** For strategic planning, impact-assessment targets and indicators for agricultural biotechnologies can be "mainstreamed" across multiple national and sector-specific plans. Indicators should not only include typical S&T metrics such as numbers of skilled personnel, publications, innovations developed, etc., but also include broader metrics to measure socio-economic

outcomes and the impacts of different agricultural biotechnologies on land productivity, incomes, food security and livelihoods.

20. ***Need for regular periodic assessments of costs and benefits of different agricultural biotechnologies over the longer term.*** Cost-benefit ratios for agricultural biotechnologies will change over time. There can be inherent risks for resource-limited developing countries to be either the early or late adopters of specific agricultural biotechnologies. Rigorous cost-benefit analysis should be conducted periodically on a systematic ongoing basis to assess possible impacts on food security and agriculture sustainability in order to inform decision-making. A key issue is to determine which institutions have capacity and expertise to do this while also effectively interfacing with decision-makers.

21. ***Reliable ex-post assessments of the impact of recent innovations in agricultural biotechnologies may not yet be possible.*** Assessing the value of innovations from newer agricultural biotechnologies is difficult due to a lack of accumulated data and evidence across many regions, seasons and countries. For many of the newer products of agricultural biotechnologies (e.g. transgenic varieties, new breeds and strains, biocontrol agents, field-level diagnostic kits, vaccines and bioprocessing enzymes or microbes) the information related to their on-farm application and socio-economic impacts in developing countries either is insufficient or is scattered and not generalizable.

22. ***Need to keep pace with evolving different agricultural biotechnologies and with the rate at which they become practical realities.*** To assess impacts of different agricultural biotechnologies it is necessary to make clear distinctions between mature "on-the-shelf" versus "pipeline" biotechnologies. This highlights a need for continual monitoring of which agricultural biotechnologies are coming to maturity over time. Such monitoring requires scientists and technical advisors with the expertise to assess both the merits and limitations of different agricultural biotechnologies over time.

23. ***Distinguish between invention and innovation in agricultural biotechnologies, and consult with end-users.*** It is important to make a distinction between "invention" (the creation of new knowledge) and "innovation" (in the sense of first, early or novel application) and recognize that there is a significant time lag and many critical steps before inventions can be realized as practical innovations. Priorities for innovation in agricultural biotechnologies should be both set and assessed by a range of stakeholders, including scientists and representatives of end-users of technology outputs (e.g. farmers, consumers).

24. ***The balance of home-grown versus imported innovation in agricultural biotechnologies is a strategic issue.*** All countries are inter-dependent with respect to technological innovations in food and agriculture. It can be important to emphasize home-grown technologies (where they are cost-effective) as they can be a catalyst for institutional/human capacity development, technology adoption and national regulatory systems development. However, depending

on national priorities and available resources, there are strategic pros and cons in decisions to become originators or early, intermediate or late adopters of new technologies including agricultural biotechnologies.

10.2.4 Promote public and private investments in agricultural research, including biotechnologies for food security

25. ***National-level investments in agricultural research, including biotechnologies, need to be increased in order to contribute to food security in developing countries.*** National investment plans for agricultural biotechnologies should focus on contributing to meeting well-defined needs and aim to leverage a range of national and international financing, including both public and private funding, and funding from donors, non-governmental organizations (NGOs), farmers and trade organizations, and philanthropic organizations.

26. ***A national policy vision defining the relative roles of the public and private sector is necessary for developing and deploying innovations in agricultural biotechnologies for different clients.*** Specific responsibilities must be mapped out to identify which sectors and stakeholders are to address the needs of poor rural producers in order to ensure that positive food security impacts are achieved from capacity development and the deployment of agricultural biotechnologies. The limited purchasing power of the poor makes it unlikely that private sector investments in agricultural biotechnologies will meet their immediate needs. Each country needs to promote an appropriate mix of public, private and public-private partnership (PPP) financing that best meets its needs, and effectively communicate the underlying rationale to all stakeholders.

