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Agricultural biotechnologies in developing countries: Options and opportunities in crops, forestry, livestock, fisheries and agro-industry to face the challenges of food insecurity and climate change (ABDC-10)

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Policy Options for Agricultural Biotechnologies in Developing Countries

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Acronyms and Abbreviations

AKST = Agricultural knowledge, science and technology
BCH = Biosafety Clearing House
BFA = Biotechnology in food and agriculture
Bt = *Bacillus thuringiensis*
CBD = Convention on Biological Diversity
CGIAR = Consultative Group on International Agricultural Research
CIMMYT = The International Maize and Wheat Improvement Center
CPB = Cartagena Protocol on Biosafety
DBT = Department of Biotechnology (India)
EC = European Commission
EMBRAPA = Brazilian Agricultural Research Corporation
ESTs = Expressed sequence tags
FAO = Food and Agriculture Organization of the United Nations
FTO = Freedom to operate
GM = Genetically modified
GMO = Genetically modified organism
GRFA = Genetic resources for food and agriculture
GURTs = Genetic use restriction technologies
HCM = Horizontal coordinating mechanism
IAEA = International Atomic Energy Agency
ICAR = Indian Council for Agricultural Research
ICGEB = International Centre for Genetic Engineering and Biotechnology
ICRISAT = International Crops Research Institute for the Semi-Arid Tropics
IFPRI = International Food Policy Research Institute
ILRI = International Livestock Research Institute
IP = Intellectual property
IPPC = International Plant Protection Convention
IPR = Intellectual property rights
ISAAA = International Service for the Acquisition of Agri-biotech Applications
ITPGRFA = International Treaty on Plant Genetic Resources for Food and Agriculture
KARI = Kenyan Agricultural Research Institute
LMO = Living modified organism
MDGs = Millennium Development Goals
MNC = Multinational Corporation
MTA = Material transfer agreement
NARES = National agricultural research and extension systems
NARS = National agricultural research systems
NBF = National biosafety frameworks
NBS = National biotechnology policy/strategy
NEPAD = New Partnership for Africa's Development
NGO = Non-governmental organization
OECD = Organisation for Economic Co-operation and Development
OIE = World Organisation for Animal Health
PBR = Plant breeders' rights
PPP = Public-private partnership
PVP = Plant variety protection
R&D = Research and development
REDBIO = FAO's Technical Cooperation Network on Plant Biotechnology in Latin America and the Caribbean
SAGPyA = Secretario de Agricultura, Ganadería, Pesca y Alimentos (Argentina)
S&T = Science and technology
SARD = Sustainable agricultural and rural development

SME = Small and medium sized enterprises
SNPs = Single nuclear polymorphisms
SPS Agreement =WTO Agreement on the Application of Sanitary and Phytosanitary Measures
TBT Agreement = WTO Agreement on Technical Barriers to Trade
TRIPS Agreement = WTO Agreement on Trade-Related Aspects of Intellectual Property Rights
TTO = Technology Transfer Office
UNCED = UN Conference on Environment and Development
UNCTAD = UN Conference on Trade and Development
UNEP-GEF = United Nations Environment Programme-Global Environment Facility
UPOV = International Union for the Protection of New Varieties of Plants
USDA = United States Department of Agriculture
VCM = Vertical coordination mechanism
WTO = World Trade Organization

Introduction

This Conference takes place against the backdrop of global food, energy and financial crises, and a number of worrying statistics and trends concerning hunger, food insecurity, the state of the world's climate, and its resources of land, water and biodiversity upon which everyone ultimately depends for their livelihood and very existence.

It benefits from the comprehensive and thought-provoking insights provided by the World Development Report 2008: Agriculture for Development (World Bank, 2007), the International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD, 2009), and the State of Food Insecurity in the World 2008 (FAO, 2008a) into the challenges faced and the opportunities available through agriculture at regional and global levels for meeting hunger and wider sustainable development objectives, such as reducing poverty, food insecurity and environmental degradation.

These and other reports serve to highlight the fragility and vulnerability of the world's food system. They also raise serious concerns about the adequacy of the "business as usual" response that has characterized the individual and collective actions of so many countries since the World Food and Millennium Summits for avoiding the prospect of many millions more falling into poverty and chronic hunger and for getting back on track for meeting the Millennium Development Goals (MDGs) and other internationally agreed development goals.

The vast majority of the world's hungry people live and work in rural areas as do three-quarters of the 1.4 billion living on less than US$ 1.25 per day (Chen and Revallion, 2008), and most depend on agriculture for their livelihood both directly and indirectly through rural off-farm activities. Addressing food insecurity therefore requires policies, strategies and programmes that (a) stimulate widespread and long-term increases in the production of staple foods and other products through enhanced productivity, (b) doing so in ways that protect the environment, conserve and use agricultural and wider biodiversity sustainably, (c) ensure food safety and quality to protect the health of consumers, and (d) promote fair trade.

At the same time, incentives must be provided for encouraging broad-based rural development and private sector investment through e.g. diversification into higher-value horticultural, livestock and aquaculture products and providing greater access to services such as credit, insurance, market information and technical support. And while not neglecting the importance of larger scale and/or higher input commercial agriculture that is practised in more favourable environments, in order to cut poverty significantly the focus of national and international initiatives must be on empowering the roughly 1.3 billion smallholders and landless workers to broaden their opportunities for engaging in local, national and international markets, reducing food prices and generating demand for locally produced goods and services.

Technologies and knowledge that increase productivity, facilitate diversification and marketing of products, and improve natural resource management can be powerful forces for reducing hunger, food insecurity, poverty and environmental degradation. Other background papers for this Conference document the main scientific and technological advances offered by biotechnologies in crops, livestock, fisheries/aquaculture and forestry for producing food, feed or fibre in developing countries and for processing, marketing and trading in products.

This paper deals with policy[1] options for strengthening national capacities to make informed choices about using biotechnology in food and agriculture (BFA). It recognizes that views vary widely among countries, institutions and individuals about the contributions - particularly of advanced biotechnologies like genetic modification - to improving agricultural productivity and food security in developing countries, and whether, for example, strengthened intellectual property regimes are necessary to achieve these goals. Beneficial or regrettable, both are facts of life, but this paper neither advocates the use nor the avoidance of any particular biotechnology or approach towards its development and application, although it does highlight some key and unique considerations that should be taken into account when pursuing some modern applications.

Rather, by analysing documentation available from 15 developing countries (Table 1), and many peer-reviewed papers and global assessments, the objectives of this document are to describe the policy/strategy roadmaps that have been prepared by a spectrum of countries from different regions for exploiting BFA, and some additional options for consideration by these and other countries.

The document is organized in three broad sections. The first, Section A, attempts to provide a framework for targeting biotechnologies to the poor, emphasizing the essentiality of placing biotechnology in the context of wider policies for national agricultural and rural development while stressing also the international dimensions of these policies and the importance of priority setting. The second, Section B, deals with enabling policies for BFA, covering issues ranging from scientific and technical capacity-building for research, development and diffusion and approaches to, and mechanisms for funding, through to environmental and food/feed safety regulation. The third, Section C, deals with ensuring access to the benefits of biotechnology, and covers aspects like intellectual property rights (IPR), public awareness and participation and the roles of extension services.

[1] For the purposes of this paper a policy refers to a documented plan of action announced by a Head of State and/or agreed by a Government, Ministry, legislature, regulatory authority and national and international standard setting or other legally recognized body e.g. research institution, university, funding agency. Policy instruments can include laws, regulations, rules, standards, and politically and legally authorised funding instruments and programmes. A strategy refers to an integrated package of policies for the sector, a sub-sector, technology or issue. Policies may, or may not, be legally binding.

Table 1. National biotechnology policy and strategy frameworks of 15 selected developing countries.

Country	Year	Lead ministry	Prepared by	Approved by
Argentina	2004	Econ. & Prodn.	Secretariat of Agric., Livestock, Fisheries & Food	Ministry of Production
Brazil	2007	Sci. & Tech.	Interministerial Committee	Congress
Chile	2004	Econ.	Nat. Committee on Dev. Of Biotech.	Government
China	1988	Sci. & Tech./ State Dev. & Plan. Committee	Ministry Sci. & Tech.	State Council
India	2007	Sci. & Tech.	Department of Biotech.	Government
Jamaica	2006	Nat. Commission on Sci. & Tech.	National Biotech. Coord. Committee	Government
Kenya	2006	Sci. & Tech.	Nat. Council Sci. & Tech.	Government
Malawi	2009	Educn., Sci. & Tech.	Nat. Res. Council	Government
Malaysia	2005	Sci. & Tech. & Innovn.	Ministry Sci., Tech., & Innovn.	Government
Namibia	1999	Higher Educn., Vocat. Trng., Sci. & Tech.	Namibian Biotech. Alliance	Ministry
Peru	2006	Educn.	Nat. Council Sci., Tech., & Innovn.	Congress
South Africa	2001	Arts, Culture, Sci. & Tech.	Universities, Private Sector and Research Council	Government
Thailand	2005	Sci. & Tech. Dev. Agency	Nat. Econ. & Social Dev. Board	Government
Uganda	2008	Finance, Planning & Econ. Develop.	Nat. Council Sci. & Tech.	Government
Zambia	2003	Sci., Tech., & Vocat. Trng.	Ministry Sci., Tech. & Vocat. Training	Government

A. Targeting Agricultural Biotechnologies to the Poor

1. Agricultural and national development policy contexts

Agricultural policies that address a single issue (e.g. BFA) in a piecemeal manner without considering the totality of its dimensions will not contribute positively to meeting the challenges faced by the sector, its sub-sectors or the people whose livelihoods depend directly and indirectly upon it. This is because each policy initiative (e.g. using semen or embryos to upgrade livestock as part of a dairy development programme) can have enormous knock-on effects, positive and negative, on others e.g. the people involved in small-scale integrated crop-livestock production systems and the suppliers of feeds and veterinary services.

Likewise, policies aimed at fostering biotechnology for improving the livelihoods of small-scale/subsistence farmers will neither help them nor promote their interests without prior consideration of the constraints to the productivity of the plant and animal species used within the specific farming systems in which they are currently engaged. Holistic or "joined up" analyses of proposed interventions are therefore not just sensible, they are essential - in the first place for identifying the possible direct and indirect, immediate and longer-term ramifications of the intervention itself, and then for designing and implementing policies and practices that will give a "pro-poor" direction to intended improvements in national agricultural and rural development and food supplies.

The institutional arrangements for developing new agricultural technologies into tangible products and the social contexts that influence the incentives for farmers and markets to adopt them must also be taken into account. This cannot simply be based on a "science push". Scientists, industry, farming, consumer and other groups can legitimately "inform" but it is the role of governments and their delegated ministries and agents to "decide". In addition, essential to the process of deciding about BFA is that it fosters collective and transparent national ownership and an outcome consistent with meeting the country's priorities for economic and social development in general. Ensuring coherence with the country's overarching policies for agriculture and food security, as well as for science and technology (S&T) are also clearly essential for achieving this outcome.

Before dealing with policies for BFA a brief overview is given of some of the complexities of agricultural and associated rural development policy-making and of the basic principles for formulating sound policies and follow-up actions. Since these principles apply across the sectors and irrespective of the particular issue within it, they are not discussed further in relation to policies for using biotechnology. However, implementing them within national contexts is essential for developing sound policies for such applications, whether these be in connection with developing and applying the S&T, deciding on a regulatory framework for safety, dealing with IPR, or involving the public in decision-making.

(i) National and international dimensions of agricultural policy-making and policies

The national settings within which public policy operate are wide, highly variable, complex and unpredictable, and since governments have obligations and are answerable to society, balances have to be struck and priorities set among a wide range of competing economic and social interests. For example, policies for agriculture have to deal not only with a multitude of different issues concerning the use of plants, animals, land and water within different production systems, they also have to include consideration of issues like food insecurity, poverty and wider rural development, environmental services, processing and marketing, human health, trade, S&T, intellectual and other property rights – and of course financial investments.

These cross-cutting issues cannot be tackled effectively by an individual ministry and clearly different interests will drive negotiations on desired outcomes and priorities. Also, agriculture has

to compete for treasury appropriations against other commercial and social sectors such as manufacturing, infrastructure, education and health, a task made increasingly demanding in the face of rapid urbanization and in nations where it is no longer the backbone of economies e.g. in countries characterized as "transforming" and "urbanized" (World Bank, 2007). In addition, within agriculture itself, small-scale subsistence-oriented farms, farmers and their organizations have to compete with larger, more commercial and possibly export-oriented systems and their better-organized representatives at the tables of decision-making on levels, locations and orientation of government policy and direct and indirect financial support. None of this favours targeting biotechnologies towards the poor - only strong and persistent political commitment can achieve this.

National agricultural policies and the legal and regulatory frameworks that support them are also increasingly influenced by legally-binding instruments negotiated globally, regionally and bi-nationally. While countries may choose not to take part in one or more of these international agreements, they increasingly set the scene e.g. for global trade and their influence cannot be ignored. Of particular relevance to biotechnology are the global rules that:

- govern trade i.e. the Agreements of the World Trade Organization (WTO) and in particular those on Sanitary and Phytosanitary Measures (SPS) and related Codex Alimentarius and International Plant Protection Convention (IPPC) standards (see Section B), Technical Barriers to Trade (TBT) and on Trade-Related aspects of Intellectual Property Rights (TRIPS);
- aim to conserve and sustainably use biodiversity and share the benefits from using it i.e. the UN Convention on Biological Diversity (CBD) and its Cartagena Protocol on Biosafety (CPB); and
- make special provisions for the plant genetic resources used in food and agriculture i.e. the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).

Added to this are globally and regionally agreed commitments to tackle hunger, poverty, environmental degradation and trade disparities urgently and in a concerted manner through a combination of national and international private and public goods (e.g. the MDGs, the Plan of Implementation from the World Summit on Sustainable Development, the New Partnership for Africa's Development (NEPAD) and the Doha Development Round of trade negotiations).

This document does not detail the history and current status of negotiations leading to these international agreements and their constituent provisions, nor does it attempt to describe the positions taken by individual or groups of nations in such processes. Interested readers are directed elsewhere for this information (e.g. Stannard *et al.*, 2004; Bragdon, 2004; Tansey and Rajotte, 2008). What is important to note, however, is the dynamic interaction that takes place between policies negotiated within different global forums (e.g. between trade and biodiversity).

Introducing, amending and implementing national laws, regulations, structures and practices to tailor the requirements negotiated through these forums in ways that are most appropriate for national development are challenges that policy-makers in even the most technologically advanced countries struggle to meet successfully. For low income and food deficit countries, crafting policies for protecting/ balancing the interests of small-scale producers and the systems they manage against competition from within and outside their national borders is much more onerous. And yet, the decisions made and paths chosen by all countries for meeting the obligations embedded in these agreements will profoundly influence both the speed and direction of both R&D and diffusion of biotechnology products, as well as the distribution of any benefits (and risks) arising from them. This holds for all biotechnologies, but especially so for GMOs[2]

[2]The CPB uses the term Living Modified Organism (LMO), defined as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology", where modern biotechnology is defined as "the application of in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family". Technically,

which are singled out for "special treatment" within the framework of some international legally-binding agreements.

(ii) Towards comprehensive agricultural development policies and strategies

From the foregoing, it is clear that now and in the future, agriculture needs to contribute to a much more complex set of outcomes than simply producing more food and other primary products. There can therefore be no single strategy for putting all the pieces together for achieving sustainable food security and wider development objectives through national agricultural and food policies and there will be many potential entry points. For a start, policy-makers rarely begin with a clean sheet - they have a baseline of knowledge and experience which evolves over time, and it is a well-known maxim that "each policy has its own politics" (Inter-American Development Bank, 2006). Also, given the tremendous diversity of the agricultural and wider productive and socio-economic sectors across countries and within and even between sectors, and in the cultures of the institutions and individuals that make and implement policies or regulatory standards, it should not be surprising that the process of reaching agreement nationally and more particularly internationally on a particular issue is inevitably protracted with many twists and turns.

While there are many options open to countries for developing agricultural policy (see e.g. Dargie, 2007), certain principles should be followed for formulating a national policy or strategy framework if it is to attract widespread legitimacy and "buy-in". In particular, the mechanisms that are set up should have the following overlapping features:

- the processes should be both forward and outward looking e.g. based on informed predictions of climate, technological, demographic and other changes and look at how other countries are dealing with the sector;
- the information available about each sub-sector should be evidence-based i.e. come from a wide range of sources that are transparent, take account of past lessons and consider a range of costed and appraised options;
- they should be inclusive i.e. involve stakeholders directly and meet the needs and/or take account of the impact of the policy on all groups directly or indirectly affected by it i.e. it should involve key stakeholders directly;
- processes should take a holistic or "joined up" view, looking beyond sub-sector and institutional boundaries to ensure that the "sum" of agriculture's contributions to the nation's strategic sustainable development objectives are greater than the "parts" contributed by its different sub-sectors;
- they should be "balanced" i.e. consider both the scientific and social and economic issues as well as the cultural and ethical dimensions. For example, just because something can be done doesn't necessarily mean that it should be done; consideration should also be given to how the policy will be communicated to the public, reviewed and evaluated; and
- the anticipated outcomes should improve or at least should not disproportionately harm the sustainability of agriculture or the livelihoods of the most vulnerable groups contributing directly to, or affected by, the sector.

Developing these frameworks requires consideration and prioritization of many different policy options - inevitably a very difficult call with many caveats and trade-offs since the contribution of agriculture to pro-poor growth will vary with the stage of development of the country and also between locations within countries, the key determinant being the existing conditions (Dorward *et al.*, 2004; Byerlee, Diao and Jackson, 2005; Hazell, 2008; World Bank, 2007).

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there are differences between a GMO and an LMO but for the purposes of this paper the more commonly used term "GMO" is used, although reference may be made to an LMO. It is also questionable technically, whether some products referred to as GMOs are in fact GMOs since processing has removed all traces of the organism from which the product was obtained. Clear definitions are, however, essential when making laws and regulations transparent and predictable, and differences in these can lead also to misunderstandings between nations; this aspect is not expanded upon further in this paper.

Nevertheless, possibly the most fundamental policy issue faced by governments is deciding on the types and levels of public support that should be directed towards small and large farms for reducing hunger and poverty e.g. through introducing technological change via biotechnologies. The dilemma arises because the benefits of a technology can be both direct and indirect. In the former, they arise through e.g. improving growth rates in yields for home consumption and generating incomes for poor farmers thereby increasing food security largely at the household level. Indirect benefits, on the other hand, have a "wider reach", arising from the effects of adoption by both poor and non-poor farmers; they include improving food availability through lower food prices and creating employment opportunities both on- and off-farm, thereby improving the welfare of a broader spectrum of the poor e.g. landless farm workers and rural and urban non-agricultural workers. So, although technological change in agriculture can help to reduce hunger and poverty, the distribution of these gains between direct and indirect effects is highly dependent on e.g. the structure of the economy, the location of hunger and poverty and on the focus of the envisaged technological change. If the technologies used to produce these two effects are not the same, there may be trade-offs in allocating public funds such that using (bio)technology to improve smallholder welfare leading to a lesser aggregate gain in total productivity and a lower reduction in poverty and access to food (de Janvry *et al*., 1999; Hazell *et al.*, 2007*)*. Relying on the direct route to hunger/poverty reduction therefore requires knowledge of national land distribution patterns, the specifics of production systems (crops, biotic and abiotic constraints), access to markets and institutional support etc. of poor small-scale producers. In highly diversified systems, the biotechnology option could be costly if restricted e.g. to changing any one crop since the overall effects on household income may be small (de Janvry *et al.*, 1999). On the other hand, over time and certainly in climate- or input-challenged areas, positive effects may be more significant.

