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:

[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 Cientifíca 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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