27. ***Need to consider the role of intellectual property rights (IPR) in promoting innovation and restricting (unlicensed) access to proprietary agricultural biotechnologies.*** IPR recognize the creativity of inventors by providing a temporary exclusive property right over inventions. As legal instruments, IPR promote private sector investment while also requiring disclosure and dissemination of new innovations. IPR predominantly relate to the use of proprietary technologies in commercial markets. The effect of IPR systems in stimulating research investment, invention and innovation in each country and sector is a strategic issue, particularly in relation to what forms of innovation IPR promote and which stakeholders benefit from proprietary technologies. Lack of comprehensive and updated national IPR regulatory systems can limit the import of biotechnologies developed abroad.

28. ***Determine whether and how IPR are likely to limit the freedom to innovate or trade in relation to agricultural biotechnologies.*** Because many biotechnology innovations (and enabling technologies/tools) are subject to IPR, countries need to have the capacity to assess their freedom to operate (nationally and internationally) in terms of the IPR landscape for different biotechnology innovations. For IPR, this can apply to freedom to export

products containing proprietary innovations into other jurisdictions, although freedom to export agricultural biotechnology products can also be affected through a range of other regulatory approval issues.

29. ***Determine whether IPR are a critical barrier to technology adoption and the diffusion of agricultural biotechnologies for the poor.*** IPR are a barrier to technology access whenever licensing is desired but not facilitated. Where assessments of needs for poor rural producers identify IPR-protected innovations that would be likely to benefit such farmers, subsidized or humanitarian exemption routes to the licensing of such proprietary innovations should be investigated.

30. ***Improve aid effectiveness regarding agricultural biotechnologies through both national- and donor-level harmonization and coordination of donor-funded projects and programmes.*** Coordination and harmonization of donor-support to agricultural research (including biotechnologies) can enhance the use and impact of resources at the national level. The Paris Declaration on Aid Effectiveness (2005) and the Accra Agenda for Action (2008) provide frameworks for coordination of donor investments across all areas, including donor investments in agricultural biotechnologies.

10.2.5 Facilitate national and international linkages in agricultural biotechnologies that can strengthen food security

31. ***Successful governance of biotechnologies requires well coordinated policies and strategies that address all stages of the innovation chain.*** For agricultural biotechnologies to impact on meeting national development needs, approaches that consider the entire agricultural innovation system can have advantages over a fragmented project/programme-based approach (operating independently across different sectors and ministries). Such an approach considers national agricultural innovation systems, including the complete network of institutions across the public, private and informal sectors whose activities and interactions initiate, develop, import, modify and diffuse new technologies and innovations.

32. ***Successful governance of biotechnologies requires horizontal and vertical systems of coordination.*** Horizontal coordination is needed to ensure that different ministries can agree on the goals and objectives of a national system of innovation, including the role of agricultural biotechnologies, while vertical coordination is needed to ensure that the different sectors and subsectors (e.g. animal breeding, animal nutrition, forestry) are included in the process. Both horizontal and vertical coordination should occur across all levels from policy, institutional and field levels. Coordination mechanisms should include stakeholders from farmers' organizations, the business sector and NGOs representing poor rural producers.

33. ***Lack of policy coherence and consistency across ministries and sectors can be a barrier to harnessing agricultural biotechnologies.*** Lack of coherence in national and international

policies and regulatory systems creates uncertainty, and can lead to reduced investments (public or private) in agricultural research and biotechnologies. For policy coherence, intersectoral policies in the scientific, economic, environmental and trade areas need to be mutually supportive and well coordinated.

34. ***Foster links with other countries that can strengthen capacities for policy and regulatory analysis, planning, research and institutional development and technology flows in agricultural biotechnologies.*** Improved North-South and South-South collaborations (e.g. using regional biotechnology centres such as the Biosciences eastern and central Africa [BecA] hub) to facilitate capacity development and innovation are crucial. The nurturing of scientific, policy, administrative, NGO and business network building is essential for promoting strong national innovation systems that can effectively develop and adopt agricultural biotechnologies that contribute to food security.

35. ***Leverage the capacity and knowledge in the agricultural biotechnologies of other countries in order to meet national needs.*** When resources are scarce, it does not make sense to attempt to develop all innovations within one country. Strategies regarding agricultural biotechnologies that focus on adopting and adapting existing innovations to local needs require more effective international linkages, as do strategies based on the regional pooling of expertise and capacity.

10.2.6 Foster linkages between agricultural biotechnologies and other areas within national innovation systems

36. ***Promote stronger linkages between national research institutes and universities.*** Disconnects can occur between higher education and training conducted in universities, and research conducted in national research institutes. Staff and student secondments and exchanges, and joint research projects between universities and research institutes (nationally and internationally) will promote mutual-learning, build networks and enhance training, research and the impact of agricultural biotechnologies on food security.