Other considerations include the reality that in some localities (e.g. where soils are fertile, water readily available and where input and output markets and other infrastructure are relatively well developed), smallholder development can drive growth and equitable development through the rural non-farm sector and more widely through rural-urban linkages. Conversely, in areas where significant and widespread increases in productivity cannot be achieved (e.g. with poor resources and high population pressure), agriculture will not be able to drive the growth needed for significant hunger and poverty reduction. In these situations, it still has an essential role in protecting livelihoods and the natural resource base and therefore the policy dilemma is whether to invest in technology and other services or provide safety nets and help people out of farming. *Thus, while few would question the need to substantially re-direct public investments to rural areas, policies concerning technologies and other means of support for smallholders need to be tailored to context, in particular to location and resource endowments.*

Much of this comes down to setting wider fiscal and monetary policies since these have as much to do with how well the sector achieves its objectives as do more traditional agricultural and food policies *per se*. Recent reports (World Bank, 2007; UNCTAD, 2008) provide much useful analyses of the roles of macroeconomic, price and trade policies and of public spending and development assistance bias towards urban needs, and describe how the effects of these on agricultural production and socio-economic development have been far from benign. This again reinforces the need to go beyond policies for improving crops, livestock, fisheries and forestry when developing agricultural and food policies and to ensure that inter-sectoral, economic, environmental and trade policies are mutually supportive. Success in doing so *depends very much on the quality of the coordination mechanisms used to shape, implement and sustain policies.* While participation will depend on country-specific ministerial and other structures, these should provide a basis for effective interministerial relations, foster partnerships with all stakeholders, and build open and transparent processes to increase public understanding and confidence. Options used by countries for establishing such mechanisms to deal with BFA are described below.

2. National biotechnology policy/strategy frameworks

(i) Biotechnology issues from a policy perspective

Government and agricultural policy-makers have to make hard choices amongst the many legitimate demands made on public finances, and in considering their options they will inevitably be confronted with questions like: why biotechnology?, which biotechnology?, is it safe?, what will it cost?, who will benefit from it?, can the products be traded freely?

In addressing these and other questions, the following issues appear most pertinent for consideration:

- Contrary to the impression given by the popular and scientific press, biotechnology is much more than GMOs. Other FAO background papers prepared for this ABDC-10 Conference document the fact that biotechnology represents a broad collection of tools that are being used for a variety of different purposes in food and agriculture in developing countries. Notable examples include genetic improvement of plant varieties and animal populations to increase their yields or efficiency; genetic characterization and conservation of genetic resources; plant or animal disease diagnosis; vaccine development; and improvement of feeds. There are thus many potentially useful tools included in BFA both "traditional" and "modern".- to be considered by policy-makers for contributing to the "technological mix" needed to advance sustainable agriculture and rural development (SARD), and which will continue to offer wide choice in the types of agriculture being pursued. GMOs also have potential; however, their development and use, as well as the use of products derived from them, requires attention to scientific, legal, regulatory, financial and other considerations that are not generally encountered with other biotechnologies (see below and Sections B and C);
- At its "top end", biotechnology is best described as a "platform" or generic technology, embracing applications of genomics and bioinformatics, microarray technologies, high throughput DNA sequencing, genotyping, polymerase chain reaction, transgenesis, robotics, mass spectrometry etc., across sectors and biological boundaries, i.e. it is both sector- and scientifically cross-cutting and requires the determined pursuit of multi-disciplinarity. *Policies and strategies for research involving a wider application of modern biotechnology should therefore be developed in ways that maximize the opportunities arising from its cross-fertilization features. This requires strong inter-ministerial coordination and collaboration;*
- *Biotechnology approaches to agricultural research are not alternatives but complements to conventional technologies*, but whereas developments in the former are generally driven from within applied science research settings, modern biotechnology evolves from discoveries, knowledge and innovations coming from the basic sciences. *There is therefore an institutional "disconnect" between these two research environments* e.g. between institutions involved in mapping, isolating, discovering the function of genes and producing gene constructs, and those using genetic markers, gene constructs, strands of DNA to characterize or provide improved germplasm, vaccines, diagnostic tests etc;
- Even at the more downstream end of modern biotechnology (e.g. using validated molecular markers, diagnostic reagents, tissue culture and micropropagation), *biotechnology R&D comes at additional cost*. Working further upstream (e.g. in structural and functional genomics, basic immunology and cell biology), bioinformatics and genetic transformation increases both start-up and maintenance costs considerably. This is particularly so in the veterinary field or when dealing with diseases transferred from livestock to man (zoonotic diseases) where laboratories and animal facilities with high levels of physical containment may or will be required;
- *Biotechnology R&D needs physical facilities, expensive and sophisticated equipment and a critical mass of scientists with new skills to complement existing expertise* in the traditional agricultural specialities e.g. plant and animal breeding, disease management etc. Shortcomings in either these new or conventional knowledge arenas (arising from

quantitative or qualitative deficiencies in school and tertiary education, opportunities for continuous learning and funding of more traditional research including monitoring the status and trends in agricultural and wider biodiversity and the environment) will seriously limit the potential of BFA;

- *Realizing the full potential of biotechnology takes more than laboratory-based research.* Innovations from upstream research need to be developed and scaled up through further innovations into tangible products (e.g. seeds, plantlets, diagnostic kits, vaccines, batches of enzymes, foods) that are useful, affordable and acceptable to farmers, to diagnostic and other support and input providers and to consumers; and of course to be useful, they have to be delivered to them. Assuming regulatory requirements are satisfied (see Sections B and C), these critically important aspects – development/scaling up and delivery - are invariably the major "missing links" or stumbling blocks to deploying most biotechnologies in developing countries *i.e. the capacity to "commercialize" biotechnology through the creation or support of demand-driven private sector firms or public-private enterprises is key for success;*
- Underpinning the success of such firms and arrangements is *the availability of entrepreneurial and business management skills and financial capital;* and
- The international legal and regulatory framework surrounding biotechnology R&D and the diffusion of some of its products is complex and constantly evolving; it also adds significantly to the cost of innovations and to uncertainty about returns on investments. While certainly not restricted to GMOs, the following should be noted:
  - Research involving, and products derived from recombinant DNA (rDNA) techniques, need to satisfy additional scientific and other requirements for ensuring the safe use of laboratory techniques and field testing of new products before they are released for general use i.e. biosafety[3] (Section B; see also National Research Council, 2002 and 2008). Products may also require environmental monitoring after commercial release and restrictions may be placed on how and where they are cultivated or used (National Research Council, 2002; Jepson, 2007). Products entering food and feed chains also have to meet safety regulations. Meeting regulatory requirements requires additional legal and scientific skills and laboratory, administrative and management infrastructures. Ideally, these should be independent from those available within public and private research and product development institutions.
  - GMOs and products derived from them and other evolving technologies (e.g. animal cloning) can potentially come up against trade restrictions due to national differences in approaches to, interpretation of, or enforcement of laws and regulations (e.g. labelling and IP), as well as asynchronous approvals (Section B). These differences may increase if, as expected, new products with additional features come to market, but they may also decrease if adoption of the technology and products become more widespread.
  - *Related to the above, there are many social and economic issues surrounding the use of modern BFA. These require more complex ways of organizing the interplay between science, decision-making and society to address public concerns about risks and benefits.* In any event, a number of international instruments, such as the CPB, specifically address the issue of public awareness and participation regarding GMOs (Section C2).

[3] The CPB does not define biosafety. Judging by the scope of their primary laws and regulations on biotechnology, countries surveyed for this paper employed the term variously in relation to protecting agricultural or agricultural and wild biodiversity, or the "environment" as a whole (i.e. both the biotic and abiotic components of landscapes or ecosystems); they may or may not include human health in all its dimensions or one particular aspect e.g. food safety. For the purposes of this paper, the term biosafety refers to assessing and managing the potential risks to the environment and human health, including food and feed safety arising from R&D, use (contained and not contained), and marketing for food and feed uses of GM products and the processed materials derived from them.

- *Many of the tools and much of the biological information used for some of the biotechnologies considered at ABDC-10 have intellectual and tangible property (IP/IT) protection (Section C1).* Also, access to some genetic resources (particularly animals, microorganisms and from plant and tree species not covered by the ITPGRFA) will inevitably be subject to bilateral access and benefit-sharing (ABS) arrangements. In addition to private sector companies, public sector universities and research institutes as well as the international research centres of the Consultative Group on International Agricultural Research (CGIAR) increasingly seek IP/IT protection for the fruits of their research. All of these increase substantially the complexity of R&D management, can restrict "freedom to operate" and could be barriers to technology transfer and diffusion; as shown later (Section C1) promotion of public-private partnerships may be useful for reducing such barriers.

Introducing any technique and product into the research mix is one thing – introducing it into the marketplace is quite another. Both require careful consideration – and priority setting, but in view of the costs and the legal, scientific, managerial and other complexities involved, using some modern biotechnologies to develop products that will be released into the wider environment for producing foods and feeds for marketing nationally – and particularly internationally - does raise the bar very substantially in terms of identifying "opportunity" and justifying "need".

Countries have many options for tackling these challenges through public policy. The instruments they choose will be determined by the prevailing macro-economic environment, the structure of the sector, the legal and regulatory environment within which it operates, and the strength of the innovation systems (scientific, technological, marketing) including the regional and global links that support it. But choices will also be determined by vision, i.e. belief based on realistic analysis that if biotechnology is appropriately integrated with other science-based and traditional knowledge, then it will make R&D more efficient and farming more productive and competitive while not by-passing the most vulnerable in society.

While there is general agreement within scientific establishments and international bodies regarding the scientific principles of most biotechnologies, positions between and within countries differ on a variety of issues connected primarily with applying genetic modification and using GMOs for agriculturally important species. These include their potential compared with both other technologies and economic and social policy instruments for contributing to reduced hunger and poverty, their potential risks and the adequacy of the regulatory frameworks to deal with them, the role of multinational companies and public institutions, the role of communities in decision-making, and their ethical dimensions.

Increasingly, developing countries and regional groups are beginning to "come to grips" with these and other related issues by pursuing dialogue with key stakeholders and ordinary citizens and developing longer-term policy and strategy frameworks and specific laws and regulations for using biotechnology within their agrifood sectors. Some principles and examples of how some countries have gone about doing this are now described.

(ii) Purpose and content of biotechnology frameworks

The foundation for appropriate governance of agricultural biotechnologies is a comprehensive national biotechnology policy/strategy (NBS) framework. Research for this paper showed that most countries do not have a single "joined up" NBS – what they have is usually a patchwork of many sector and sub-sector -specific policies and strategies overlaid by cross-sectoral frameworks at international, national, state and even local levels. There appears to be a general absence of overall responsibility and control, indecision, ineffective priority setting and therefore a high likelihood of duplication of effort and wastage of resources.

As noted earlier, biotechnology cuts across several sectors and is of interest to a wide spectrum of stakeholders. Therefore, notwithstanding the need to develop policies, strategies and programmes that are aligned with those existing for the agricultural sector and its sub-sectors and tailored to

meet the requirements of BFA, *the governance of biotechnology at national level should be horizontal.*

A NBS framework should provide a shared longer-term vision and a coherent and integrated framework for how government intends to work with key stakeholders to capture the benefits and deal with the challenges presented by biotechnology, describing the core priorities and linking the key issues that emerge from the setting up of a national horizontal coordination mechanism. As such, it should cover the strategic goals that will support that vision and the guiding principles that will be followed in the process of implementation. Each goal should have specific objectives and a set of actions/strategies to achieve these objectives. These can include actions already underway or new initiatives, and some objectives and actions can contribute to more than one goal. Objectives should be specific, measurable, achievable, and time bound with performance indicators against which progress can be measured.

In essence therefore, a NBS sets out the roles and responsibilities of government in realizing the opportunities from, and dealing with the challenges posed by, biotechnology. These should be based on a detailed audit/inventory of the current situation nationally with respect to human, financial, and institutional assets, of national laws and regulations, and a detailed knowledge of international obligations and developments. All this helps to identify the specifics of where, why and in what areas biotechnology is important for the country's future development as well as what can reasonably be expected to be achieved over say the next 10 years. A NBS should also describe "who" will be responsible for "what" and how progress will be monitored and necessary changes introduced. The NBS document should not be considered as "set in stone" but rather as a guide that can be revised to take care of new technological advancements or unforeseen developments.

Putting all this together is a formidable challenge, requiring much effort to collect and analyse national baseline data and information as well as on how other countries have approached the issues in question. In addition to close interministerial coordination at scientific, technical, legal, administrative and financial levels, it requires the widest possible engagement with the public, including with representatives of farmer/producer organizations, private companies, non-governmental organizations (NGOs), civil society organizations (CSOs) etc., the ultimate aim being "participatory decision-making" (Section C). Bijker (2007) provides an excellent description of the key criteria for building policies via a policy dialogue and a methodology for carrying out a diagnostic study, emphasizing the importance of ensuring that the policies and strategies identified (a) support institutional reforms, including greater cooperation at national, regional and international levels, (b) strengthen national capacities, and (c) identify new funding mechanisms.

(iii) Developing and approving national frameworks

The institutions involved in developing and approving the frameworks in the countries analysed for this paper are shown in Table 1. Key features regarding the development, approval and oversight of these frameworks, as well as of those from the two countries that have prepared strategies specifically for biotechnology in food and agriculture, are described in Annex 1. Most national biotechnology policy documents are available from the FAO biotechnology website (www.fao.org/biotech/country.asp), while other information was obtained from ISAAA's AfriCenter, and from similar documents on the internet from other countries.

While there were several commonalities to the mechanisms established to develop these frameworks, there were also significant differences between countries - particularly with respect to the level and degree of cross-ministerial engagement, but even more noticeably in terms of involving or consulting non-ministerial and non-scientific entities in the process. For most countries, the process could be described as "top down" and lacking involvement of both industry and civil society groups. For most countries also, the NBS was directed at modern biotechnology and particularly the governance of R&D and diffusion of GMOs and their products. Moreover, within that context virtually every country stressed as a fundamental principle the importance or

essentiality of protecting health and sustaining the environment as pre-conditions for success in applying biotechnology. Many also mentioned precaution, liability and redress, and labelling of GMOs and their products as important regulatory principles, with one country placing a moratorium on the use of genetic use restriction technologies (GURTs). Others emphasized the importance of integrating and protecting indigenous knowledge, resources and practices and of benefit-sharing.

Countries took, or intended to take, one of three routes for approving their policy/strategy documents i.e. creating new primary legislation that embraced substantial elements of the entire document, obtaining full government approval for the NBS and separately creating primary or secondary laws and regulations to cover specific aspects e.g. on biosafety; IPR, establishment of funding instruments etc., and obtaining approval from the ministry given the lead responsibility for the issue and creating non-binding guidelines for specific matters.

A comparatively recent development in an increasing number of countries is the development of biotechnology policies and strategies at sub-national levels. An important policy issue for countries that have moved, or are moving, towards decentralized decision-making is therefore the extent to which powers are invested in sub-national governments and agencies to make laws or regulations with respect to R&D, technology diffusion, local and international markets and any risks to these markets associated with the introduction of e.g. GMOs.

(iv) Issues for policy consideration

Core government roles and responsibilities identified within most NBS frameworks were:

- coordination nationally, regionally and globally;
- strengthening the scientific knowledge base and scientific infrastructure;
- encouraging investment in commercial development (particularly Argentina, Brazil, Chile, China, Malaysia, Peru, Thailand and South Africa);
- providing strategic investments and other incentives to foster partnerships between universities, public research institutions and commercial companies (Argentina, Brazil, China, India, Malaysia, Peru, Thailand, and South Africa);
- providing a regulatory system that is both transparent and effectively assesses and manages the risks from developing and introducing new and modified products while allowing innovation (all countries);
- introducing, reviewing and/or if necessary proposing amendments to laws and regulations concerning intellectual property and access to and benefit sharing from plant and other biological resources (all countries with reference to GMOs);
- fostering community understanding about biotechnology by improving access to understandable information and providing the means by which citizens can express their views; and
- providing opportunities for considering cultural and ethical issues (some countries).

How the countries concerned proposed to deal, or have actually dealt, with each of these issues forms the basis of much of the remainder of this document. An attempt has also been made to identify “gaps” or “areas in need of further attention” within each of these themes both nationally and internationally (regionally and globally). However, although many countries have established biosafety frameworks (see Section B) very few countries have actually prepared NBS frameworks and even fewer have done so for BFA, leaving considerable scope for the remainder to consider their options on both fronts.

3. Governance structures and organization

(i) Leadership and coordination: principles and options

Because of its inherently science-driven character and with applications across a range of sectors and activities being undertaken within different jurisdictions, successful governance of

biotechnology requires policies and strategies that address all stages of the innovation chain i.e. from fundamental through to adaptive research, from there to the development of tangible products and then on to their diffusion to end users i.e. both farmers and consumers. This, as well as related trade issues requires coordination across government, across government departments, with sub-national governance structures as well as with other governments via bilateral, regional and multilateral mechanisms.

Without active and specific government-level intervention, individual sectors (including sub-sectors within food and agriculture) are unlikely to coordinate effectively, including dealing with issues that require reconciliation. Government coordination is clearly appropriate also from an efficiency perspective, as a total government approach reduces duplication, enhances consistency of work and should facilitate more effective international networking and formation of strategic alliances by putting out a single consistent message. It could also facilitate investment by donors, private companies, national and regional investment banks, thereby facilitating achievement of other policy/strategy objectives.

Coordination, horizontal as well as vertical, is therefore essential for a comprehensive and balanced policy on biotechnology, the key issue being to ensure that whatever approach is taken within each will be effective in achieving concrete objectives which should include:

- reinforcing the importance of biotechnology as a government priority;
- providing leadership in developing and implementing relevant laws, regulations, policies and practices;
- integrating strategies and activities and avoiding duplication of effort;
- ensuring that initiatives advance a common vision and don't work at cross purposes; and
- informing and educating government officials and the public.

Horizontal coordination

While the options for a horizontal coordinating mechanism (HCM) include a national working group, commission, council or task force with a coordinator, its composition should be organizationally sound i.e. interministerial and engage those ministries that form the nucleus of competencies involved in a coordinated response. Inclusion of the economic ministry would improve understanding of biotechnology and the role it plays, or could play, in economic development, and for maintaining dialogue on budgetary issues. These links would also be vital for advocating increased budgetary allocations.

One issue that has an important influence on the effectiveness of a HCM is its reach. Irrespective of the number or identities of the ministries involved, the officials serving on an HCM will only have some of the competencies, jurisdiction and expertise needed to successfully coordinate biotechnology efforts, and it is therefore important to determine how to involve others who are not at the table. This will be a major challenge since jurisdictions and competencies among and within ministries may overlap while at the same time being highly specialized and compartmentalized.

Another factor to be considered is the scope of its work. The distinction between working at policy and at the operational level is a significant one, although the lines between the two are often blurred. The policy level relates to establishing, strengthening and coordinating the overall legal, regulatory, institutional and strategic frameworks used to plan and implement biotechnology. The operational level, on the other hand, is geared towards building or enhancing the professional capacities and effective implementation of service providers e.g. National Agricultural Research and Extension Systems (NARES), universities, regulatory bodies, NGOs, CSOs.