37. ***Consider infrastructure development as a platform for technological learning and innovation.*** Infrastructure development projects can be used as platforms for research and technological learning. Government procurement (tenders) can be made conditional on research, development and innovation occurring within the infrastructural project. This approach can be used to foster capacity development for research and innovation in agricultural biotechnologies.

38. ***Share biotechnology platforms, resources and tools across agriculture, health and other sectors.*** The cost efficiency of using expensive biotechnologies can be improved by using the same/similar biotechnology techniques and equipment across multiple countries, sectors or subsectors (e.g. the BecA facility, Kenya). Greater integration of publicly-funded

biotechnology research platforms across biomedical, agriculture, food, environmental and industrial sectors is desirable.

39. ***Integrate human health concerns to accelerate capacity development in agricultural biotechnologies.*** Zoonotic threats to public health from domestic animal diseases have accelerated the strengthening of national animal disease diagnosis and control systems. The development of biotechnological capacity for animal health and food safety testing can be pursued through closer relationships with the medical and epidemiology communities.

10.2.7 Promote evidence-based and multi-stakeholder policy development in agricultural biotechnologies for food security

40. ***Involvement and constructive engagement of key stakeholder groups in development of policy and capacity in agricultural biotechnologies is important***. The engagement of multiple stakeholders in the identification of key needs and the development of policies can lead to mutual learning and understanding regarding where agricultural biotechnologies can play a role in strengthening food security and agricultural sustainability.

41. ***Evidence-based policy development is essential for decision-making regarding agricultural biotechnologies for food security.*** While it is important to engage a broad range of stakeholder groups in policy-development processes, this should not lead to an erosion of the role of scientific (and other, including socioeconomic) expertise and evidence in the policy-development process.

42. ***Policy and regulatory development regarding agricultural biotechnologies needs to balance both risks and benefits for the poor.*** More emphasis and activity have been focused on developing policies and regulations related to preventing risks arising from GMOs than to facilitating the use of agricultural biotechnologies for the benefit of poor rural producers. Strengthening the voice of stakeholders representing poor rural producers to make informed (and independent) decisions regarding which biotechnologies they consider could benefit their livelihoods remains a critical need for developing pro-poor agricultural biotechnologies.

43. ***Over-emphasis on and polarization within the "GMO debate" has distracted and diverted scientific and policy resources from focusing on the needs of poor rural producers.*** The controversy regarding GMOs in food and agriculture over the past decade has had significant effects in stalling, reducing and redirecting some public sector research efforts in agricultural biotechnologies, including non-GMO biotechnologies, from addressing the needs of the poor rural producers, in addition to diverting significant scientific resources from research to regulation. The portfolio of investment across different types of agricultural biotechnologies (including GMOs) has to be assessed with reference to the needs of the poor rural producers and the speed and cost of delivering benefits to them.

44. ***Integrate the biosecurity approach across agricultural biotechnology policies and regulations.*** The biosecurity approach is defined by FAO as a "strategic and integrated approach to analysing and managing relevant risks to human, animal and plant life and health and associated risks to the environment". Biosafety regulations for agricultural biotechnologies should be coherent and in harmony with other national regulations and relevant international agreements, regional frameworks and standards, especially those related to plant and animal health, and food safety. The biosecurity approach can allow efficiency gains for regulatory bodies.

45. ***Promote transparency and participation in all processes involving policy development and regulation regarding agricultural biotechnologies.*** To build overall trust in policy-making and regulatory processes regarding agricultural biotechnologies, it is important to ensure transparency and participation in the decision-making processes of relevant stakeholder groups and organizations that represent the public at large. Appropriate communication strategies are needed to ensure informed and meaningful participation.

10.2.8 Develop national capacity in agricultural biotechnologies for food security

46. ***Many developing countries have limited capacity to develop or use agricultural biotechnologies.*** This relates to limited capacity to generate, adapt or utilize potentially beneficial biotechnologies due to existing limitations in their agricultural research, extension and regulatory systems. Even a reliance on research results/innovations obtained from abroad will need significant "adaptive" research, as well as regulatory and dissemination capacities at national level.

47. ***Strategic strengthening of existing research, extension and regulatory systems will facilitate future innovations in agricultural biotechnologies.*** Agricultural biotechnologies are best applied within existing research, extension and regulatory systems where scientific knowledge is already generated, documented and organized. The strengthening of existing agricultural research, extension and regulatory systems is necessary if agricultural biotechnologies are to be used successfully to contribute to food security and agricultural sustainability.

48. ***Sustainable capacity development for agricultural biotechnologies will require both science-push (supply) and science-pull (demand) effects.*** Poor rural producers and consumers have not been capable of exercising a strong science-pull to harness agricultural biotechnologies for their needs. The strengthening of the capacity of farmer organizations to interface with technology providers (whether public or private sector) is a key need.

10.2.9 Strengthen downstream systems that facilitate positive impacts of agricultural biotechnologies on the poor

49. ***Strengthening existing channels/systems for technology access and adoption by poor rural producers is of paramount importance.*** Development of agricultural biotechnologies should be strongly linked with strategies for dissemination, evaluation and adoption by poor rural groups that can benefit. Where such functioning "downstream" evaluation, dissemination and extension systems are not in place, investments in such systems will likely have greater initial impacts than investments in advanced agricultural biotechnologies, and should have at least equal priority.

50. ***To interface with farmers, consider the reform of agricultural extension services towards more pluralistic and decentralized extension and technology advisory systems.*** In recent years, agricultural extension systems have undergone significant and rapid changes including in their financing and governance systems. Within the same country this can lead to better coordination of a diversity of advisory services within the public, private and NGO sectors, including farmer-led and farmer-participatory extension systems.

51. ***If existing diffusion channels for enhanced agricultural technology are not functioning, it is unlikely that agricultural biotechnologies can reach poor rural producers.*** Inefficient and gender-biased extension systems (public, private and informal sector) can represent a major hurdle for poor rural producers to gain access to enhanced germplasm, improved vaccines and other outputs from agricultural biotechnologies for agriculture and food production.

52. ***Farmer-participatory approaches can improve the likelihood that agricultural biotechnologies reach and benefit poor end-users.*** There are examples of the application of farmer participatory research approaches for better connecting agricultural biotechnologies with the needs of smallholders.

53. ***Determine the critical barriers to adoption and diffusion of agricultural biotechnologies to poor rural producers.*** There is a need to identify key agricultural biotechnology innovations that could improve the income and food security status of poor rural producers, and to explore ways to overcome the many significant barriers that poor rural producers, especially women, face in gaining access to beneficial agricultural biotechnologies.

10.2.10 Strengthen communication and engagement with priority stakeholders

54. ***Information delivery to politicians and other decision-makers about the strategic importance of S&T in general, and biotechnology in particular, is a key issue.*** The promotion of political awareness of the relevance and limitations of agricultural biotechnologies for meeting national needs, including food security, is essential. Science communication and

advisory mechanisms for politicians and other decision-makers are critical for ensuring that decision-makers are aware of technological opportunities, limitations and timescales and are better enabled to take informed decisions.

55. ***Communication is critically important for increasing public and political understanding and engagement regarding the role of different agricultural biotechnologies in relation to food security.*** Knowledge and information are essential for people to respond successfully to the opportunities and challenges of technological changes. However, to be useful, knowledge and information must be communicated effectively. A number of international policy instruments (e.g. Cartagena Protocol on Biosafety, Aarhus Convention) consider some issues about public awareness and participation regarding GMOs. It is critical that communication regarding all agricultural biotechnologies be accurate, balanced, participatory and science-based. Communication for Development (ComDev) methods and tools, which facilitate active participation and stakeholder dialogue, could be considered an essential component of any national innovation system.

10.3 DRAFT PRIORITIES FOR ACTION FOR THE INTERNATIONAL COMMUNITY

56. In the context of ABDC-10, the term "international community" encompasses FAO and other United Nations (UN) organizations and bodies, non-UN intergovernmental and non-governmental organizations, international and regional organizations, including donors, development agencies, the private sector, philanthropic foundations and academic or scientific institutions[3].