While countries have the option of separating these roles and responsibilities, a fully functioning HCM should be able to develop, support and advance both policy and operational elements of the government's biotechnology policy/strategy framework. This makes the structural challenge all the more demanding since the coordinating body needs to be able to accommodate and bridge

distinct but overlapping policy and operational activities, even though these may be organized in different ways in the relevant offices by different nations e.g. when "agriculture" is covered by separate Ministries for Agriculture, Livestock, Fisheries and Forestry and, as noted earlier, when Ministries of Environment, Trade, Natural Resources etc. engage on specific issues.

Also, although setting the membership of a horizontal coordinating body at a sufficiently high level to have policy decision-making authority will increase the likelihood that coordination will be effective at the level of national policy, it has to be recognized that ministers themselves or high level ministerial representatives such as permanent secretaries are unlikely to be engaged in, or responsible for, operations on a day-to-day basis. In practice therefore, it is the work of lower ranking officials (Heads of departments, Directors of research institutes, University faculty heads etc) who have these responsibilities for planning and implementing specific programmes, projects and activities that need to be effectively coordinated.

If the coordination mechanism does not have the official authority to provide policy leadership or engage in operational decisions itself, but primarily gives advice to those who make those decisions, then it can be weighted more heavily towards individuals possessing technical expertise who are not necessarily policy and/or operational decision-making officials. One option then is to delegate much of the work of the high level interministerial mechanism to a more technical mechanism that provides information to all the relevant offices and officials within each of the represented ministries and in the government, thus making it possible for them to be involved and coordinated.

Vertical coordination

Setting up working sub-groups to incorporate some of the broader range of expertise needed is one mechanism. Since efforts to promote responsible development of biotechnology centre on planning and delivery at the sectoral level, an appropriate action by government would be to direct sector ministries to work with their stakeholders and other interested parties by setting up a *vertical coordination mechanism (VCM)* based on sub-groups to refine or develop sector–specific strategies and plans. As noted earlier, only two developing countries appear to have done so for BFA, although it is possible that others have embedded these in national S&T frameworks.

Because not all of the relevant competencies, expertise and perspectives that are needed to respond most effectively and appropriately to the opportunities and challenges posed by biotechnology reside within government or a particular ministry, *there are important roles to be played by NGOs, the business community and other partners from civil society within coordination mechanisms.* Recognizing this, some relevant international treaties (e.g. the CBD) contain specific provisions calling for coordination, cooperation or strategic partnership with NGOs and civil society in the process of developing national coordination mechanisms, strategies and other components necessary for pulling together measures and activities. This aspect is expanded upon later, but it is part and parcel of engaging all relevant stakeholder groups in providing inputs to the development and implementation of both a NBS and a strategy for BFA that is consistent with the NBS.

Analysis of the country frameworks surveyed shows that while all governments recognized that no one ministry could hold all responsibilities in moving their national agendas forward and therefore the need for effective inter- and intraministerial coordination and decision-making, *in only a few cases have new formal structures been established or proposed to oversee biotechnology's development and in very few cases do these appear to involve collective government.*

In most countries the option chosen was to assign responsibility for implementation as an "add on" to the ministry assigned to lead development of the framework (normally the Ministry of S&T), with no indication given about delegation of responsibility for specific areas such as BFA or for bringing policy issues to the "top table" for discussion and decision-making.

A further gap seems to exist in countries with federal and local systems of governance i.e. the lack of a specific national forum for coordinating policy, raising the distinct danger of e.g. policy and funding overlaps and production and trade distortions.

In the case of the African Union, a Ministerial Council on Science and Technology (AMCOST) was set up as the overall governance body to provide political leadership and make recommendations on policies while the AU Commission and the NEPAD Office of Science and Technology are responsible for mobilizing financial and technical resources to implement programmes and projects.

(ii) Independent advice: principles and options

Institutional arrangements are needed at all levels of government to advise on both generic and specific issues on biotechnology and ensure that appropriate government or ministerial responses or actions can be established which are both cost-effective and expeditious. There are many options available in terms of roles and responsibilities, size, terms of appointment and range of expertise. Membership should, however, be based on individual expertise, knowledge and experience; it should be "balanced" i.e. represent a broad spectrum of society including science, private sector, further education, law, ethics, etc.; and it should engender trust, credibility and inclusiveness.

Issues should be addressed in an inter-disciplinary manner, and there should be opportunities to introduce emerging issues such as the role of biotechnology in mitigating climate change, dealing with avian influenza etc. In addition, the committee should meet regularly (say twice yearly), be prepared to provide *ad hoc* inputs between meetings, and its reports should be made widely available. Appointment should be through a nomination and selection process agreed by the members of the HCM and VCM as appropriate.

Options for advisory structures include:

- an individual acting as chief scientific advisor to the Head of State or to the government and chairing a broad-based panel of well-respected individuals;
- establishing permanent advisory committees within sectoral ministries;
- dealing with specific/emerging issues through *ad hoc* committees; and
- engaging the expertise available within a National Science Academy or Research Council, one of whose roles is to ensure that the best possible evidence and advice are available to policy-makers. That said, it should be emphasized that the issues where these institutions should put their reputation on the line are restricted to science - how it's done, funded, applied and taught. Strengthening of these institutional capacities in relation to biotechnology is much needed in many countries and is one important strategy for fostering its responsible development.

While some countries established an independent Biotechnology Advisory Committee (BAC) or Council to provide strategic policy advice to government, more often the mechanism was set up to advise an individual ministry or department. Details are provided in Annex 1.

Concerning the representation of NGOs and CSOs in advisory mechanisms, there was no evidence for this having been done or intended in any of the countries reviewed. Only Argentina appeared to have set up an advisory mechanism to cater specifically for food and agriculture, the remaining countries relying on a broad-based/horizontal mechanism reporting to government or more often the Ministry for S&T. Other countries should consider their options for obtaining more focused advice relating to BFA rather than leaving this up to "generalists".

4. Setting priorities for R&D

(i) At the level of government

Agricultural research can provide high returns on investments, but as noted earlier, investing in biotechnology can be an expensive business. Because the demand for research outstrips the available resources, *priority setting involving biotechnology in general and specifically for BFA is arguably the biggest challenge faced by government and sectoral level policy-makers, particularly if the goal is to tackle hunger and poverty in rural areas.*

Priority setting is fraught with difficulties due to the lack of credible socio-economic information (e.g. about where poor people live, their vulnerabilities and livelihood strategies), and because many priority setting processes lead to decisions that tend to be *ad hoc* and occur more by chance than by well-founded choice. *Priority setting is also value-laden* and there is no consensus either about the values or the criteria that should guide it. For example, *although it is relevant, cost-benefit analysis should not be the only approach when dealing with "pro-poor" technology choices, since this would bias investments towards commercial crops and high potential areas*.

Priority setting reflects the values of the people and institutions involved and, apart from lack of information, the major challenges in trying to "get it right" involve overcoming the disconnects between who is setting, and who should be setting, priorities; between the values that are driving priority setting and those that should be; and the limited capacities of the institutions and people who are making decisions.

As the principal funder of public research institutions, the government's main business is to maximize the effectiveness of its investments in building and sustaining national capacities to produce innovations that benefit society. It should therefore have a more outcome- and impact-oriented approach to the governance of R&D than e.g. the typical university and research institute approach which is geared towards outputs of scientific publications (and in biotechnology, increasingly patents). As such, g*overnment level policy-makers should ensure that research investments are closely aligned to national development priorities and that both structures and transparent and fair mechanisms are in place not only for selecting, funding and monitoring research performance but also for improving priority setting*.

A number of approaches can be considered:

One is to establish a *national system of biotechnology statistics and indicators* to inform policy actions, bearing in mind that this should include more than data about biotechnology R&D (e.g. funds allocated, researchers involved). Data on e.g. productivity improvements, environmental impacts and social/economic benefits are also required. The first step in this process is to define the term biotechnology, a list-based definition being probably the most useful when the policy interest relates to benefits (see http://stats.oecd.org/glossary/detail.asp?ID=218, and Van Beuzekom and Arundel, 2009).

- another strategic direction is to set up *reliable systems for biotechnology foresight* to monitor and assess the relevance for national agricultural and rural development of global patterns of technological change as well as demand from both home and export markets for biotechnology products including market potential, acceptability by users and consumers, and pricing. This helps guide formulation of technology policies and strategies. Currently, only some industrialized countries appear to have such systems in place.
- yet another is to introduce instruments that encourage the *transformation of traditional research institutions* and related higher education centres from "silos" of often pure discipline-oriented activity into innovation systems that put a premium on multi-disciplinarity and networking and a much greater number and diversity of actors. *Of the developing countries reviewed, only Argentina, Brazil, China, India and South Africa signalled their intention to move in this direction, and as illustrated later, have actually done so.* Other countries were silent on such initiatives.

(ii) For biotechnologies in food and agriculture

Although not specifically addressing priority setting for BFA, the papers by Hazell and Haddad (2001), Byerlee and Alex (2003) and Meinzen-Dick *et al.*(2004) provide many useful pointers for making pro-poor investments in agricultural R&D and should be consulted for further information.

As noted earlier, essentially all countries have accorded high priority to BFA in their policy/strategy frameworks, and in these and very many more countries, research institutions and university departments are increasingly undertaking biotechnology research in fields relevant to food and agriculture (see e.g. Dhlamini *et al.*,2002; Cohen, 2005; Spielman, Cohen and Zambrano, 2006). In many cases the research appears fragmented, uncoordinated "horizontally" with other national biotechnology initiatives and "vertically" within agriculture or one its sub-sectors e.g. plant breeding and seed production systems, and internationally. In other cases, the range of activities being pursued is so vast and resources thereby so widely and thinly spread that the attainment of successful outcomes within a reasonable timeframe has to be seriously questioned. Clearly, most countries do not seem to be prepared to make critical choices about their investments in BFA, reflecting no doubt absence or insufficient rigour in priority setting, and perhaps undue influence from donors, supporters of particular technologies and scientific journals.

Of course, all the technologies being used within the confines of laboratories or experimental stations could *potentially* play a role in improving productivity, incomes and trade and thereby contribute to reducing food insecurity and poverty. But what was the rationale behind their introduction?; who asked for them?; what was the process that led to their initiation?; what steps were taken to assess the need for, and to identify partnerships to achieve the project's aims?; how will the R&D and subsequent transfer to end users be conducted and funded?; how will the risks be managed and the benefits captured by those who need them most - directly, or indirectly by "trickling down" from others able to capture them earlier?; were regulatory (environmental, food/feed safety and IPR) implications considered before the work was started?

These are questions not normally requiring answers from scientists, but they are questions for which convincing answers are needed to produce and transfer technologies that are supposed to improve livelihoods irrespective of whether the products are being developed and disseminated by public and/or private sector entities. Answers to these types of questions are critically important for setting priorities for R&D. If the research simply "bubbles up" through the initiative of an individual researcher rather than being embedded in a more structured and hunger/poverty outcome/impact-driven process that involves not simply the public sector but also the private sector and e.g. voluntary organizations, the possibility of anything coming out of it by way of contributing to "pro-poor growth" is remote indeed.

This is not to imply that more fundamental and curiosity-driven research is unimportant, or that biotechnologies used in laboratory settings or e.g. as "pen- or crop- side" tests by agricultural protection and extension agents are not worthwhile. In fact, probably most biotechnology research aims to generate innovative intermediate products, protocols, markers, information, new "tricks" for getting answers to research questions etc. that can be used by other researchers rather than products that can be taken up directly by farmers and government and private support services. And diagnostic and genetic characterization tests/methods certainly have a proven track record for improving disease surveillance and control, increasing the efficiency tackling some national, regional and global constraints e.g. the virtual eradication of rinderpest. *Rather, it means that in setting priorities, decision-makers have to decide on research entry points appropriate to different national objectives* (basic/fundamental or applied research?; cell or tissue culture?, immunoassay or molecular methods?; molecular or other markers?; rDNA or other methods for developing new plant varieties, animal vaccines, bacterial strains etc?), *bearing in mind that producing scientific knowledge is one thing but having it absorbed and appreciated by society is quite something else!!*.

A related strategic policy consideration is therefore to ensure adequate breadth in the R&D portfolio and thereby an appropriate balance between what's available and can be relatively easily applied through local adaptation (e.g. immunoassays for some animal and plant diseases, cell and tissue culture), and what needs more upstream and therefore much longer term work but which may make the research enterprise or service more efficient and the products potentially more useful to beneficiaries (e.g. molecular markers, GMOs). The point here is that despite the claims of some scientists and commentators, there is no reason to believe that, in the absence of much smarter policies and institutions for development, diffusion and possibly regulation, the uptake of any new technology, including GM crops with their claimed advantage of faster development relative to traditional breeding methods, will generally be other than slow and incremental (see Pardey and Beintema, 2001; Nightingale and Martin, 2004). That said, and as demonstrated by the growing of *Bt* cotton in China and India, some technologies can be taken up very rapidly indeed if beneficial to farmers and their communities.

A further fundamental consideration is ensuring that priorities for public sector engagement in R&D take due account of which technologies can or will be developed exclusively by or in partnership with local or international private sector companies. The strategic importance of ensuring an appropriate "division of labour" between the public and private sectors has been highlighted by Byerlee and Fischer (2001) and more recently by Naseem, Were Omamo and Spielman (2006). Although rapidly evolving particularly in relation to plant breeding (Raney and Pingali, 2004) and poultry production (Narrod, Pray and Tiangco, 2008), and therefore requiring continuous adjustment to the scope and intended beneficiaries of public goods research interventions, trends in financing agricultural R&D by developing countries coupled with the generally low investment of the private sector in all but a handful of these countries suggest that without significant government inducements, the role of private sector R&D and delivery systems will remain limited, particularly for small-scale/subsistence farmers in marginal areas.

The reasons for this include the strengthening of IPR on biological innovations (Section C1), and because private R&D investments will be largely directed at medium and large-scale commercial agriculture (especially export crops, fruits, vegetables, flowers, aquaculture and livestock products) and food processing. Also, some technologies and particularly the key platform technologies employed in genetic modification, disease diagnosis and molecular analysis - and which are needed for downstream and adaptive research - are controlled by private firms. Most of these are not applied to the crop or animal-trait or disease combinations important to small-scale and resource poor farmers, and therefore there is substantial "space" for the public sector to engage in pro-poor biotechnology R&D by complementing and not duplicating or substituting for private initiatives and filling gaps relevant to the poor who cannot pay. It does, however, mean that the NARES are going to have to largely "go it alone" – a reality with substantial policy implications for governments, not least of which is the emphasis to be placed on "home grown" production/ self-sufficiency , and if so, for what commodities, and deciding on the proposed beneficiaries of R&D investments.

Some argue that by putting the emphasis on local rather than national problems and on small-scale farmers, the "pay off" from R&D investments in biotechnology in terms of aggregate poverty and hunger alleviation would be compromised, and that other "social" policy instruments would be more appropriate for tackling household food insecurity particularly in resource poor environments. On the other hand, there is now growing pressure to change research strategies and target research on the production systems within disadvantaged regions to generate direct benefits for the poor.

This pressure is both political and, in some situations, justified on the grounds that the combination of market liberalization and private sector investment is already reducing the need for continued public sector research investment (e.g. in areas most relevant to commercial farmers). *Are these issues being factored into national and international R&D priority setting processes?* For example, in addition to the small number of well-known major global crops such as maize, rice, wheat and cotton, many more crops are regionally and nutritionally as important if

not more so for poor farmers and households e.g. sorghum, millets, bananas and plantains, roots and tubers like cassava and yams, groundnuts and indigenous crops like tef and quinoa. These under-researched "orphan" crops are nutritious, well adapted to harsh environments, and genetically diverse and have great potential for improving food security, livelihoods, cropping system stability and genetic diversity. *Is the biotechnology being considered targeting the crops and animals of, and traits needed by, small-scale (and poorer farmers)?*

Yet another challenge is setting priorities between sub-sectors e.g. between crops, livestock, aquaculture and forestry. Here again, although not by any means suggesting that R&D on crop biotechnologies is even close to adequate, policy-makers should be aware that livestock and livestock products now constitute 40 percent of global agricultural GDP and that in many countries forestry and aquaculture are assuming increasing importance. Irrespective of whether one or a number of ministries is responsible for "agriculture", *a collective decision-making forum for priority setting and resource allocation for R&D within or between the ministry(ies) involved would seem appropriate*. As noted later, a number of countries are beginning to establish such mechanisms for dealing with regulatory issues, *but no country seems to have a similar forum for biotechnology priority setting across the sector as a whole.*

Clearly, the potential for R&D to reduce hunger and poverty will be strongly influenced by the types of farms and production systems, and by the strength of the research, extension and higher education institutions available. And its focus should be directed at areas where the largest number of poor people live and respond to their vulnerabilities and livelihood strategies (Dargie, 2007). For subsistence farmers, this means reducing production risks for staple food and feed crops for home and on-farm livestock/fish consumption and encouraging marketing of higher value crops, milk, eggs, fish etc. *Is the biotechnology package being considered "matched" to the location, livelihoods and vulnerabilities of the people living there and engaged in agriculture (farmers/livestock keepers/landless labourers), and do these locations intersect with high levels of hunger and poverty?*

This type of information then needs to be fed into a process that considers *all the technical options* available for dealing with the issue(s) in question. Depending on the level and source of investments being considered, this may require a team of competent economic and social analysts to conduct an *ex ante* impact assessment supported where possible by *ex post* assessments to assess whether a particular biotechnology "adds value" to more conventional and probably lower cost and technically less demanding R&D approaches for improving livelihoods through productivity or quality enhancements, the effectiveness of government or private services and the returns on government investments.

And particularly, but not only for GMOs and derived products, this *ex ante* assessment should take account of socio-economic issues like IPR and the associated costs and assumptions concerning user and consumer acceptability nationally and internationally for commodities earmarked for trade. Also there is a need to consider the additional skills and infrastructure to cover possible R&D as well as post-release costs of biosafety and food/feed safety regulations. *Have these costs/issues been assessed and factored into the research agenda/priority setting exercise*?

Several methods are available for conducting impact assessments, most of them feeding into top-down approaches, but some can be adapted to bottom-up mechanisms. The most common are:

- *Precedence*: uses previous funding levels as the basis for the next programme cycle; quick, not to be recommended, but all too common;

- *Congruence*: ranks alternative themes on the basis of a single criterion; quick, demands very little data, questionable rigour;

- *Weighted scoring*: ranks alternative programmes and projects by identifying and weighting multiple criteria; easy, does not require advanced quantitative skills, relatively transparent,

promotes multi-disciplinarity and stakeholder involvement. The *Analytical Hierarchy Process* (AHP, Braunschweig, 2000) is one variation of this. It involves breaking the decision problem down into a number of more easily understood sub-problems. These elements are then played off against each other in pairs using both evidence-based and subjective data, and with uncertainty in cost, benefit etc. The essence of the approach is that human judgements and not just hard factual data are used to inform decision-making;

- *Cost-benefit analysis methods:* widely used, the simplest involving examining the streams of both costs and benefits of a particular technology in financial terms only. Another approach takes into account the costs of alternatives;

- *Economic surplus models* such as the DREAM model (Alston, Norton and Pardey, 1998) are also available to guide priority setting based on the expected financial return to investments from research or uptake of a particular technology. The recently published economic analysis by Foltz (2007) supporting priority setting for investment in modern biotechnologies to deal with biotic and abiotic constraints to crop production in countries in West and Central Africa is an excellent recent example of this approach. Similarly, Vitale and Boyer (2007) have employed the approach to assess the economic impacts of introducing *Bt* technology in smallholder cotton/maize production systems in Mali, concluding that the use of the technology in cotton would have a much higher priority than in maize due to the price differentials between these crops and the fact that farmers spray cotton but not maize for controlling insect pests - a conclusion consistent with studies conducted elsewhere (Brookes and Barfoot, 2005). This approach requires a great deal of data, is done independently of stakeholder input, and while appropriate for ranking benefits from research or user uptake from particular commodities, it is not well suited to ranking upstream research or bringing in social issues.