57. FAO Members can consider at ABDC-10 the following Priorities for Action by the international community regarding agricultural biotechnologies for food security. These Priorities for Action are intended to provide a framework for international cooperation and funding support for the generation, adaptation and adoption of agricultural biotechnologies in developing countries. At ABDC-10, Members can provide guidance on these Priorities for Action. A recent international policy "gap analysis" study[4] on agricultural biotechnologies prepared for the FAO Commission on Genetic Resources for Food and Agriculture highlighted the lack of an international policy instrument providing guidance on how agricultural biotechnologies can be better harnessed for poverty reduction and food security.

58. These Priorities for Action should support the broader objectives of key internationally agreed policies. Governments have already adopted a series of resolutions and declarations in support of science and technologies, including on some occasions explicit references to biotechnologies in food and agriculture[5]. The most recent occasion was the World Summit

3 This definition is derived from Agenda 21, Chapter 16 on Environmentally Sound Management of Biotechnology (http://earthwatch.unep.ch/agenda21/16.php).

4 Working Document CGRFA-11/07/13 (www.fao.org/nr/cgrfa/cgrfa-meetings/cgrfa-comm/eleventh-reg/en/)

5 See www.fao.org/biotech/abdc/about-abdc/rationale/

on Food Security, where 60 Heads of State and Government and 191 Ministers from 182 countries and the European Community met at FAO headquarters in November 2009. They unanimously adopted a Declaration which, *inter alia*, stated that "We recognize that increasing agricultural productivity is the main means to meet the increasing demand for food given the constraints on expanding land and water used for food production. We will seek to mobilize the resources needed to increase productivity, including the review, approval and adoption of biotechnology and other new technologies and innovations that are safe, effective and environmentally sustainable".

59. It should be noted at ABDC-10 that while decisions related to adoption of technologies, including agricultural biotechnologies, are the prerogative and ultimate responsibility of each country, some policy issues regarding biotechnologies are already being addressed within a range of intergovernmental policy fora and frameworks. These include the Aarhus Convention (UN Economic Commission for Europe); Codex Alimentarius Commission (FAO/WHO); Convention on Biological Diversity and its Cartagena Protocol on Biosafety; FAO Commission on Genetic Resources for Food and Agriculture; International Plant Protection Convention (IPPC); International Treaty on Plant Genetic Resources for Food and Agriculture; International Union for the Protection of New Varieties of Plants (UPOV); UN Commission on Science and Technology for Development; UN Commission on Sustainable Development; World Intellectual Property Organisation; World Organisation for Animal Health (OIE); and the World Trade Organization (WTO).

60. The Priorities for Action to be considered are organized below in three categories covering policy-level decision-making, capacity development and coordination options respectively.

10.3.1 Policy priorities

10.3.1.1 Developing and implementing international and national policies to facilitate pro-poor biotechnologies for sustainable development, including food security

61. ***Action***: FAO Members can recommend at ABDC-10 to establish an international policy instrument (e.g. Plan containing Priority Actions) to be implemented by the international community specifically focused on agricultural biotechnologies for food security, which promotes broader international development policy goals.

62. ***Action***: The international community can consider continuing to meet developing countries' requests for assistance in formulating strategic action plans for agricultural biotechnologies at the national and regional levels.

63. ***Action***: Relevant intergovernmental bodies may wish to reaffirm their efforts to promote international policy coherence regarding agricultural biotechnologies for sustainable development and food security.

10.3.1.2 Supporting public and private sector investment in agricultural biotechnologies for greater impact on food security

64. ***Action***: Donors and international funding agencies may wish to highlight the importance of public sector research in agricultural biotechnologies for food security and agriculture sustainability, and consequently consider dedicating an appropriate share of their assistance to promoting and strengthening public sector research capacity in agricultural biotechnologies in developing countries.

65. ***Action***: The international community can continue to recognize the crucial role of the CGIAR as a provider of international public goods in research for development, including agricultural biotechnologies for food security, and continue its support for the CGIAR's work in this regard.

66. ***Action***: The international community can consider promoting policies that facilitate increasing (or redirecting) public and private sector investment in agricultural biotechnologies towards the targets of reducing poverty, increasing food security and agricultural sustainability.

67. ***Action***: The international community may wish to recognize the possible contribution of private sector investment, including in research and development, to food security programmes and endeavour to provide policy advice on "good practice" models for public sector engagement in PPPs regarding agricultural biotechnologies.