Traditional economic impact studies make important contributions to decision-making on the appropriateness and priority to be given to different technological approaches, but they do not take into account their environmental, human health, food insecurity and poverty dimensions (Falck-Zepeda, Cohen and Komen, 2003; Hazel, 2008; IAASTD, 2009). Falk Zepeda, Cohen and Komen (2003) have suggested a *Sustainable Livelihoods* approach to examine the context in which poor people live in a rural community. It includes issues of vulnerability, natural, physical, financial, human and social assets that are valued by the community and how policies, institutions and processes affect the use of and access to these assets in pursuing different livelihood strategies. *Simulation models* such as computable general equilibrium (CGE) models (Lofgren, Harris and Robinson, 2002; Dorward *et al*., 2004) are increasingly being used for tasks ranging from the collection and analysis of socio-economic data to the conduct of model-based policy simulations. These could also respond to some of the constraints associated with economic-based models and to the need for combining social and economic data in biotechnology R&D decision-making; however, like the Sustainable Livelihoods approach, data requirements are substantial.

Getting well grounded information and answers using one or a combination of these methods is important. However, the methods themselves should not drive the process, but rather inform it. They should not be used to replace sound judgement, experience and ingenuity or to leave so little room for manoeuvre that freedom to explore new avenues is inhibited. Nevertheless, impact assessment should be part and parcel of the priority setting process and overall research evaluation and management system within research organizations and therefore should be institutionalized throughout. Further information on impact assessment for agricultural research is available at http://impact.cgiar.org/methods/docs/sofart.pdf, while Anandajayasekeram *et al.* (2007) provide specific examples of using these methods in an African context.

Other priority-setting considerations include:

- *the current status and likely future strength of the national breeding, management and disease/pest control programmes* for the crops, trees and animals in question and for processing their products bearing in mind (a) that the biotechnologies being considered would normally complement rather than fully replace the technological package available to the farmer or used by

the plant protection and veterinary services, and (b) in the case of improved genetic traits, that these would need to be "added on" singly or more likely combined to local germplasm containing other agronomic traits valued by farmers and rural households (e.g. higher yield, tolerance to drought, resistance to other diseases or pests, high nutritional value, better cooking quality etc.) and not included in the new technology itself;

- *the delivery systems for the technology in question and their sustainability* – how and by whom will the new technology be disseminated?; is there a formal market for seeds or planting materials of the crops concerned or for the semen, embryos, chicks and broodstock for the livestock and aquaculture enterprises?; will dissemination be carried out by public agencies, the private sector, NGOs or the local community? Pointedly, in Cohen's (2005) paper dealing with GM crop development in a range of developing countries, *few of the research groups surveyed had considered how their products would be diffused to farmers, let alone identified partners for doing so;*

- *the national and international "science and technology landscape"* to decide e.g. whether to rely on spillovers from R&D conducted through other national or international initiatives or engage actively in the entire basic-applied-adaptive research continuum, the decision on which to choose being determined by the assumptions made about the "strings attached" to each (see Section C1 under IPR). Information that has to be gathered here includes: availability of the technology; who owns it; best guesses of the effort, time and costs to develop it from scratch or adapt it for local use; interest of, and conditions for, private sector investment in the required R&D, mechanisms of product delivery and skills in its use through partnership with the public sector and availability of policy instruments to encourage such partnerships (Section B); and acceptability of the product to farmers and communities in terms of both price and cultural considerations.

In relation to costs of GM crop development, Manalo and Ramon (2007) estimated the cost of developing MON 810 *Bt* corn in the Philippines from the confined greenhouse stage at US$ 2.6 million. Costs in the USA which preceded the work in the Philippines (i.e. for gene discovery, making of the gene construct, introgression of the gene, selection of transformed plants, laboratory and greenhouse testing, confined field trials, multi-location field trials) were US$ 29 million. Over 65 percent of the costs in the Philippines were for meeting government regulatory requirements. Other estimates of regulatory costs include those for virus resistant papaya and herbicide resistant soybeans in Brazil (US$ 700 000 and US$ 4 million respectively, in the latter case due to requirements for animal studies), and US$ 160 000 for insect resistant maize in Kenya (Atanassov *et al.,* 2004). Also, a study of regulatory costs in 10 countries concluded that the cost of introducing a GM trait can run between US$ 6-15 million (Kalaitzandonakes, Alston and Zilberman, 2007). These costs will, of course, be heavily dependent on national regulatory requirements (Section B).

Also, the introduction of GM crops (whether obtained in the form of the owner's protected variety, by backcrossing this with a local well-adapted variety, or by introgressing an imported or local gene construct into a local variety), will inevitably involve charging farmers a "technology fee" or higher price for the seed. The price at which this is set will influence both adoption rates and social welfare benefits and will vary with the profitability of the crop, in general being higher for industrial/export crops than for traditional subsistence crops (see, for example, Vitale and Boyer, 2007). At the same time, consideration needs to be given to the issue of collecting technology fees. Inability of technology owners to collect these at the time of seed sale due either to lack of appropriate IP laws or their enforcement (see Section C) could significantly affect estimates of social and economic benefits.

Policy-makers must therefore consider these and other cost, price and benefit variables when setting priorities for BFA development and diffusion but few, if any of the *ex ante* approaches currently available build assessment of these costs into models of cost-benefit analysis..

Important to stress here also is that technologies described by some scientists as being "on the shelf", "simple", or "quicker" are nevertheless "new" for many countries and can require substantial and consistent investments in building knowledge, know-how, infrastructure etc. to adapt and use them appropriately within local contexts. Policy-makers should be aware of the tendency of some academics, the biotechnology industry and some governments to exaggerate the ease of developing and commercializing technology and transferring it between countries and institutes.

Advanced biotechnologies in general, and GMOs in particular, have not been immune from inappropriate expressions of optimism. For example, the costs and time savings involved in establishing traits through GM in crops compared with conventional breeding are sometimes exaggerated. It took approximately 16 years from the cloning of the first gene coding for the *Bt* toxin until the commercialization of maize *Bt* hybrids (Goodman, 2004). While advances in genomics and breeding technologies may accelerate that process, since most traits that would be useful for farmers and consumers are polygenic, the tasks of finding, cloning and inserting the requisite gene combinations, and more particularly getting such products through regulatory processes, may not be any quicker or less costly than introducing e.g. an already well established trait for insect resistance.

In summary, priority setting ultimately comes down to assessing the *appropriateness of the technological packages* being considered i.e. their technical feasibility, economic viability, social acceptability, environmental friendliness, relevance to the needs of farmers, consumers etc. - issues that inevitably vary over time and space. Assessing appropriateness requires capacity to identify and make hard choices among the many critical problems facing rural communities that can be addressed better with biotechnology than by taking other approaches, and this in turn depends on the quality of the background information available, the methods used, and who participates, and how, in informing decision-making.

Priority setting therefore requires a comprehensive approach for assessing the technology itself and its transfer to end users and in so doing takes account of both its functional and institutional dimensions. The results will always be speculative, open to uncertainties and different interpretations and certainly cannot reliably be extrapolated from one country to another or even from one location to another within a country. It is therefore important to review results against studies from other countries with similar and different socio-economic conditions. Rigour can, however, be improved by considering the results of *ex post* impact assessments and in both cases, by comparing the proposed biotechnological with the conventional package.

Given the paucity of information about the long-term costs, benefits and risks associated with essentially all biotechnologies, especially for the rural poor, and particularly the conflicting conclusions reached by different authors concerning GM crops (Smale, Zambrano and Cartel, 2006; Smale *et al.,* 2009; IAASTD, 2009), new approaches are needed to assess and compare with conventional approaches the likely impacts – social as well as economic, immediate and long-term, positive and negative - of all major modern biotechnologies used in food and agriculture.

Priorities should be need- and demand-driven, and decisions therefore based on national priorities and policies for agricultural and rural development and wider food security. Nevertheless, in most countries research priorities for BFA are still neither examined nor defined systematically, and much still needs to be done to accelerate priority setting methods at national and institutional levels.

Government level policy-makers should encourage the introduction within their NARES of more rigorous and participatory mechanisms and methods to inform decision-making on these matters, including allocation of resources through specific programmes, projects and activities. Possible mechanisms for doing so are presented in Section B.

Regional research organizations and the CGIAR could also foster more systematic priority setting for BFA by focusing on capacity-building and advocacy, possibly through a web portal and community of best practice to promote appropriate methods. Related to this, it is important that methodologies are developed to improve impact assessment practices for biotechnological products based on economic, environmental and social data, particularly for smallholders in disadvantaged areas.

B. Enabling Policies for Agricultural Biotechnologies

1. Building scientific, technical and innovation capacities

"Science, technology and innovation underpin every one of the MDGs – it is inconceivable that gains can be made without a focused science, technology and innovation policy" (UN Millennium Project, 2005).

This 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. Yet, while 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, 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 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 countries listed in Table 1 put the agricultural and food sectors among, or at the top of, their priorities for national development, in the vast majority of cases, the overwhelming emphasis to date of their actions is on biosafety laws, regulations and "structures". Little consideration has been given either to non-GM biotechnologies 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, nonetheless, fraught with many difficulties. As described in Annex 2 new investors such as the Bill and Melinda Gates Foundation are creating significant opportunities to stimulate innovation in biotechnology. Yet, many challenges face agricultural S&T globally - the R&D agenda has become more complex, market-driven and private sector led. The key social challenge, however, 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. At the same time, there is increasing realization that the standard linear or "vertical" model of generating and transferring 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 NARES) is fast becoming obsolete and is being replaced by "innovation systems" approaches. One notable example of this "participatory" and self-organized "bottom up" approach to biotechnology identification, development and uptake within the context of subsistence agriculture is control of the castor semilooper (*Achea janata*) pest in Andhra Pradesh, India (Puente-Rodríguez, 2007).

(i) Capacities and funding of agricultural knowledge, science and technology, including biotechnology

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 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 GM content (this Section, part 3).

S&T capacity cannot easily be quantified. It is so multi-faceted and subject, country and even jurisdiction-specific that no set of indicators for measuring or policies for improving capacity can cover all circumstances (IAASTD, 2009). Attempting to measure "innovation" adds to the complication. Some countries have weak agricultural research systems, 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 USA and Europe - sometimes with limited or no involvement of their NARES.

Budgets for R&D expressed in absolute terms or research intensities (see below) are both necessary and informative but 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 the 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 i.e. 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 (ASTI) which deal primarily with investments in R&D suggest a very similar categorization for most countries (Table 2). 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 agricultural GDP has increased at a faster rate than R&D spending although this has also increased dramatically in both countries over the last 10 years.

Table 2. Agricultural research intensity of 15 selected developing countries, measured as public agricultural R&D spending as a share of agricultural GDP. Year of data is within brackets. NA indicates not available.

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	NA
Kenya	1.23 (2000)
Malawi	0.67 (2001)
Malaysia	1.92 (2002)
Namibia	NA
Peru	NA
South Africa	2.81 (2000)
Thailand	NA
Uganda	0.61 (2000)
Zambia	0.62 (2000)
Developed Country Average	2.35 (2000)

Source: Agricultural Science and Technology Indicators (ASTI) Data Tool available at www.asti.cgiar.org/data/; developed country average from Beintema and Stads (2008a).

At the global level, US$ 23 billion was used for publicly-funded agricultural research in 2000 (Pardey *et al.*, 2006; Beintema and Stads, 2008a). 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 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 over US$ 2.35 (Table 2). If the contribution of private sector funding is included, that gap increases to more than 8-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 ten cents for every US$ 100 of agricultural GDP (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, 2008a), 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 between 5 and 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 EC [Chaturverdi, 2005; Jayaraman, K. 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).

These figures, together with the data available from the CGIAR and FAO on biotechnology applications in the crop sub-sector leave little doubt that investments in BFA now constitute a significant and possibly increasing component of agricultural R&D in some developing countries. And despite the limited data, both the figures provided above and results of Wagner *et al.*(2001) indicate that the categorization of NARES 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 "proficient", "developing" and "lagging" categories.

Although no hard data are available, it is noteworthy that the focus of the new additional public BFA investments in developing countries seems to be overwhelmingly on plants and on plant genomics and rDNA technologies with work on livestock, farmed fish, trees and microorganisms 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 all the 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 arise 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* and the information given below illustrates how some countries are attempting to tackle this in relation to BFA; and
- 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).

(ii) National and regional initiatives

In their national 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 these goals.

As illustrated in Annex 3, 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 globalize, with nationals from essentially all the countries covered in this document 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. Also, for countries in Africa, the Biosciences eastern and central Africa (BecA) hub which has been set up on the campus of 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 (see http://hub.africabiosciences.org).

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 (details in Annex 3). 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, and*
- *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.

2. 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 (Annex 3). Most of these options revolve round 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 funders 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. They 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 by Fingleton, (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 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 these 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 BACs is wide, one option is to create a R&D sub-committee with S&T, innovations and socio-economic development expertise, 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; these 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; and
- *encouraging and enforcing intellectual property protection*.

As described in Annex 3, 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 which, although not always specific to BFA, 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.

3. Regulation

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 (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 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 SARD and wider development.

The main challenges faced by policy-makers are first of all deciding on 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 (a) because the desirability of a particular activity depends on societal values which themselves can vary greatly within and between particular societies, and (b) because national regulatory frameworks themselves increasingly have to be adapted both to the "rules of the game" imposed by international, regional and bilateral agreements, and 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 -now known collectively as *Biosecurity* measures (FAO, 2007)- have been used to balance the needs to produce, market and trade in 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 for striking 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 other 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. And into that debate, as it has done in the discourse on agriculture over the last half century, come two overarching questions about BFA: 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 SARD 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, molecular markers and diagnostics, immunoassays), 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 obligations; 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, specifically genetic modification, in the 21st century.

This document 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 it is worth mentioning that 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 not regulated) has had serious repercussions on livestock biodiversity and the livelihoods of many small-scale farmers.

What is significant from a policy-making 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 CBD and its CPB, as well as through the all-embracing WTO Agreements on trade and the standards set by the Codex Alimentarius Commission, 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 Spreij (2007) describes the 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 document 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 developing countries surveyed 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 DBT India, SAGPyA Argentina); the National Biosafety Frameworks (NBFs) prepared through the UNEP-GEF (United Nations Environment Programme/Global Environment Facility) project (www.unep.org/biosafety/); information provided by countries to the Biosafety Clearing House (BCH, http://bch.cbd.int/); publications from IFPRI (e.g. Sengooba *et al.*, 2005); and the Fact Sheets on national biotechnology developments prepared by the USDA's Foreign Agricultural Service (www.fas.usda.gov/info/factsheets/reports.asp).

(i) Coverage of regulation within national biotechnology policies/strategies

At the outset, this document emphasized 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 national biotechnology policy/strategy (NBS). It also described some principles 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. Describing how to balance enthusiasm for agricultural biotechnologies with the need to protect the agricultural and food sectors, the wider environment and peoples' health, livelihoods and cultures against unforeseen risks should be an integral part of that policy/strategy. This provides 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 4 provides a synthesis of how the selected developing countries dealt with regulation within 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 relatively little or much less detail. In the former category (e.g. Chile, Kenya, Malawi and 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 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 depth of coverage, all countries have established or intended to set up 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.

(ii) 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 consistent with other international obligations (e.g. on trade) requires substantial inter-institutional involvement: (a) to conduct inventories of national and international laws, national regulations, research agendas and institutions directly and indirectly concerned with biotechnology and biosafety, (b) to analyse these and identify gaps and overlaps, and compare them with other national systems, (c) to assess available human and other capacities, and (d) to 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 Section C). While countries should find the conceptual framework developed by the International Service for National Agricultural Research (ISNAR) 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 other countries.

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:

- using their existing primary laws, and the delegated legal authorities within these, to promulgate regulations for dealing with GM activities. This provides a basis for regulating GMOs within a short time. At the same time create or strengthen inter-institutional linkages voluntarily; and
- introducing 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 Manzella and Vapnek (2007).

While the majority of developing countries surveyed have introduced new biosafety or GM acts/laws, Argentina, China and Chile, 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 GM-specific specific laws, while India does so through rules concerning implementation of 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" and like Brazil, have to be re-negotiated by national legislatures or simply adjusted through changes/ additions to 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.

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 BFA applications throughout a chain that stretches from R&D through to use and consumption. The survey for this document showed that the systems put in place 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 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 (GMOs) coordinates 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 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). And in many cases, these committees are advisory only i.e. they make recommendations to the Minister for Agriculture in China and South Africa; Environment in Malawi, Malaysia, Peru and Thailand; 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 Brazil and Argentina, separate procedures are in place for advising the President and Secretary 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 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 established Institutional Biosafety Committees (IBCs) 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 of the most 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.

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, combined with 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" or "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*. It 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:

  (a) 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. 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"; and

  (b) 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 in 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 similar across national jurisdictions.
- *while there will always be room for improving understanding between regulatory authorities of 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 between 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 (technically, economically and socially) of 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 biotechnology will increasingly require that socio-economic impacts are evaluated along with 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, 2001b).

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 countries, 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 GM 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 biotechnology along entire food chains. It may also lead e.g. to "asynchronous national approvals" for different uses.

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, although e.g. the Stockholm Convention on Persistent Organic Pollutants 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, leaving countries with essentially two options for dealing with the issue i.e. through IPR 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 (Section C1). Options for making information available to the public are covered in Section C2.

(iii) 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). All four texts are available at www.fao.org/docrep/011/a1554e/a1554e00.htm.

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) which was developed under the auspices of the IPPC is of key importance for environmental risk assessment. Readers are also referred to the (non-binding) Asean Guidelines on Risk Assessment of Agriculture-Related Genetically Modified Organisms (www.aseansec.org/6226.htm).

Other relevant documentation includes the OECD's work on risk/safety assessment of modern biotechnology covering food, feed and environmental safety. The main output of this programme is 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 (available online at www.oecd.org/biotrack). These tools were developed for helping decision-makers and other stakeholders in biosafety assessments of a number of cultivated plants (including on their basic biology), trees and microorganisms as well as providing general information about traits. The documents for assessing the safety of safety of novel foods and feeds include elements on key nutrients, anti-nutrients, toxins and allergens. The "Biotrack Online" website also contains a variety of other documents and an on-line database of products of modern biotechnology. These information sources are constantly updated, 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" 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 hazards, if any, and

appropriate approaches and methods to assess potential risks from employing GMOs 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 between and reduce regulatory costs among developing countries through the pursuit of informal collaborations and mutual recognition of voluntary guidelines, *prospects for comprehensive harmonization of biotechnology regulatory oversight within developing country regions do not look promising*. This is because: *(*a) decision-making is essentially about dealing with uncertainty and societal value judgements concerning levels of acceptable risks, (b) within all developing country regions, national policies on GMOs currently range from moratoria to approval of field trials through to commercial field releases, and (c) science can only inform, but never replace, the decisions of policy-makers and societies regarding what they consider to be legitimate and justifiable reasons for particular courses 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; for conducting post-release environmental monitoring; for producing consensus documents on the biology of plants used by smallholders in developing countries etc.

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 the different relevant government ministries within a country. Nevertheless, for countries interested in designing 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.

This 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, 2007). 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 GM specific) approaches and could 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.

(iv) Final considerations

- *developing a regulatory framework for GMOs can be a complex, resource-intensive and daunting process*;
- *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 etc. all require the development of standards, technical and procedural guidelines, forms etc. These then have to be followed by institutes and companies that wish to undertake particular

activities and by the structures within the regulatory decision-making authorities themselves. These include, but are certainly not limited to, preparing dossiers for and responding to notifications, guidelines for conducting risk assessments, issuing and refusing permits and specifying conditions, certifying and inspecting facilities and field sites, guidelines for post release monitoring, methods for testing etc; and

- 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 externally financed projects have drafted NBFs 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 UNU-IAS (2008) assessment 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 NBFs. 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 regional consultations (information documents from Africa, Latin America and Asia are available at www.cbd.int/doc/?meeting=MOP-04).

It is probably no exaggeration to state that the financial commitments made over the last five-seven 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. On the other hand, a few developing countries have reaped substantial rewards from their investments. This is a significant issue for reflection among national policy makers and the international community.

Other noteworthy trends are:

- *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 biotechnology compared with e.g. producing new cultivars through traditional breeding. As discussed in Section A4.ii), 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?;* and
- *related to this on the one hand, is the mass of information, guidelines and other "decision-support" materials available through e.g. the BCH and elsewhere for conducting risk assessments, and on the other, 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, so much so that the COP-MOP set up an Ad Hoc Technical Expert Group on Risk Assessment and Management to consider the need for (even) further generic guidance materials. Their report (CBD, 2009a)

> 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 e.g. of yields, quality, efficacy, they would not have the same potential to affect (a) existing farming practices in national landscapes, (b) arrangements for product harvesting, storage and shipment within and between national borders, and (c) 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.

After due consideration, 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 such uses, 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 regulation of the environmental and human health of the technology, and ensuring the establishment and operation of a regulatory framework that works in the best interests of the country while respecting its international obligations. *Unfortunately, many countries have not considered regulatory demands outside of laboratory and other strictly contained environments before investing in GMOs for developing products that will be used by both farmers and consumers.*

C. Ensuring Access to the Benefits of Agricultural Biotechnologies

1. Intellectual property rights

Significant interest has been shown by the scientific and research communities in developing and developed countries alike in using biotechnologies to both understand and improve how biophysical resources are transformed into food and other products to enhance agricultural productivity and the quality and safety of products. As noted earlier, the success of these efforts clearly depends on having a solid scientific and technical skills base and infrastructure, as well as a wider "enabling environment" that includes a sound regulatory framework. Clear and transparent policies for accessing and using both the necessary research tools and tangible end products is also an essential component of the enabling environment for fostering biotechnology innovation and diffusion. Increasingly these materials and associated information have become the subject matter of grants of IP protection. Consequently, a further critical dimension of a national biotechnology policy/strategy is that it describes how the country intends to deal with the associated IP issues. Policies for accessing genetic resources for food and agriculture (GRFA) and sharing the benefits from using biotechnology to develop useful products have likewise become increasingly important.

Against this background, it is instructive to examine how the countries surveyed for this document intended to deal with the IP and (related or unrelated) genetic resources/biodiversity issues associated with biotechnology, in particular BFA.

(i) Coverage of intellectual property rights and genetic resources issues in national biotechnology policies/strategies

This is summarized in Annex 5. Noteworthy is that while most countries did indeed mention IPR and the importance of their genetic resources, very few indicated the existence of a national IP strategy or the need to change their existing, or introduce new, IP legislation, regulations and other polices to cater for the specific challenges posed in particular by modern biotechnology and how these would be harmonized with the global IP and genetic resources/biodiversity legislative architecture. Also, few described how their research institutions intended to go about accessing or sharing with others either the research tools, gene constructs or genetic resources needed for R&D or any end products arising from such efforts nationally or in other countries, and none mentioned the role to be played by their research funding bodies in influencing the policies and behaviour of their national research communities.

(ii) The global context

National policies on IPR and genetic resources seek to optimize the balance between the interests of creators (e.g. scientists, breeders) and investors on the one hand, and those of wider society (farmers and consumers) who wish to use directly and indirectly innovations that are protected by IPR. Finding that balance has proven to be increasingly challenging since the progressive advance of modern plant and animal breeding and other methods in agricultural production and processing, the increasing involvement of private sector companies in both R&D and the placing of innovations into national and international markets, and in the case of crops, of IP grant to plant breeders for such innovations usually in the forms of a plant breeders' right (PBR) (e.g. in Chile, India, Kenya, Malaysia, Thailand, South Africa), variety or community variety rights holder (China) or a plant variety protection (PVP) certificate (e.g. Brazil).

It has proven to be even more challenging since the arrival on the scene of BFA, particularly advanced biotechnologies which, supported by relatively recent policies within some national and regional jurisdictions, extended patent grant from innovative selection and breeding processes for genetic improvement to cover "life forms" (e.g. plant transformation tools, gene markers, DNA sequences, and improved germplasm and varieties). This had the effect of stimulating major R&D investments by the private sector in the biosciences and encouraging company mergers and the establishment of "biotechnology industries" in industrialized countries.

Multinational corporations (MNCs) and SMEs that provide seeds and other agricultural inputs as well as biotechnological reagents and diagnostic, genetic profiling and other services form the backbone of this "privatization and industrialization of biotechnology". These entities, for example, hold proprietary claims in the form of patents on many of the basic research tools e.g. molecular markers and trait-specific genetic constructs (most noticeably for insect resistance and herbicide tolerance, but more recently also for resistance to abiotic stresses like drought and salinity), transformation and marker-assisted selection technologies and tangible products in the form of plant varieties and breeding lines (Henson-Apollonio, 2007).

However, driven by reduced or stagnant levels of core funding and increasing demands for both cost-recovery and partnerships with private sector entities, many public research institutions in most developed and some developing countries are also now commercializing their IP which can be in the form of patents, seeds and related biotechnological services. For example, with respect to the widely used *Agrobacterium*–mediated transformation system, the share of patents held by the private sector fell from 71 percent in 1996 to 49 percent in 2004, while the share of public sector patents increased from 19 percent to 30 percent over the same period (Michiels and Koo, 2008). Brazil's national research corporation EMBRAPA, for example, currently holds 206 patents, 290 protected cultivars and copyrights on books, software, videos etc., and reputedly earns around US$ 7 million in royalties or about 1 percent of its operating budget from these assets (Texeira, 2008).

With animals, the advent of new reproductive technologies (particularly cloning involving nuclear transfer), molecular biology and sequencing of genomes e.g. that recently announced for the bovine ((Bovine HAPMAP Consortium, 2009) has likewise stimulated considerable expansion in both the scope and number of technologies applied to cells, tissues, organs and whole animals that are now protected though patents. Relating to animal breeding these include DNA markers for improved milk production, superior milk products and litter size, transgenic and cloned animals and methods to produce them, new methods to measure traits, methods to identify animals, and methods for assessing milk and beef characteristics ((Rothschild, Plastow and Newman, 2003). There are, nevertheless some uncertainties at the international level regarding the ownership and patentability of the basic processes of animal cloning through nuclear transfer, the patentability of the animals created and the derived products (Gamborg *et al.*, 2006).

The introduction of *sui generis* systems of PVP, and more particularly, of patenting into BFA coupled with computer software and database rights legislation and the use of copyrights to restrict or withhold access to genomic and other biological information ("bioinformatics") held in private databases has become increasingly controversial. These trends have generated much debate in developed and developing countries alike about the ethical and moral dimensions of biotechnology, the links between IP and the efficiency of R&D, and the prospects of biotechnology contributing to sustainable agricultural and wider national development.

Fundamental questions raised include: the criteria for patentability of gene fragments or mutations (e.g. in some jurisdictions, expressed sequence tags (ESTs) and single-nucleotide polymorphisms (SNPs) may be patentable subject matters even in the absence of proven utility/industrial application, although the rules on this have since been tightened in industrialized countries); the role of IP protection in stimulating agricultural R&D and bringing new innovations to market, and in fostering the transfer and diffusion of techniques, processes, products and information within and between the public and private sectors and between developed and developing countries. The feeling often expressed by the scientific community is that access to key platform technologies and even research tools and data has become increasingly limited, and threatens to slow progress in both the fundamental and applied biosciences (e.g. Chapter 6 in FAO, 2001a).

Against this background all countries should develop IP policies that carefully balance their needs to generate and access the basic tools, techniques, breeding lines and varieties for both research and the production of seeds and other tangible products, while promoting diffusion of these products to small-scale and particularly resource poor farmers. These are particularly important

for those developing countries where the entire agricultural "value chain" running from R&D through to the production, distribution and oversight in using biological inputs remains largely a public responsibility rather than a series of commercial operations.

A further critical consideration is that irrespective of where national responsibilities lie for breeding, and despite the emphasis given to seed industry development through e.g. policies encouraging the development of local seed companies and the entry of regional and global players, in virtually all developing countries where small-scale farming predominates it is farmers' systems of selection, improvement, multiplication and diffusion that provide by far most of the crop seeds (and animal types) used by farmers. For example, only about 7 percent of wheat seed and 13 percent of rice seed in India are sourced from the formal (public and/or private) sector, and in many parts of Africa and Asia it is estimated that over 80 percent of total farmers' seed requirements are met from outside the formal sector (Rangnekar, 2002). These systems are also the only way that farmers' varieties of plants and animals can be maintained and evolve *in situ*, thereby contributing to both national and global agro-biodiversity and food security.

IP protection systems must consider both the structure and multifunctional roles of the agrifood sector in developing countries and be consistent with the minimum requirements laid down in international IP agreements, the most important from a BFA perspective being:

- the 1961 International Convention and Union for the Protection of New Varieties of Plants (UPOV) and its revised Acts of 1972, 1978 and 1991 which currently has 68 country members, mostly from the Northern hemisphere but increasingly also from Latin America; and
- the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) which had 153 members as of July 2008. Particularly relevant here is Article 27.3 (b) which although not referring specifically to biotechnology, contains provisions concerning patentability that are relevant to it and offering countries three options for protecting plant and animal inventions i.e. (a) through patents, the criteria for which are novelty, involve an inventive step and usefulness/capable of industrial application, (b) a system created specifically for the purpose ("*sui generis*") which may or may not conform with one of the UPOV Acts but must be "effective", or (c) a combination of the two. Such flexibility is also available for essentially biological processes for producing new germplasm and varieties of plants and animals.

These differ in terms of eligibility and scope of protection, and it is beyond the scope of this document to deal with these differences in detail, or to dwell on the many "creative interpretations" by individuals concerning definitions, commitments (or lack thereof) and inter-relationships. The book by Tansey and Rajote (2008), however, provides valuable reviews.

In designing and managing national IPR systems, countries should be aware of the following issues:

- *the core assumptions of the TRIPS Agreement and indeed of the UPOV Acts* – namely, that IPR will stimulate international transfer of technology and therefore (bio) technology-related R&D in developing countries as well as the wider exchange of improved breeding lines and varieties.

Fact is, the relationship between the strength of IP protection and all these factors is highly complex, and as noted by Pray and Naseem (2003) and others in relation to biotechnology, *IP is only one factor influencing technological innovation, transfer and diffusion*. Others include: S&T capacity and wider infrastructure, structure of the agricultural sector, potential market size, ecological similarities between countries, the subject matter of protection (e.g. hybrid or open pollinated crops, poultry, pigs or cattle), national policies concerning foreign direct investment, trade, and the macroeconomic environment.

- *the inter-relationships between IPR* (specifically the UPOV Acts and TRIPS Agreement) and (a) *the core aims of the CBD and ITPGRFA* – namely, access to and fair and equitable sharing of benefits from using genetic resources, conservation and sustainable use of GRFA, and preservation of and respect for knowledge, innovations and practices of indigenous and local communities/farmers' rights, and (b) *national food security.*

Each has been, and remains, the subject of much contentious debate within and between countries (see e.g. Gehl Sampath and Tarasofsky, 2002; Helfer, 2002; UNCTAD-ICSTD, 2003; Gepts, 2004), all of which only serves to emphasize the need for further empirical work to clarify the relationship between IPR, the protection of agro-and wider biodiversity and food security at national and global levels.

- *inclusions and exclusions to patentable subject matter* – namely, standards of patentability, rights granted, conditions of disclosure, what constitutes an "invention", "novelty", " an essential biological process", a "variety" and other issues . Also, what constitutes an "effective" *sui generis* system and the procedures in place for enforcement of both patenting and UPOV or UPOV-type PVP laws.

National patent and *sui generis* PVP laws and regional rules contain the same or similar terminology and incorporate similar principles with respect to IP through patents, variety, product and process technology protection. However, there is considerable diversity in how countries interpret their meaning and in the specifics of their implementation for protecting plant, animal and microbial innovations irrespective of how these are achieved. It is therefore not surprising that the global community holds widely differing views on many of the underlying technicalities and the validity of different systems. Modern biotechnology has served to further widen these differences.

- *the costs and benefits of implementing national IP legislation for BFA innovations consistent with international rules*

These are simply unknown, but will certainly be country–specific and depend e.g. on the status of current legislation, technical and administrative capacity, subject matter eligibility criteria such as number of plant species protected. Costs of implementing patent administrative systems will certainly be higher than for *sui generis* PVP systems, while potential benefits (with many underlying caveats) include contributions to greater productivity, trade, incomes and food security. Developing countries intent on building strong breeding capacity involving biotechnology should nevertheless be aware that granting patents for gene constructs and GMOs will increase the price of seeds, propagating materials and other products because of the IP-related "technology fees" charged by patent owners. But higher input prices must be balanced against potential yield, quality and other benefits and costs, all of which have to be factored in when assessing uptake and distribution of economic and social benefits (see Section A).

The principal policy goal of these international agreements is to provide incentives to biotechnologists and breeders to develop new products that are useful to the agricultural and food sectors and for seed, breed/brood stock and food and other input supply companies and government support services to market or use these nationally and/or through international trade. One complication is that they cover what might be termed "conventional" IPR. Since the main driver for developing IPR policies and using IP systems is the strength of the domestic science and (bio) technology capacities within the public and private sectors of a country, where these capacities are weak the IP system will be used primarily to protect imported technologies. This reality is clearly illustrated with respect to modern BFA applications in both Brazil and Argentina where foreign ownership of BFA patents reaches over 90 percent (Biotecsur, 2005); for modern varieties in South Africa that figure is around 70 percent (Van der Walt and Kloster, 2005).

Another consideration is that these agreements do not have provisions for rewarding farmers, local communities and indigenous peoples for their roles in conserving and providing the genetic resources used by scientists and breeders to develop the new IP-protected varieties and other

products using agricultural biotechnologies or other means; neither do they protect farmer-bred varieties (i.e. "traditional" and more informal communal systems of innovation by farmers and indigenous communities). These are concepts covered under multilateral biodiversity agreements (the CBD, particularly Articles 12 and 16, and the ITPGRFA), and which countries also have to address in ways that are both consistent with international trade agreements and between different pieces of legislation. How they do this - through biodiversity or PVP laws or other instruments - is also a matter of some controversy, but is outside the scope of this document. Details are provided by Bragdon (2004) and Stannard *et. al.*(2004).

This document also does not cover the options open to countries for organizing their national IP systems (and their systems for managing access to, and sharing the benefits of, applying biotechnology to GRFA) in ways that are consistent with their obligations under international, regional and bilateral treaties and arrangements. However, given the importance of IP and access/benefit-sharing issues it would be important for countries to formulate a national strategy outlining the measures to be taken by government and other stakeholders to foster the creation, development and management of IP for serving national objectives. Excellent guidance on the legal and technical options available for developing strategies consistent with the UPOV Acts and TRIPS Agreement is available from IPGRI (1999) and Helfer (2002). These should be consistent with strategies for managing GRFA, guidance on the formulation of which is available from Spillane *et al.*(1999).

Inevitably, no single IP system will suit the needs and goals of all countries or serve all agricultural systems within an individual country. Consequently, in the process of designing IP legislation and related policies, countries wishing to use IP as an "enabler" of BFA should (a) make realistic projections about the future role of biotechnologies in helping to meet their national agricultural and wider food security and poverty reduction goals, and (b) make maximum use of the flexibility inherent in internationally agreed rules. Because of the "minimum standards" framework of both the UPOV Acts and the TRIPS Agreement, national governments have considerable discretion in interpreting and applying their provisions. For example, the discretion offered by TRIPS to protect plant varieties through three distinct approaches allows TRIPS members to balance the protection offered to breeders against other important (and possibly competing) development goals, including those found in e.g. the CBD and the ITPGRFA.

Nevertheless, in pursuing biotechnology, an important consideration is how to avoid overlaps and contradictions between national patent and *sui generis* PVP systems, and thereby balance incentives for plant breeding using biotechnology and traditional breeding. Here, it should be borne in mind that TRIPS does not prevent patent laws being modified or *sui generis* systems being created to include exemptions for farmers and/or breeders, and it does not define the scope of protection of patents for biological material and biotechnology processes. In other words, countries, for example, can include genes but not the plant in which the gene is contained i.e. limit the scope of protection of a gene patent so that it does not "carry through" to plants into which the gene has been inserted.

Countries should also be aware that there are options outside of IPR instruments to protect developers and suppliers of plant, animal and microbial materials e.g. biologically, through seed, contract and biosafety laws, material transfer agreements and trade secrets. These options are well covered by the World Bank (2004).

(iii) Establishing laws and institutions

Principles, requirements and mechanisms for reviewing, updating and possibly introducing legislation to meet their international obligations, and establish complementary policies, mechanisms and responsibilities for undertaking the related regulatory and administrative tasks assigned to particular institutions were described earlier in relation to agricultural and biosafety policies; these apply equally to coverage of IPR and related biodiversity issues and are therefore not repeated.

Nevertheless, the daunting technical, legal, judicial, administrative and financial challenges in doing so should not be under-estimated. Few developing countries have amended or introduced legislation that describes the scope of biotechnology-type patent subject matter, often because of the complex technical, social and ethical questions it raises e.g. should inventions from publicly-funded research be patentable and who should benefit from IPR considering the various social groups that may have contributed to the development of the final product? (FAO, 2002). Similar comments apply to IP protection of animals and micro-organisms and related inventions, all of which are highly relevant to BFA and potentially relevant to biotechnology applications in other sectors, micro-organisms being particularly so.

Additionally, few public research institutions and funding bodies in developing countries have established and implemented ground rules, principles and guidelines for managing biotechnology IP and knowledge transfer e.g. by concluding agreements concerning research cooperation with third parties which may be public, private, national and foreign. These are also highly complex and inter-connected tasks, the outcomes of which may be influenced significantly by national and international development, research funding and commercial organizations.

Using the principles outlined earlier, consultative mechanisms therefore need to be established to reach agreement and strike compromises between groups *both within and outside the food and agriculture sector* which invariably will have widely different perspectives on a number of fundamental questions (particularly with respect to patents) concerning legislation, its implementation and enforcement. These include:

- *To what extent and in what forms should IP protection be available?*
- *Who can or should own those agreed property rights?*
- *What institution (s) will be put in place and how will it/they be resourced (staffed, equipped) to identify and manage technologies to be accessed and protected?*

Graff (2007) provides an excellent account of the laws and institutions established by Argentina, Brazil, Chile, China, India, Kenya, Malaysia, South Africa and Uganda at central and decentralized levels to deal with IPR issues.