68. ***Action***: The international community may consider providing policy advice on establishing mechanisms and tools that assist the public sector and small to medium-scale enterprises in meeting regulatory requirements for the deployment of agricultural biotechnologies for food security.

69. ***Action***: Relevant organizations can develop criteria and tools to better identify those areas where additional public sector support is needed for agricultural biotechnologies for the poor (e.g. areas relevant to non-commercial markets, food security, minor and orphan crops, poverty reduction).

70. ***Action***: Relevant international organizations can consider providing assistance (with appropriate monitoring) to strengthen agricultural biotechnologies for food security and environmental sustainability in sectors such as forestry and fisheries that tend to be somewhat neglected.

71. ***Action***: The international community can consider developing models to assist countries establish Orphan "crop, breed and farming systems" Acts (akin to Orphan Drug Acts) to promote greater investment in agricultural research on the crops, breeds and farming systems relevant for poor rural producers.

72. ***Action***: The international community can consider within climate change adaptation frameworks, funding mechanisms to support, *inter alia*, innovations in agricultural biotechnologies that can help both counteract and mitigate the adverse effects of climate change, in order to better protect poor rural producers and consumers from the negative effects of climate change on their food security.

73. ***Action***: The international community can promote complementarities between public and private sector financing of agricultural biotechnologies by more clearly defining the relative roles of the public and private sectors, particularly in terms of their relevance for delivering S&T innovations to the rural poor.

10.3.1.3 Development of science-based policies, regulations and standards which promote sustainable agriculture, and maximize the benefits of agricultural biotechnologies for food security

74. ***Action:*** FAO, in cooperation with other international agencies, can collect, systematize and disseminate documentation on the development and adoption of agricultural biotechnologies and analyse their socio-economic impacts in developing countries. This includes the compilation of statistics, the establishment and maintenance of biotechnology application databases, studies etc. This is necessary to generate an evidence base for policy-makers on the cost-benefit implications of the application of different biotechnologies.

75. ***Action***: FAO, in cooperation with other international agencies, can compile annotated collections of methodologies and tools for *ex-ante* analysis of the socio-economic impacts of development and adoption of agricultural biotechnologies in developing countries, in order to assist policy-makers in developing countries in decision-making about the adoption of biotechnologies.

76. ***Action:*** The international community may wish to reiterate the role of the relevant existing intergovernmental fora in addressing international policy issues regarding biosafety and biosecurity, including food safety and plant and animal health, and trade matters relating to agricultural biotechnologies, particularly GMOs.

77. ***Action:*** The international community may consider increasing efforts to facilitate participation by developing countries in the three relevant international standard-setting organizations for the WTO Agreement on the Application of Sanitary and Phytosanitary Measures, namely the FAO/WHO Codex Alimentarius Commission (food safety), World Organisation for Animal Health (animal health) and the International Plant Protection Convention (plant health), all of which are addressing issues of relevance to agricultural biotechnologies.

78. ***Action***: The international community may wish to continue supporting the concept that biosafety (regarding GMOs) be integrated within a broader biosecurity approach.

79. ***Action:*** The international community may emphasize the fundamental importance of transparency and public participation when establishing and implementing biosafety or biosecurity frameworks or policies.

80. ***Action:*** The international community can assist in promoting subregional/regional cooperation and harmonization for the establishment and implementation of biosafety or biosecurity frameworks.

10.3.1.4 Facilitating access for poor rural producers and consumers to agricultural biotechnologies for food security

81. ***Action***: Relevant intergovernmental fora can consider promoting policies to facilitate greater access for poor rural producers to products and processes of agricultural biotechnologies essential to food security.

82. ***Action:*** The international community can encourage the private sector, and its representative umbrella organizations, to endeavour to develop transparent mechanisms to facilitate low- and no-cost humanitarian access to proprietary biotechnologies, specifically for strengthening food security in developing countries.

83. ***Action***: Relevant intergovernmental bodies can consider whether there are creative ways to use international policy instruments to ensure that internationally agreed IPR policies better meet the needs of the poor.

84. ***Action***: The international community can encourage private and public sector research institutions (including PPPs) to consider modifying terms of access to their proprietary agricultural biotechnologies so that such technologies can be better harnessed to meet the needs of poor rural producers in developing countries.

85. ***Action***: Donors can consider supporting organizations and programmes that can provide strategic advice and capacity development to developing countries regarding IPR and agricultural technologies, including biotechnologies.