- *How will legislation be enforced?*

The economic and social consequences of GM crops grown from illegally obtained seed are described by Giannakas (2003), and these may be relevant for other agricultural biotechnologies. Unlicensed copying, particularly when combined with systems allowing use of farmer-saved seed, reduces the economic rents that come to the innovator. Also, the price of the new technology to all farmers who purchase legally obtained GM seed will likely increase. Countries should also bear in mind that weak enforcement of IP laws may reduce incentives for further innovation, negatively impact bilateral and multilateral relationships, open the possibility of trade sanctions and restrict the in-flow of foreign direct investment and technologies needed by other sectors of the economy.

(iv) Intellectual property management options for research institutes

Accessing proprietary biotechnology tools and products

IPR allow holders to exclude others from making, using, selling and distributing their technology. However, this right is not absolute. One restriction is the national jurisdiction of protection, another (in all UPOV Acts and many national patent laws) being the so-called “research” or “experimental use exemption”. Article 30 of the TRIPS Agreement also describes exceptions to patent rights i.e. they must be limited, should not provide unreasonable conflict with normal exploitation of the patent, should not unreasonably prejudice the legitimate interests of the patent owner, while "taking account of the legitimate interests of third Parties".

The strategic IP management choices open to public organizations to access biotechnology tools and technologies for research, development and diffusion are described by Byerlee and Fischer (2001) and Nottenburg, Pardey and Wright (2001). The option(s) chosen will depend on R&D capacity, objectives, cost, conditions, public acceptance etc.

The IP and tangible property rights (e.g. germplasm, clones, expression vectors, computer software, equipment) surrounding BFA can be highly complex involving products, processes and components, and knowledge of variables such as owners, who controls them, how they were obtained, whether they were purchased or licensed (Kowalski *et al.,* 2002.). Other aspects like where the product will be produced, whether it will be used for national production and consumption and/or enter international trade must also be evaluated as must the IP laws of all the potential countries concerned.

Unravelling this complexity by deconstructing each component and method followed by identifying all the potential patents, PBR and licenses relating to each in order to conduct a product clearance analysis and determine freedom to operate (FTO) requires considerable IP management skills and access to patent, PVP and other databases as well as the scientific literature. For individual scientific tools, the task is relatively straightforward; for single gene expression systems it is arduous; for stacked or multi-gene systems, it becomes an enormous task-made all the more difficult by the "time lag" between what is contained in a patent or PVP database and what is actually protected through filing. Unravelling the complexity of product clearance for FTO in relation to Golden Rice exemplifies that challenge (Kryder, Kowalski and Krattinger, 2000).

In conducting a product clearance for a GMO, breeders must also clarify the IP rights in the germplasm used to produce transgenic materials. The plant cells used for genetic modification are often from lines or varieties that are not suitable for growing in the intended location and therefore the transgenes have to be backcrossed into agronomically more suitable germplasm.

Without seeking the owner's permission

- Using gaps in patent and protected variety jurisdictions

Patents are only valid in countries in which they are registered and under *sui generis* laws, plant varieties are only protected in the country issuing the PVP certificate or PBR and in other countries that are members of the same UPOV Act. One option therefore is to use the research tool or technology (e.g. a transformation or selection tool, specific transgene, molecular marker, or novel variety) without seeking the owner's permission. This option is legal in those countries where the particular patent or plant variety is not registered. Many current and important biotechnologies (both research tools and finished technologies) appear to be unprotected in all but a relatively small number of developing countries (major exceptions in the countries covered here would be large producers and/or exporters of cotton, maize, and soybeans and derived products such as Argentina, Brazil, China, India, South Africa i.e. countries with Type I NARS, but also some of those with Type II NARS.

There are, however, legal and technical caveats to this option:

- that the use of the material in laboratory, greenhouse and/or field settings and/or products derived from biotechnology (plant, animal or micro-organism, food and feed products) is covered by other relevant national laws (e.g. seed, environmental/biosafety/plant protection, animal health and/or food safety);

- that any product derived from the proprietary technology is not exported to a country where the invention is protected (i.e. establishing freedom to trade is also important); this would require systems to segregate production and these may be logistically impossible in many situations;

- that even where a technology is not legally protected in a particular jurisdiction, if a patent or PBR has been granted on a tool, technology or variety that means it is under IP protection in the owner's country.

Research institutes should therefore seriously consider the option of requesting permission as, most likely, the owner would be prepared to make it available (subject e.g. to agreement on liability issues or a stewardship plan), particularly for developing countries with Type II and Type III NARS working on staple or orphan crops, and possibly also for use within small/subsistence production systems. The advantage of this approach is that it encourages partnership and access to the "know how" needed for facilitating adaptation of the technology to the laboratory or field conditions of the requester.

There have been several instances of IP-protected GMOs entering, being used and exported from countries that lacked biosafety or other relevant (e.g. seed) legislation. Also, while public research institutes in some developing countries are increasingly engaging in crop transformation activities using genetic constructs developed nationally or by multinational companies (Cohen, 2005), the FTO status of these materials is unclear e.g. whether their use for research is itself legal, restricted to research, and/or may be extended to commercialization and trade activities.

From Cohen (2005), it is also clear that few transformation events have moved out of laboratories or greenhouses into farmers' fields. Whether this is due to concerns about potential litigation for patent infringement, weak scientific, research and breeding capacity, lack of partnerships for delivery to end users, biosafety and/or related trade issues is a matter of speculation. Cohen and Paarlberg (2002) believe the last of these to be the main constraint to the approval and availability of GM crops in developing countries. The reasons, however, are both more complex and context-specific than that – an additional factor being the general lack of a clear strategy and expertise on moving products from laboratories to farmers at the domestic level and from there, to marketing and export of commodities (FAO, 2002).

Regarding the trade dimension, Binnenbaum *et al.*(2000) examined the production and trade patterns between 168 developing countries and 29 developed countries for the 15 staple crops that are most important for food security in the developing world. Their analysis revealed that exports from developing to developed countries constituted less than 5 percent of the total production and consumption in developing countries; that the value of these exports was concentrated in only four crops i.e. bananas, soybeans, rice and coconuts, and that these came from very few countries (Costa Rica and Ecuador for dessert bananas, Brazil and Argentina for soybeans, Thailand for rice and the Philippines for coconuts). Further, the bulk of these exports was to Western Europe (64 percent) followed by the USA (16 percent) and Japan (11 percent). The data also showed that for other crops covered by the CGIAR centres, the share of developed country imports originating from developing countries varied from around 90 percent (in the case of cassava, chickpeas and groundnuts) to figures ranging from 5-40 percent for wheat, maize, barley, sorghum, millet, lentils and beans.

The implication of these findings is that *for now*, and at least with respect to food/feed crops, constraints to FTO in developing countries are most likely to occur with soybeans and their processed products, but could well become more serious if, and when, additional staples and products produced through or derived from advanced biotechnologies in developing countries enter international trade. *They also indicate that IPR established in foreign countries should not be a major stumbling block to the pursuit of either R&D or commercialization of BFA in most developing countries.*

- Using the research and experimental use exemption within national legislation

The generality of the criteria, and vagueness regarding the scope and nature of exceptions in IP laws for using other peoples' proprietary technology, makes it difficult to interpret rights and obligations. For example, defining the scope of a "research tool" or the cut-off between "basic" and "applied" research or between "research" and "development" is fraught with difficulty. A rice line with resistance to a bacterial pathogen is a research tool. It can be used as a breeding tool by some, but to biotechnologists it is source material for mapping, sequencing and cloning the gene coding for the resistance trait, and subsequently for the grant of a patent on the gene sequence. Through an exclusive license negotiated with the patent owner to a company it then becomes a

research tool for a commercial company to develop pest-resistant GM crops (and to gain access to the gene, the developers of the original rice-resistant line would have to negotiate conditions for using the gene sequence for furthering its own applied research).

In some jurisdictions, the present position is that experimental use exception to patent rights is very narrow and that even projects undertaken without direct commercial application could be perceived in law as furthering an institute's legitimate business interests by undertaking projects that, in using proprietary IP, serve to increase their status and attract research grants, students and faculty. Most national laws permit private, non-commercial/industry and experimental uses, although there is lack of clarity about whether experimental uses include work done for commercial and industrial purposes.

In short, the situation with respect to the experimental use exemption within both national and regional arenas is far from clear. Researchers and breeders therefore tend to assume that when carrying out research with no direct commercial goal, they need not worry about the IPR of others because research done for purely academic or experimental purposes or under a government contract is thought to be protected from infringement due to an experimental use exemption.

Of course - and perhaps due also to the plethora of patents surrounding both upstream and downstream biotechnology discoveries - some scientists and their organizations simply "turn a blind eye" towards respecting other peoples' IP rights. In practice, both they and those who invoke the research exemption probably expose themselves to little risk of being pursued in the courts by doing so because (a) patents and PBR on research tools are rarely enforced, (b) infringement is hard, if not impossible, to detect, (c) private companies are generally loathe to pursue non-profit research institutes for infringement, and (d) as described earlier and below there are solutions to directly using or acquiring the rights to practise proprietary biotechnology innovations (Walsh, Arora and Cohen, 2003).

Appropriate courses of action to follow for building and retaining trust (as well as funding) within national scientific, breeding and commercial establishments could be:

- for governments to ensure an appropriate exemption for research directed towards providing public goods e.g. for crops grown and traits important to small-scale subsistence farmers;

- for research funding organizations and implementing institutions to be aware of their legal rights and to develop general and specific policies, strategies and operating procedures that set the conditions and obligations for both protecting (and sharing) their own IP and for using technologies and resources developed by others; and

- as a "rule of thumb" for those working in the BFA arena at both R&D and commercial levels, to determine whether the permission of the owner(s) is needed to use the material(s) in question i.e. whether there is FTO.

With the owner's permission

Byerlee and Fischer (2001) outline options available to research institutes to use BFA with the owner's permission. These include MTAs, licensing agreements, purchasing outright, PPPs, public sector partnerships, patent pools and open source licensing:

- Material transfer agreements (MTAs)

They are likely to remain the main mechanism for accessing (and providing) BFA for non-commercial uses, although researchers seeking access to genetic resources in another country (and sometimes also in their own country) may have to contact the National Biodiversity Authority to obtain the agreement of the provider on the transfer, and clarify the conditions under which the transfer and use are authorized. The MTA may include provisions on whether IPR can be sought and under what conditions i.e. joint ownership of rights arising from inventions derived from the resources, preferential access to any technology developed, or monetary or non-monetary benefit-sharing arising from their use.

- Licensing agreements

The main difference between licensing agreements and MTAs is that usually the recipient (licensee) is granted the right to make, use and /or sell the technology in question. However, they are also widely used for obtaining access rights to bioinformatics databases and for using computer software. Like MTAs, these agreements will define the property to be licensed, field(s), and sometimes the territories of use. They can also define use within regions of countries, type of farms by size, products and income levels and therefore (in theory at least) provide access or preferential access to small-scale and subsistence farmers. If the technology is covered by a patent, the subject matter of the licence can be for the product (e.g. a new micro-organism) and/or for the method of using it to manufacture/process something e.g. an enzyme, biopesticide etc. Although access to public bioinformatics databases may be free or based on a modest subscription, payment of royalties to the licensor is the norm, the cost of which varies enormously depending on the status of the licensee (public, SME, MNC), and the perceived value of the invention or data.

- Purchasing outright

This needs skills in technology valuation. Although there are models available for valuing some BFAs (Nadolnyak and Sheldon, 2002), the high volatility in returns from marketing many biotechnologies renders this option less appropriate than MTAs and licensing for obtaining tools and products, especially for smallholder farming situations.

- Public-private sector partnerships (PPPs)

As noted earlier, there is increasing recognition in developing regions of the importance of collaboration between public institutions and private firms for applying biotechnologies to improve fundamental biological knowledge, agricultural productivity and the livelihoods of farming communities. Government policy in both developed and developing countries has therefore moved (decisively in some instances) to bring biotechnology R&D closer to filling perceived market failures, resulting in a diverse set of institutional arrangements for fostering partnerships between the public and private sectors and within the public sector itself at both national and international levels. These include university and NARES-industry collaborations, government grants to support technology development and commercialization, and global partnerships in BFA.

For governments, the motivations include increasing the competitiveness and social welfare benefits of the agriculture sector, reducing market failures in both knowledge (through basic S&T research which is risky and long-term) and consumer surplus spillovers (product and process development where profits will not be sufficient to cover the costs of R&D), and improving the mission orientation of their research and innovation systems by sharing costs and risks. For the private sector, motivations can range from gaining access to knowledge, technology and markets that would otherwise be difficult to tap, to showing that the company can deliver something useful or is simply a good corporate citizen. Potential risks to participants include conflict of interest, losing public trust or control of proprietary technology, compromising missions etc., and there are context-specific challenges concerning governance.

A flavour of the wide range of relevant ongoing PPPs can be obtained from presentations at the recent Crawford Fund Annual Conference that explored ways in which the private sector can engage in international agricultural research, development and extension to the benefit of the rural poor (www.crawfordfund.org/conference/2009/ppt.htm). One of these is the Hybrid Parents Research Consortium (HPRC), initiated by ICRISAT and private sector seed companies in 2000 as a R&D partnership for improving the availability of seeds of high yielding cultivars. It was the first PPP arrangement in the CGIAR system, and ICRISAT has now partnered with many private sector seed companies in India, Indonesia, Egypt and Mexico through the HPRC to deliver its improved sorghum, pearl millet and pigeonpea hybrids to poor farmers. As a member of the CGIAR, ICRISAT adheres to policies concerning the transfer of germplasm in line with the CBD and the agreement between the CGIAR centres and FAO by which designated germplasm held in-

trust for the world community is made freely available through the Standard MTA under the ITPGRFA (Gowda *et al.*, 2004).

There are a variety of options available to promote partnerships with the private sector and with other public entities in both research and commercial undertakings on pro-poor BFA without, or with limited, complications arising from IPR. These could be more actively explored by research institutions and funding bodies in industrialized and advanced developing countries committed to assisting countries that do not have strong scientific capacities, by the CGIAR centres, and by countries where small-scale and subsistence farming involve primarily staple and non-export crops. They include:

1. Negotiating royalty-free access to proprietary genes, genetic constructs, and germplasm.

There is increasing evidence of the willingness of MNCs to donate proprietary biotechnology with no, or limited, restrictions on FTO. This should be recognized as a step in the right direction. Recent examples include:

- Syngenta has committed to provide its technology royalty-free to benefit subsistence farmers in developing countries. It has also stated that it will not pursue patent protection for any plant biotechnology or seeds invention for private and non-commercial use in least developed countries (LDCs). Furthermore, IPR related to the rice genome will not be enforced in LDCs for non-commercial use by subsistence farmers (www.syngenta.com/en/corporate_responsibility/syngentathinks.html).

- Monsanto and Syngenta have provided royalty-free licenses to the Golden Rice Humanitarian Board for technologies that can help further the development of pro-vitamin A (beta carotene) enhanced rice;

- Monsanto and BASF are partners in a large project on Water Efficient Maize for Africa (WEMA) being funded by the Bill and Melinda Gates and Howard Buffet Foundations with the participation of CIMMYT and a number of NARES in Africa (www.monsanto.com/droughttolerantcorn/WEMA.asp). They will provide proprietary germplasm, transgenes and advanced breeding tools without royalty for the research, and any products developed will likewise be made available to small farmers without royalties; and

- the US agricultural biotechnology company Arcadia Biosciences Inc. has agreed to provide compensation-free technology for the development of nitrogen use efficient and salt tolerant rice for Africa (www.aatf-africa.org/newsdetail.php?newsid=100).

2. Using the services of third party brokers.

A number of organizations and advanced research institutions work to facilitate the transfer of proprietary tools and technologies and related knowledge from private companies to public sector institutes with a focus on Africa, pro-poor crops and livestock diseases. Best known of these are:

- *The African Agricultural Technology Foundation (AATF)* based in Kenya which was set up to facilitate and promote public-private partnerships for accessing and delivering appropriate proprietary agricultural technologies for use by resource-poor smallholder farmers in sub-Saharan Africa (www.aatf-africa.org/about.php?cat=2&subcat=3). It is a “one-stop-shop” that provides expertise and know-how to facilitate the identification, access, development, delivery and use of proprietary agricultural technologies. It is backed by a number of donors, including the Rockefeller Foundation, the UK Department for International Development (DFID), the US Agency for International Development, the Bill and Melinda Gates Foundation and the Buffett Foundation, and engages actively with CGIAR centres, NARES, local and international seed and biotechnology companies, and is involved in most of the African initiatives on PPPs described above.
- *The International Service for the Acquisition of Agri-biotech Applications (ISAAA)* which was established to deliver the benefits of new agricultural biotechnologies to the poor in developing countries (www.isaaa.org/). Best known for its annual report on the global status of

commercialized GM crops, this organization also facilitates the transfer of proprietary technologies from the private sector in industrial countries for the benefit of subsistence farmers and the poor. It has been particularly active in the area of tissue culture for bananas and cassava in East Africa.
- *The Public Intellectual Property Resource for Agriculture (PIPRA)* which assists developing countries to access new technologies by reducing IP barriers to cooperation among public sector institutes for improving staple and speciality crops, and facilitating the transfer and adoption of their technologies by resource-poor farmers (www.pipra.org/).
- *GALVmed* which is an alliance of public, private and government partners established in 2005 to make livestock vaccines, diagnostics and medicines accessible and affordable to developing countries, primarily in Africa. It is funded by the Bill and Melinda Gates Foundation and DFID (www.galvmed.org/). It is part of a task force led by AU/IBAR to facilitate the registration and commercialization of a tissue culture-derived vaccine for East Coast fever that is presently produced by the International Livestock Research Institute (ILRI) in Kenya and to transfer vaccine manufacture and distribution to the private sector.

Given the limited understanding of IPR within NARES and how to access proprietary tools and technologies, these organizations clearly have considerable potential for filling an important gap. They have also been successful in brokering royalty-free licenses for particular technologies (gene constructs and varieties) and thereby provided opportunities for R&D training and capacity building in many essential aspects of project planning and implementation that otherwise would not have been available. Some technologies have moved from the laboratory to the field, but due to a combination of regulatory delays (biosafety and seed certification) and some other work being early stage research, the contributions of these projects to technology development, improved productivity and poverty reduction remain to be determined. One significant up-coming challenge for all these projects will be ensuring dissemination of the products according to the humanitarian use requirements of the tool and technology providers.

Other issues surrounding PPPs are covered in more detail by Hartwich, Gonzales and Vieira (2005) who studied 124 cases of PPPs in Latin America including a number dealing with basic and applied plant breeding. Their analysis indicated that when entering into these partnerships, public sector priorities and goals are not sufficiently addressed. Hence, while there can be no question that PPPs in BFA are an interesting approach to development and there are many promising initiatives, outside of India and Brazil convincing evidence is still lacking about the success of such partnerships in terms of products in widespread field use or employment e.g. by government plant and animal health services.

- Public sector partnerships

There are numerous examples of BFA partnerships between public sector entities involving different combinations of actors. These can include partnerships between national institutes, partnerships involving one (or a number of) NARES and individual or teams of CGIAR centres, sometimes also involving advanced research institutes in developed countries.

- Possibly the best example of a purely national effort leading to commercialization of products is the *Bt* cotton varieties developed using a modified *Bt* fusion gene (Cry lab and Cry lAc) by the *Chinese Academy of Agricultural Sciences.* This organization has also now developed *Bt* hybrid cotton which is distributed through state-owned county, prefectural and provincial seed companies and has also recently been approved for cultivation in India;

- The second type of institutional constellation is best illustrated by the *CGIAR's Generation Challenge Programme* (www.generationcp.org/) which brings traditional and advanced biotechnologies to bear on 12 target crops and 7 crop-trait combinations (with a major focus on drought tolerance) for developing tools and technologies that help plant breeders in the developing world to produce better crop varieties for resource-poor farmers. This uses a network of over 170 institutes in all regions of the world, and a cornerstone of the Consortium Agreement

and project contracts is the provisions on IP requiring outputs to be released as public goods, enabling scientists in developing countries to readily use elite genetic stocks and new marker technologies in their breeding programmes. However, a recent review of the programme has shown that these terms are not always respected, and that ways need to be found to compel compliance to the contractual documents, including ultimately requiring reimbursement of funds from partners who fail to live up to their obligations (Woolley *et al.*, 2009);

- The *CGIAR's Harvest Plus Challenge Programme* operates along similar lines, but different IP arrangements. It involves consortia of donors and over 200 agricultural and nutrition scientists in the task of developing (through conventional breeding) staple crops like beans, cassava, maize, pearl millet, rice and sweet potato which are biofortified with vitamin A, zinc and iron (www.harvestplus.org/content/about-harvestplus). In this programme, individual research partners can take out patents on their own discoveries, but they must make their results freely available in the public domain for use in developing countries;

- The *FAO/IAEA Coordinated Research Projects* organized and funded through FAO's Joint Programme with the IAEA (www-naweb.iaea.org/nafa/index.html) are other examples. These bring together public sector research institutes in developing and industrialized countries to develop and validate BFA tools and products needed to improve understanding or solve particular constraints to agricultural development. Prominent examples of technologies developed or validated and subsequently widely applied in developing countries are mutations (using radiation and targeting induced local lesions in genomes, TILLING) combined with molecular markers to develop new varieties of food and industrial crops, and immunoassay and molecular diagnostic tests for rinderpest, foot-and-mouth disease and brucellosis, the first of these being used to support the Global Rinderpest Eradication Campaign. Here again, contributors to these projects agreed to release products and other information without IPR restrictions; and

- In line with its mandate, *ICGEB* has adopted IP policy guidelines stating that "access to intellectual property rights concerning the results emanating from the research work of the Centre shall be granted to members and to developing countries that are not members of the Centre in accordance with applicable international conventions" with the objectives of (a) promoting the development, production and wide application of biotechnology in the interests of developing countries, (b) promoting the transfer of technology and know-how to its member countries, and (c) overcoming the difficulties encountered by developing countries in fostering innovation, ownership and in-house application.

With Brazil, China, India and to a lesser extent South Africa now heavily engaged in front-line fundamental and applied R&D and commercialization, and increasing numbers of developing countries beginning to enter the scene in specific niches, the scope for further globalization of partnerships between public sector institutes in BFA at all levels of activity is likely to increase substantially in the years ahead. Also, irrespective of their institutional makeup, with ever-increasing pressure on public budgets, partnerships are the way to maintain and even increase support for key public goods programmes.

- Patent pools

These are agreements between two or more patent owners to license one or more of their patents to one another or third parties. They have the potential to reduce problems caused by "blocking" patents, and to reduce significantly the transaction costs associated with licensing e.g. by providing a "one-stop-shop" for obtaining licenses essential to a core technology. At present, patent pools are of greatest relevance to commercial organizations which hold bundles of patents. Nevertheless, it would be surprising if there were not greater opportunities for public sector organizations to pool or combine their IP portfolios - proprietary and non-proprietary - based on mutually complementary assets, with a start being made by the CGIAR and by some groups of developing countries.

- Open source licensing

The Biological Innovation for Open Society (BIOS) initiative developed by CAMBIA provides open source licensing (www.bios.net/daisy/bios/home.html). It is based on the idea of a protected commons for making and using improvements to licensed technology for research or commercial purposes through a web-based meeting place for scientists. Anyone can obtain a free license to the technology, but they have to agree to put any improvements back into the licensing pool. Examples of technologies developed through this approach are Trans-Bacter™ which is a technique for transferring genes to plants using a plasmid containing a new T-DNA sequence that allows gene transfer into non *Agrobacterium* strains, and GUSPlus, a new reporter gene for sensitive visualization of gene transfer.

While there certainly appears to be a great need for this kind of operational mode, one constraint is the sheer number of patents to circumvent if an end product is to be brought to market. For researchers interested in more upstream knowledge generation and making more options available, the approach has many merits, although as noted earlier, patents are not an issue because most large biotechnology companies do not enforce their patents for research purposes and increasing numbers appear increasingly unlikely to do so when these are applied for humanitarian uses.

Potentially useful as all the modalities described above may be, it must be emphasized that it is not simply patent information or access to an IP-protected tool or product that is important for successful technology transfer. Essential also is the associated "know-how" which many owners of IP continue to guard carefully, and which can only be accessed through appropriate MTA or licensing agreements.

Establishing legal or institutional structures and intellectual property and knowledge transfer policies

Virtually all research institutes and universities in industrialized countries dealing with BFA have established Technology Transfer Offices (TTOs) staffed by people trained in advising on and processing IP applications as well as with the negotiation and business skills for securing agreements with third parties seeking access to the products in question or holding IP on products considered relevant to furthering the research or commercial interests of the institution housing the TTO. These offices also deal with non-proprietary assets e.g. textbooks, training manuals, software, audio-visual material etc. In some cases, public institutions have allowed/encouraged their staff to engage in the creation of spin-off companies.

Typically, a well-functioning TTO provides support to institutes and their scientists on all aspects of IP including creating awareness of IPR-related issues through: seminars and individual contacts; providing access to PVP and patent literature; assessing the market potential of an invention and the best way of protecting it; drafting and filing patent applications and managing the financial arrangements; negotiating the terms and conditions of MTAs, licensing and confidentiality agreements; and finding commercial partners.

.In response to changes in their laws that allow commercialization of inventions from publicly-funded R&D, a few agricultural ministries and research organizations in developing countries, most notably the Chinese Department of Agriculture and the Indian Council of Agricultural Research (ICAR), INTA in Argentina and EMBRAPA in Brazil, and the South African Agricultural Research Council (ARC) have followed suit. These are all large organizations operating many centres, and they have substantial investments in biotechnologies, breeding (of crops and animals) and seed production and distribution.

Both EMBRAPA and ICAR have legal authority to manage their own IP portfolios and technology transfers (relating mainly to both patents and *sui generis* PVP and copyrights) in conformity with existing national IP laws and other related laws/rules; ICAR even registers its own patents and PVP certificates. In the case of the ARC, IP management is through an Institutional Intellectual Property Management Office (IPMO) which works under the umbrella of

a National IPMO which was set up to harmonies IP management across all institutes supported through public funds and which deals with patent applications from these institutes.

At the international level, the CGIAR has a Central Advisory Service on Intellectual Property (CAS-IP) to assist its Centres and their partners (primarily the NARES) in managing intellectual assets as public goods. Individual Centres also have staff responsible for negotiating agreements that are within overall CGIAR policy guidelines.

Irrespective of the above, policy-makers should be aware of the following potential issues regarding commercializing IP assets within the public sector:

- there is the risk that the focus of BFA research shifts to private research interests at the expense of tackling issues with a predominant "public goods" value (i.e. from more upstream to near-market, and from species and traits important to small and resource-poor farmers to those of interest to export and commercially–oriented operations). It is important therefore that the principles for seeking protection and for managing biotechnology IP and wider assets further the mission of the institute i.e. foster both access and diffusion of their proprietary and non-proprietary assets to the poor and food insecure; and
- the ability to obtain royalties from licenses to third parties for protected varieties and other biotechnology materials, from outright selling of other intellectual assets, contracts, consultancy fees etc. can potentially raise revenue for the institute and/ or scientists involved.

Many commentators mention this second possibility. But, except in the highly unlikely event of a "blockbuster", licensing protected assets will not be sufficient to cover the costs of seeking, maintaining and licensing patents relating to BFA. Figures from the USDA illustrate this point (Day-Rubenstein and Heisey, 2005). Of the 270 active licenses negotiated by that organization in 2003, only 56 generated royalty income which had a median value of US$ 3 102. The widely quoted example of EMBRAPA which reputedly earns several million US" annually in royalties (mainly through licensing its crop cultivars to local and multinational or joint venture –owned seed companies, including for the production of GM seeds) is clearly an exception. This derives mainly from its direct and indirect involvement in seed production and the fact that its income is overwhelmingly generated from seeds of the country's dominant agricultural export (soybeans). Few other developing countries have agricultural research organizations holding such key roles in R&D, outreach and (indirectly) global commodity trade.

Less clear also is whether the earnings from EMBRAPA and indeed for all other TTOs are net of the costs of running their operations, and whether as has happened elsewhere (Rozelle *et al*., 1999), success in raising money through commercial activities leads to reduced funding by government on agricultural R&D.

- the main benefits of licensing proprietary technology are (a) the potential to facilitate technology transfer when a private partner is needed while reserving the rights of the public sector to deliver that technology to farmers who otherwise couldn't afford it i.e. as a means of market segmentation, (b) as a "bargaining chip" to access technologies owned by others, and (c) as an entry point into global or regional research consortia, often involving the sharing of research tools for non-commercial purposes.

Countries, large and small, industrialized and developing should not dismiss the option of exploiting the IP of their research institutes by publicly disclosing details of innovations though "*defensive publication"* (Adams and Henson-Apollonio, 2002). Defensive publication and patenting share the requirement for novelty but since a published description of the research product is available, it can no longer be called new and therefore patent-worthy. Defensive publication effectively prevents competitors and possibly even the originating scientist from patenting an identical or similar innovation. This strategy is especially useful for innovations that do not warrant the high legal costs and fees for patent applications, for public sector agricultural research institutes working on pro-poor issues and for keeping innovations in the public domain free from fear of patent infringement.

Before embarking on the complex and expensive business of applying for IP protection in the first place and establishing TTOs for managing such protection and accessing the proprietary assets of others, developing countries and their public sector institutes should therefore be clear about both the underlying rationale and the policies they will follow in implementing these tasks. Making such decisions should be underpinned by conducting and maintaining an inventory of the assets within both the public and private sectors irrespective of whether these are or may be covered by IPR. Only in this way can governments and institutes determine how best to use these assets to achieve their mission and goals and to develop partnerships for R&D and commercialization even if the national legislation excludes IP protection of life forms.

In some (very few) developing countries these complementary assets are substantial, extending from capacity to develop new research tools and gene constructs through to producing, multiplying and distributing GMOs, considerable capacity in structural and functional genomics, strong characterization and breeding programmes and an active private sector etc. In some others, the assets may be e.g. knowledge about local germplasm, breeds, diseases etc., technical expertise and facilities for applied breeding and running evaluation trials, cell culture for vaccine production and running vaccination campaigns, seed multiplication and delivery through extension services and/or local companies. *But in the majority of developing countries, particularly where potential private sector partners are essentially non-existent, discussion of IPR in relation to BFA is largely irrelevant to the design of national research programmes.*

Institutes with significant R&D activities and other complementary assets should therefore develop IP/knowledge transfer policies as part of their long-term strategy and mission, publicize it internally and externally and establish a single contact point. The IP policy will require guidelines on aspects like: assets to be made freely available and those which need IP protection to keep them in the public domain; clear rules for staff and students regarding in particular the disclosure of new ideas with potential commercial value; the ownership of research results; record keeping; the management of conflicts of interest and engagement with third parties.

For knowledge transfer, policies are required on licensing including the financial and non-financial aspects of compensation, on the creation of spin-offs, making clear the management of relationships between the research institute, the spin-off company and the staff involved, and policies for sharing the financial returns from knowledge transfer income between the research institute (and/or relevant department) and the scientist(s) involved.

Principles also have to be developed for engaging in collaborative and contract research compatible with the mission of each party. In the case of PPPs, they should take account of the level of private funding and maximize the commercial and socio-economic impact of the research, maintaining an IP position that allows further academic and collaborative research and avoids impeding the dissemination of the R&D results.

For public sector research institutes whose mission is pro-poor agricultural development, the policy statements published by some of the CGIAR centres are good guides for informing their own scientists, stakeholders and the public at large on their position concerning the protection and use of their intellectual assets (available for CIMMYT at www.cimmyt.org/english/wps/obtain_seed/ipPolicy.htm and for ILRI at www.ilri.org/home.asp?CCID=83&SID=1).

Few developing countries have scientists, patent attorneys or agents who are sufficiently knowledgeable to bring the required depth and breadth of understanding in biotechnology, agriculture and law to the complexity and variety of tasks required for effective filing and management of modern biotechnology-related patents. Most do so by contracting this work out to third party management companies and centres especially for the needed specialized legal and business skills. For example, the biotechnology incubators and parks described earlier have established technology transfer and commercialization offices which, in addition to undertaking IP work for companies situated within the hub, take on consultancy work for public sector

institutions.

(v) Options for national and international research funding and development agencies

National and international S&T funding agencies and donors are essential catalysts of agricultural R&D and development, and with the advent of the genomics and proteomics era in BFA, the policies adopted by these organizations including the question of disposition of rights to IP arising from the R&D supported by them play a critical role in determining the policies, practices and behaviour of the research institutes and individual scientists that rely on funding from these sources. Some of these organizations have also proven to be highly influential in intervening on behalf of the public sector, to obtain tools, technologies and data of value or potential value to developing countries either free or on preferential terms from MNCs and other private sector entities.

At the national level, funding bodies have different roles in R&D. For example, through their "in-house" programme they can be leading producers and suppliers of new tools as well as users, and as sponsors of research in external institutes they have interests in how the recipients of their grants and their contractors obtain research tools from others and how they disseminate the tools developed through the work they support. As government agencies, they may also have unique legal authorities over how they manage their own IPR and what agreements they enter into to obtain research tools for their own programme.

Administrators in many funding agencies, research institutes and universities and many scientists themselves have noted the increasing complexity of the patent landscape and the burden that this is placing on the scientific endeavour in the fields of structural and functional genomics (proteomics, metabolomics etc) through patents on gene sequences, their protein products and methods to detect, produce, study or manipulate genes or proteins which is now widespread (The Royal Society, 2003).

This has raised concerns about the freedom of publicly-funded national and international agricultural research institutions to employ proprietary tools and technologies on reasonable terms for conducting both fundamental research and more applied R&D leading to products that benefit the agrifood sector because of a patent, or, more likely, an exclusive or other restrictive license on a patent. These institutions have also warned of the likelihood that as more knowledge is created and more patent applications are filed, impediments to the exchange of research materials may become more severe. And while they also recognize that IP protection (patents in particular) may be a valuable tool to provide incentives for the translation of research results into products that benefit society, their own general policies and advice to the scientists and institutions they support both directly and indirectly through grants and contracts and to other government funding agencies is to encourage sharing, believing this to be in the best interest of all science, both basic and applied.

A number of principles and practices are now presented as options for consideration by the scientific and development communities of all countries including private sector entities when developing and implementing policies, programmes and projects that incorporate advanced biotechnologies into agricultural R&D and development to benefit small-scale and subsistence farmers.

- encourage the free exchange of materials and data;

Nucleic acid sequences, including ESTs and SNPs, are fundamental for describing and understanding the structure, function, and development of agriculturally important plants, animals and micro-organisms. Although private industry retains sequence data relating to many agriculturally important organisms in proprietary databases, these firms should be encouraged, and public sector institutions required, to place such sequences in public data banks.

- ensure that grant applicants include in their proposals an explanation of their stewardship plans, as well as plans for the sharing and dissemination of research results;
- monitor the actions of grantees and contractors with regard to data and material sharing and, if necessary, require grantees and contractors to comply with their approved IP and data sharing plans;
- extend the "Bermuda Rules" that were agreed for the human genome project to the sequencing of genomes of organisms that are essential for agricultural production in developing countries. This means releasing within 24 hours all DNA sequences longer than say 1 000 base pairs to a public database and issuing a directive against patenting newly discovered DNA; and
- foster responsible patenting and licensing strategies

Whenever possible, non-exclusive licensing should be used when technologies owned or funded by public sector institutions are transferred to the commercial sector. This facilitates making broad enabling technologies and research uses of inventions widely available and accessible to the scientific community. Options include:

- ensure that proprietary or exclusive means of dissemination are pursued by recipients of grants and contracts only when there is a compelling need. Also, whenever possible, licenses should be limited to relatively narrow and specific commercial application rather than as blanket exclusive licenses for uses that cannot be anticipated at the moment;

- because of the complexity in determining FTO and the fact that most developing countries have little experience in managing IP, industrialized countries donating proprietary technology should conscientiously supply IP/IT-clean products (Kowalski *et. al.*, 2002);

- introduce explicit reservations of rights in commercial technology licenses to protect their own institutional objectives and support humanitarian applications (Bennett, 2007).

(vi) Final considerations

The formulation of appropriate IP legislation to deal with BFA, and the establishment of institutions to administer and make rational decisions about how to use it successfully as part of the "enabling environment" for biotechnology transfer, development and diffusion is a huge challenge and still very much "work in progress" for developing economies. The needs for training and capacity-building to deal with the wide scope, complexity and interplay between all the issues involved in ways that ensure public sector research remains focused on the social needs of the many rather than the financial interests of the few must remain paramount if biotechnology is to deliver on a pro-poor agenda.

2. Public awareness and participation

(i) Context

Until recently, decision-making about technology has been in the hands of NARES, working with their specific society groups – farmers, farmer cooperatives etc. However, agricultural biotechnologies (traditional and modern) will only fulfil their full potential if all relevant stakeholders have the opportunity to provide input to decision-making processes concerning their use. This means that the public's right to choose must be respected, not only about whether they want to grow or rear a particular kind of crop or animal and eat their products, but about the other options that may be open to them. In some cases, yield, growth or milk production will be a paramount consideration in their choices, but a host of others including economic, cultural, ethical etc. may also play a role. And of course, to make choices, farmers and consumers have to be informed and educated about the "pros and cons" of particular decisions, and they will only accept biotechnologies if they consider they are "good" for them.

(ii) Participatory biotechnology R&D and extension

The farmer and technology development "participatory" paradigm of planning and in some cases, implementing and assessing the benefits of particular courses of action came from the recognition that those targeted as potential beneficiaries of R&D projects should have a say in, and influence, priorities and strategies.. Other terms used are "bottom up" and "demand driven". Combined with similar approaches to providing extension services, these were designed to encourage scientists and extension agents to work with small-scale farmers when defining problems and finding solutions – in effect to make R&D and extension more responsive to their needs and priorities. The current plethora of "participatory" planning and implementation R&D projects and extension services (these now cover for plant breeding, integrated pest management, soil and water management, gender planning, assessment of organic agriculture, risk assessment for animal diseases like bird flu etc. etc), attests to how policies within many governments and funding bodies for organizing these services, have been transformed.

Such policies have not, of course, replaced the more traditional "top down" (and often "supply-driven") option. Here, a committee (chaired perhaps by the Permanent Secretary of the Ministry of Agriculture) is normally set up composed of senior ministry officials, research leaders within NARES and relevant universities including those located regionally, and key private sector and NGOs. Other ministries (particularly of S&T, Rural Development and Economic Planning) would also be appropriate participants, the aim being to optimize the match between technical and wider policy considerations.