86. ***Action***: The international community can consider further promoting access for developing countries to essential tools and enabling biotechnologies relevant for food security[6].

87. ***Action***: The international community can continue to recognize the role of the CGIAR in facilitating the access of poor rural producers to agricultural biotechnologies, and continue its support for the CGIAR's work in this regard.

10.3.1.5 Science communication, information dissemination and public awareness regarding agricultural biotechnologies

88. ***Action***: FAO and other intergovernmental organizations can strengthen their activities related to gathering, analysing, systematizing and disseminating, among policy-makers and the public, unbiased science-based information on the generation, application and impact of agricultural biotechnologies for addressing food security and agricultural sustainability.

89. ***Action***: The international community can promote ComDev approaches for facilitating multi-stakeholder dialogue and public engagement in priority-setting and decision-making on the adoption of agricultural biotechnologies to increase food security and reduce poverty, and in support of international commitments and challenges.

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[6] e.g. through policy clauses regarding ordre public and morality in relation to protecting human, animal or plant life or health or to avoid serious prejudice to the environment (Article 27.2 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights).

10.3.2 Capacity development

10.3.2.1 Facilitating regional and national policy-setting to enable biotechnologies for sustainable agricultural development, including food security

90. ***Action***: Upon request, the international community can provide assistance to strengthen the capacities of developing countries for policy formulation and strategic planning in agricultural biotechnologies. Where appropriate, cross-sectoral strategies and frameworks can be developed, considering biotechnologies for agriculture, health, industry and the environment.

91. ***Action:*** The international community can provide support for international, regional and national efforts to enhance understanding of agricultural biotechnologies among policy-makers and the public, particularly in relation to their existing or potential contributions to food security and agricultural sustainability.

92. ***Action***: The international community can continue its efforts in meeting requests for assistance from developing countries to establish national regulatory frameworks and develop adequate institutional and human capacities in biosafety, food safety, plant health, IPR and traditional knowledge that are coherent with national development policies and in harmony with international obligations. The biosecurity framework can be adopted and adapted where appropriate.

93. ***Action***: The international community can continue to meet requests for assistance to enhance developing countries' capacities in facilitating regional collaboration and international harmonization of regulatory procedures relevant to agricultural biotechnologies.

10.3.2.2 Facilitate participatory multi-stakeholder approaches to policy development for biotechnologies for sustainable development, including food security

94. ***Action:*** Relevant international organizations, including the CGIAR, can strengthen the capacity of developing countries to engage stakeholder groups (that are representative and accountable to their members, particularly poor rural producers) in priority-setting and policy development in relation to agricultural biotechnologies.

95. ***Action***: The international community can provide assistance for national priority-setting and consensus-building efforts to identify key needs for food security, and facilitate assessments to identify where different agricultural biotechnologies can provide strategic options.

96. ***Action***: International organizations can support the development of "transparency and good governance" principles and guidelines at national and regional levels for agricultural biotechnology policy-making and decision-making processes.

10.3.2.3 Support for strengthening national expertise and increasing international cooperation programmes and action plans for agricultural biotechnologies

97. ***Action***: FAO and other specialized agencies can continue to provide support to developing countries to better assess their needs and priorities for agricultural biotechnologies, and to develop strategic action plans and programmes in agricultural biotechnologies for food security.

98. ***Action:*** FAO and other specialized agencies can meet requests from developing countries to assist their national agricultural research and extension systems to strengthen their policies, institutions and human capacities in relation to generation, adaptation and adoption of agricultural biotechnologies for food security.

99. ***Action***: The international community can provide support for regional groups of developing countries to build indigenous research, development, and advisory capacities for generating, assessing and adopting agricultural biotechnologies to address their food security needs.

100. ***Action***: The international community can consider supporting the development of international cooperation programmes in specific areas identified to be of long-term strategic importance to the least developed countries (which may currently lack even the basic infrastructure to initiate such programmes in the immediate future).

10.3.2.4 Training and education for pro-poor agricultural biotechnology development and implementation to strengthen food security

101. ***Action***: The international community should consider providing support for the upgrading of education and training in agricultural biotechnologies, including incorporating food security and sustainability challenges into training curricula.

102. ***Action:*** Donors can consider supporting initiatives to broaden the access of researchers, students and stakeholder groups (including farmers' groups and private sector) in developing countries to scientific and technological knowledge sources in the arena of agricultural research, including agricultural biotechnologies[7].

10.3.2.5 Facilitating the uptake of agricultural biotechnologies to strengthen food security

103. ***Action***: Donors and development agencies should consider facilitating assessments of the capacity-strengthening needs of extension and communication systems (in public, private and informal sectors) as a component of providing assistance for capacity development in agricultural biotechnologies.

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[7] For example, the FAO initiative on Access to Global Online Research in Agriculture (AGORA) (www.aginternetwork.org)

104. ***Action***: Donors and development agencies can ensure that technical assistance involving agricultural biotechnologies has clear communication strategies and links to extension systems that can effectively reach the intended beneficiaries.

105. ***Action***: Donors and development organizations should consider assisting developing countries in strengthening their capacity to facilitate smallholders' adoption of technical innovations, including innovations derived from agricultural biotechnologies, which can address food security and agricultural sustainability.

106. ***Action:*** The international community can endeavour to promote greater use of ComDev, farmer-participatory and farmer-led approaches for facilitating innovation regarding agricultural biotechnologies for food security.

10.3.2.6 Promoting linkages of agricultural biotechnologies to other areas, in support of food security

107. ***Action***: The international community can ensure that technical assistance in agricultural biotechnologies supports effective and intimate links to strong agricultural research and extension programmes.

108. ***Action***: Policies and programmes on agricultural biotechnologies should aim to ensure that investments in research in agricultural biotechnologies are not made at the expense of current expenditure in other agricultural research fields.

109. ***Action***: Donors and specialized UN agencies should consider facilitating more effective mechanisms for South-South collaboration regarding agricultural biotechnologies for food security. These may include the training of scientists and technicians; joint research projects (pooling complementary resources to work on project of common interest); the transfer of technologies, protocols and materials; and the sharing of information relevant to the development and adoption of biotechnologies.

110. ***Action***: Donors and specialized UN agencies should consider extending assistance for establishing mechanisms to disseminate agricultural biotechnologies developed in industrialized countries to developing countries (North-South collaborations, PPPs), including by continuing to support CGIAR efforts in this regard.

10.3.3 Coordination options

111. The role of agricultural biotechnologies relative to identified needs and priorities is a key issue that has to be considered when determining optimal financial allocations relating to agricultural biotechnologies for development. Donors and specialized UN agencies can address the fragmentation of assistance in the area of agricultural biotechnologies by taking a more coordinated and integrated approach. The Paris Declaration on Aid Effectiveness and the Accra Agenda for Action commit aid donors and partners (recipients) to increasing efforts in the harmonization, alignment and management of donor support.

112. Frameworks between UN agencies that can be harnessed to improve the coordination of support to agricultural biotechnologies at the national level include the UN's "Delivering as One" pilot initiatives launched in 2007 in eight pilot countries, and the UN Development Assistance Framework (UNDAF), the strategic programme framework for the UN country teams.

113. More specific to biotechnology, the 2003 UN General Assembly Resolution 58/200 took note of the Secretary General's proposal for an integrated framework for biotechnology within the UN system and the need to strengthen coordination between relevant organizations and bodies of the system in the area of biotechnology. The interagency cooperation network on biotechnology "UN-Biotech" resulted from this recommendation. UN-Biotech is coordinated by the UN Conference on Trade and Development and involves all UN agencies undertaking biotechnology-related activities.

114. ***Action:*** Donors may wish to consider improving aid effectiveness in the area of agricultural biotechnologies through coordination of assistance projects and programmes in agricultural biotechnologies at the national (and regional) level.

115. ***Action:*** The international community can promote greater use of the UN-Biotech coordination framework to enhance this interagency framework to ensure that agricultural biotechnologies can better contribute to food security.

116. ***Action***: The international community can enhance their coordination efforts at the country level for integrated agricultural biotechnologies capacity development to support sustainable development.

117. ***Action***: The international community can explore the wider use of the "Delivering as One" pilot initiative as a basis for working with governments to develop integrated planning systems for agricultural biotechnologies for sustainable development.

118. ***Action***: The international community can explore and promote measures to use and coordinate biotechnologies for national development through UNDAF to achieve national food security objectives.