Ideally, both approaches are needed (and in fact, usually practised) to provide balance, objectivity and transparency to government, ministerial or institutional decision-making.

Several constellations are possible for "participatory/bottom up" approaches (see e.g. Boerse, Bunders and Loeber, 1995; Cohen, Falconi and Komen, 1998; Puente-Rodríguez, 2007). Their common features are that they involve farmers, extension services, scientists, local or national policymakers and NGOs in identifying and prioritizing problems and finding solutions at grass roots levels that are amenable to R&D. Critical challenges include:
- establishing a multidisciplinary coordination team/steering committee with a wide policy, scientific and cultural background to support the process which involves substantial dialogue to reach common ground;

- supporting the process with "evidence-based" data and information obtained through one or a combination of the methods described below; and

- ensuring that the process goes beyond diagnosis and priority setting by involving the communities concerned e.g. in farm or village experiments to test new technology.

Another challenge with all these approaches is deciding on who participates and the manner and extent of their involvement. In setting up participatory priority setting, decision-makers have to establish criteria which should be guided by research objectives and proposed target groups which in turn will depend on whether the exercise is purely national or part of a wider regional or global programme with involvement of one or a number of regional research organizations, CGIAR centres, bilateral donors, banks and philanthropic organizations. In such cases, agreement has to be reached between the government or responsible ministry on participatory principles and administrative arrangements. Important here is to retain national ownership and identity.

Also, focusing on applications of biotechnologies through participatory approaches raises both opportunities and restrictions for all concerned. For farmers and their communities, if the programme being considered has to include a biotechnology, this limits enormously the scope for prioritization of problems and possible solutions. The same applies to scientists and policy-makers, who have the additional dilemma of deciding on the geographic or production system focus of operations (i.e. which poor farmers?).

Kenya (World Bank, 2008) and Bolivia (Hartwich and Jansen, 2007) provide examples of options for pursuing priority setting which can be suitably adapted to include biotechnology. In the case

of Kenya, the Kenyan Agricultural Research Institute (KARI) has an Annual Research Forum to set the national strategic research agenda, and a number of Research Coordination Committees to approve proposals, and Centre Research Advisory Committees to screen proposals at the national and regional research centres. The KARI Biennial Science Conference is where agricultural policy makers, researchers and the private sector participate and provide feedback on on-going research activities and identify emerging issues. The national and regional research centres identify research topics in consultation with various stakeholders in their districts including district agricultural officers, farmer groups and scientists in local universities and, after technical review meetings submit their recommendations to KARI headquarters. KARI is also now establishing a monitoring and evaluation system.

Bolivia, on the other hand, introduced the Bolivian Agricultural Technology System (SIBTA) by which government support to agricultural research and extension was partly delegated to regional semi-autonomous foundations with advisory boards. These work with organized farmer groups with legal status e.g. producer associations, community-based organizations or indigenous groups, and have been able to effectively identify and priorities the demands of small farmers and provide transparency and accountability on decision-making and funding. The government's roles through the Ministry for Rural and Agricultural Development are to provide strategic direction, develop national level priorities through inputs from regional foundations, regulations for funding mechanisms and in general to acts as a "one-stop-shop" for linkages to international R&D agencies.

(iii) Participatory policies for regulation of biotechnology

Extending participation into the realms of national and international policy-making on biotechnology is more complex, involving a much broader range of relevant stakeholders with more diverse and conflicting positions.

The importance of doing so was first recognized by policy-makers through Principle ten of the Rio Declaration on Environment and Development (1992), its essential messages being: the right of citizens to information held by public authorities, to participate in environmental decisions that affect them, and to have access to judicial and administrative proceedings, including redress and remedy. Noteworthy here is the linkage to biotechnology through UNCED's Agenda 21. Since UNCED did not carry the weight of international law, public participation on biotechnology matters only became a legal requirement when countries acceded to issue-specific instruments:

- to the *CBD through its Article 14.1* which *encourages* public participation in environmental impact assessment of proposed projects that are likely to have significant adverse effects on biological diversity;
- *the CPB which like UNCED, and through its Article 23,* lays out three areas: (awareness, education and participation) for involving the public in relation to GMOs and the conservation and sustainable utilization of biological diversity. It also requires Parties to cooperate, as appropriate, with other States and international bodies by endeavouring to inform the public about how to access national nodes of the BCH. Specifically, within their national laws and regulations (Article.23.2) *they are required* (a) to consult the public in decision-making processes while respecting confidential information, including on importing GMOs, and (b) to inform the public about any decisions made, and they should endeavour to include information about imported goods in the processes of public awareness and education (Mackenzie *et. al.,* 2003). In other words, the specific scope and methods for engaging the public have to be enshrined in national laws or regulations, and while there is a *requirement* to promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of GMOs in relation to the conservation and sustainable use of biological diversity**,** there *appears to be no requirement* to provide for public participation in decisions concerning importations, although of course countries are free to include that requirement in national legislation.

- *The Aarhus Convention* (www.unece.org/env/pp/treatytext.htm). Its full title is the United Nations Economic Commission for Europe's (UNECE) Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (UNECE is one of five regional commissions of the UN and has 55 Member countries from North America, Western, Central and Eastern Europe and Central Asia). Although a UNECE Convention, it has a global significance as it is also open to all non-UNECE States which are members of the UN. This is the most recent and comprehensive international agreement relating to public participation, adding much "meat" to government obligations. At their 2nd meeting in Kazakhstan in 2005, Parties to the Convention adopted an amendment aiming to strengthen the rights of the public to participate in decision-making on GMOs. The amendment, which enters into force when it has been ratified by three fourths of the Parties, would require the Parties to inform and consult the public in decision-making on the deliberate release and placing on the market of GMOs. The public would have the right to submit comments and the public authorities would be expected to take these into account in the decision-making process. Once made, the decision taken should be publicly available together with the reasons and considerations upon which it is based. Excepting cases of commercial confidentiality, information associated with GMO decisions would be made available to the public i.e. Parties could not withhold as confidential, information on the intended uses of the release or on the assessment of environmental risk (www.unece.org/press/pr2005/05env_p06e.htm). The amendment requires that the provisions made by Parties be complementary and mutually supportive with their approaches for meeting the objectives of the CPB.
- Likewise with food safety, where the *Codex Alimentarius "Principles for the Risk Analysis of Foods Derived from Modern Biotechnology"* (mentioned earlier in this document) appear particularly relevant from the standpoints of public awareness and participation. On risk communication, it states: "Effective risk communication is essential at all phases of risk assessment and risk management. It is an interactive process involving all interested parties, including government, industry, academia, media and consumers. Risk communication should include transparent safety assessment and risk management decision-making processes. These processes should be fully documented at all stages and open to public scrutiny whilst respecting legitimate concerns to safeguard the confidentiality of commercial and industrial information. In particular, reports prepared on the safety assessments and other aspects of the decision-making process should be made available to all interested parties. Effective risk communication should include responsive consultation processes. Consultation processes should be interactive. The views of all interested parties should be sought and relevant food safety and nutritional issues that are raised during consultation should be addressed during the risk analysis process".

Codex standards are reference points for national implementation of the SPS Agreement, suggesting a clear linkage between public awareness and participation and this WTO trade agreement.

As noted in Section A, governments have two roles: (a) fostering community understanding/awareness about biotechnology including by improving access to understandable information, and (b) providing means by which citizens can express their views. This doesn't mean that they "go it alone", but rather that they create the environment/provide the incentives for others e.g. schools, universities, extension services, farmers' and business organizations, NGOs, CSOs etc. to take initiatives. And because biotechnology needs horizontal governance, this should include developing a "top level" strategy to which all ministries commit through a shared programme of work that includes agreement on the combination of mechanisms that can be realistically applied and financed in the light of national circumstances.

Since biotechnology is also a very broad topic, with intersecting thematic areas including biosafety, food and feed safety, consumer protection, intellectual property, seed certification, bio-ethics, as well as access to genetic resources and benefit-sharing, national capacity for fostering public awareness information sharing needs to extend to these topics. In the resource-constrained

environments within which all developing countries operate and given the reality that options for enhancing public empowerment need to compete for scarce funding, decisions may have to be made as to whether communicating e.g. to small-scale farmers about how biotechnology might improve crop or animal productivity should take priority over communicating to urban consumers the advantages of consuming food derived from these crops.

International agreements do not provide guidance on how the public should be informed, educated or engaged in decision-making processes, or how any decisions about GMOs would be communicated to the public. For providing information, obvious channels of communication include the internet, publications, radio, television, newspapers, workshops, public hearings, official bulletins, and even labelling of products, whereas education would be through public educational systems. Concerning public participation, this would depend on whether participation is "passive" i.e. meaning that information would be posted e.g. on the Government Gazette and a public register maintained by the Competent Authority and "feedback" required within say 30 days, or "active" i.e. involves sharing and communicating information and views through public consultations and hearings, the results of which would then be fed into decision-making and regulatory processes. Since most rural communities do not have access to the internet or understand the main international languages used in that and much print media, governments and their agencies, NGOs, CSOs and others will need to rise to the challenge of creating spaces for activities that foster public participation by these communities.

***(*iv) Coverage of public awareness and participation in national biotechnology policies/strategies and regulatory frameworks**

In national biotechnology policies/strategies

The survey of NBS documents showed that scientific and technical capacity-building in biotechnology from under-graduate through to PhD levels was a key element of essentially all national plans, and that in a few countries, efforts would be made to initiate awareness-building among schoolchildren. But apart from that, more than half of the national plans surveyed were either silent on public education/ awareness and on participation, or made only short generic statements to the effect that "civil society would be engaged", "public information/ education programmes would be set up" etc.

Noteworthy is that all policy/strategy papers that raised the issue of public awareness and participation were either vague or silent on the rationale for involving the public at all, and none defined whether such involvement would be (a) for developing wider policies, (b) confined to regulatory aspects, (c) purely advisory or entail involvement in decision-making, and (d) if the latter, whether this would be "arms reach" participation e.g. providing comments in writing or verbally which would then be fed into decision-making by people traditionally considered to be better qualified to make judgements e.g. scientists, regulators etc., or sitting at "the top table" and being directly involved.

Only two countries were more specific:

- *Chile* made public participation one of its "Flagship Initiatives" with thrusts to include ensuring dissemination of accurate and reliable information, particularly on regulatory matters, decisions based on ethical values as well as scientific principles, and a commitment to respect the value of considering different societal options; and
- *South Africa*, in recognizing the critical importance of public participation, outlined a number of specific strategies: (a) the Government would articulate a single vision of biotechnology so that it is not confronted with different opinions from different ministries and departments, (b) that public education campaigns on biotechnology would be initiated to give accurate information based on the inputs of various ministries/public sector agencies charged with supporting or implementing a particular initiative, (c) that biotechnology issues would be included in high school curricula to encourage debate on potential benefits, risks, and ethical and environmental issues, and (d) that the media would be provided with information representing all sides of debates on potential

benefits, risks and ethical issues. Further, it recognized that government on its own could not bring about fundamental changes in peoples' views/perceptions and therefore that support would be needed from the private sector, civil society and others to promote alignment between government objectives and the activities of other players.

- On further detail, only the Peruvian document provided any insight into the government or public sector structures that would be involved in leading or coordinating national initiatives in these areas. In this case, a National Forum on Biotechnology (FONABIO) would be established to connect citizens with up-to-date information on biotechnology, receive and respond to feedback and thereby create an environment of consultation and educated opinion. There would also be a Committee on Ethics to discuss, review and make recommendations to its regulatory authority on all aspects related to the promotion and development of modern biotechnology.

In national regulatory frameworks

Analysis of national regulatory frameworks provided little further insight on these issues. As noted earlier, in the majority of countries the main link between public awareness/ information and biosafety lay in the reference by many countries to labelling of GMOs and products. Given the considerable practical difficulties and cost of labelling - let alone of implementing the necessary systems of co-existence between GMO and non-GMO production and harvesting - making the public aware of the full implications of such a policy is a legitimate part of information sharing and awareness- building about modern biotechnology. Other frequently quoted mechanisms were through the BCH or national nodes of the BCH, providing information and requesting feedback through the Government Gazette and through national newspapers (e.g. Kenya and Zambia) on proposed releases into the environment (and in some cases even on laboratory/greenhouse research activities), and in one case (Namibia) by holding public hearings, the outcomes of which would be fed into higher level decision-making. Of the 15 countries surveyed, only five appeared to have consumer or farmer organization representatives on their national biosafety committees, and only two appeared to have civil society representation.

Noteworthy also were the confidentiality provisions in most of the national instruments (see Section B) but again, these were stated in generic terms and it was not possible to determine how countries would use them and whether they would restrict the public's access to relevant information for policy or regulatory decision-making.

Some Biosafety Laws/Acts did not cover food safety, raising questions as to whether opportunities for pubic participation of any form existed on this important issue within the countries concerned. On the other hand, as pointed out by Glowka, (2003) who examined public participation in policy-making and regulatory decision-making in a number of developing and developed countries, the lack of specific public participation provisions in a Biosafety Law does not necessarily mean that the public is barred from participation. Relevant environmental, consumer protection and other laws on public participation may already exist in a country and the criteria established in these would also be applicable for addressing modern biotechnology.

Concerning the BCH, the type of information envisaged includes applicable laws, regulations, guidelines, agreements with other countries, the results of risk assessments, decisions on imports and releases of GMOs as well as information on scientific and technical issues concerning dealings with GMOs. At the present time, the BCH contains relatively little information from developing countries, indicating that it may be some time before regulatory information can be shared electronically between countries to foster transparency. Also, it would seem appropriate for countries to use their national BCH nodes not just as a conduit for documentation and one–way dissemination of information on biosafety, but to extend this both to biotechnology as a whole and to encouraging feedback, discussion and debate amongst their citizens.

Also, making laws and regulations is one thing – implementing them is quite another. The extent to which public awareness and participation are actually facilitated or exist in a country is impossible to determine from a simple review of the country's biotechnology-related legislative

instruments. Fine legally-expressed words may not translate into actual participation if, as is clear for many of the national instruments examined, additional criteria are not provided on the form public participation may take. Also the best public participation provisions may not be used if the public does not have the capacity to participate effectively.

As pointed out by Glover (2003), and demonstrated through case studies of public participatory processes within a number of countries surveyed for that paper (Glover *et al.*, 2003) and others (Fransen *et al.*, 2005, CBD, 2009b), the way in which participation is practised in different countries depends on local contexts, perspectives and public concerns. These determine when and how transparency and public participation are demanded or considered politically necessary for decision-making as well as what participatory mechanisms are possible in different circumstances. In effect, because the issue of choice arises differently in different countries, there is no "one size fits all" or "toolkit" approach that can be applied everywhere.

Similar conclusions were reached through an e-mail conference organized by FAO on public participation in decision-making regarding GMOs in developing countries, which focused on how to effectively involve rural people (FAO, 2005). While there was broad agreement that citizens, including rural people, should be involved in decision-making when it is likely to impact on them, opinions on the degree and nature of the suggested participation differed, although many contributors felt that in many cases participation of the rural people could usually be indirect i.e. through their chosen representatives.

It was also felt that effective participation depended on access to unbiased and comprehensive information on the nature and consequences of GMOs, and that this information would have to be adapted to the needs and capacities of the various groups of rural people and their representatives in order for it to be helpful, and that it would have to be communicated effectively e.g. through extension services, radio; use of local languages was particularly emphasized. Many participants complained that misinformation abounded (both for and against GMOs) and some were quite sceptical that a real public participation exercise might take place on this issue and, if it did, that its outcomes would have any impact. Interestingly, international agreements were regarded as being useful, but concern was expressed that commitments to these agreements might compromise the outcomes of an eventual national debate on GMOs – a point that also emerged from the analysis of Glover (2003).

From the perspective of this document and although rarely articulated in the NBS documents and not mentioned in any NBF or regulatory framework examined, what is essential is that poor people must have a voice, that decisions on biotechnology do not further marginalize those already marginalized, and that citizens of developing countries are able to make their own choices rather than having these defined for them by donors. Also, as concluded by FAO's independent Panel of Eminent Experts (FAO, 2001b): "the right to food carries with it obligations on the part of States to protect individuals' autonomy and capacity to participate in public decision-making fora, especially when other participants are more powerful, assertive or aggressive. These obligations can include the provision of public resources to ensure that those fora take place in a spirit of fairness and justice".

3. Agricultural extension

One important issue that has been neglected in the biotechnology policy frameworks developed so far is that of agricultural extension. Lack of information and skills is one of the main reasons for the gap between potential and actual productivity/profitability of smallholder farmer systems, constraining the adoption of available technologies and practices and reducing their efficiency if eventually adopted (World Bank, 2007). For example, Guei, Somado and Larinde (2008)**.** noted that farmers in sub-Saharan Africa do not use improved seed because very often it is not available to them or they are not aware of its advantages. Good quality seed is also not accessible to smallholders because there is often a weak linkage between farmers, extension systems, research institutions and the market. In the recent e-mail conference organized as part of the build up to

ABDC-10, the weakness of the extension system was identified by participants as one of the reasons for the failure in adoption of biotechnologies in developing countries (FAO, 2009c).

Once biotechnology products are commercially available, extension services also play an important role in providing impartial information about them, as illustrated by Stone's (2007) analysis of adoption of *Bt* cotton in the Warangal district in India. Farmers there had difficulties in accessing reliable independent information about the new cotton seed as government-sponsored extension programmes were virtually non-existent and the most common source of information on cotton seed was corporate promotional material. An equally important role that a strong functioning extension service plays is channelling farmer needs into practical demands. By helping farmers to frame their demands (for improved seeds, for example) and then to organize the demand into an effective strategy (demands to governments, seed supplies, others), extension personnel can play a vital role in ensuring that products that are demanded are eventually supplied.

The term "agricultural extension" covers public and private sector activities relating to technology transfer, education, attitude change, human resource development, and dissemination and collection of information (FAO, 2009d). Over the last two decades, national agricultural extension systems have undergone dramatic changes, driven by forces such as the growth of the commercial farm sector, particularly in developed countries; trade liberalization, contributing to a rapidly developing global food system; as well as the perceived lack of success of public agricultural extension systems in many countries. National agricultural extension systems have therefore been in transition worldwide, with the major trends including the movement from single main public systems to pluralistic systems involving the private sector, public sector and CSOs; from centralized top-down systems to decentralized systems where decision-making is delegated to the district or field level; from systems that are entirely publicly funded to those in which an increasing amount of the financial support comes from the farmers themselves and where specific advisory activities/services are effectively privatized (FAO, 2008b). Further, extension systems are now focusing on being demand-driven and market-oriented. In practice, this means that farmers are not passive recipients of technology developed by researchers. Rather, it is the farmers' demand which should partially drive the research agenda and the educational and organizational work of the extension agents (Neuchatel Group, 2007). Similarly, research and extension interventions should respond to market conditions and market signals (Neuchatel Group, 2008).

In this dynamic situation, a shift of power may take place in some countries, but the role of government and government policy still remain significant. When and if the decision is made to reform agricultural extension, the government is faced with significant policy and strategy choices which will also indirectly impact the issue of farmers' access to the fruits of biotechnology R&D. As highlighted in Annex 2, the paradigm now in vogue for describing the process of agriculture development is that of an agriculture innovation system. It calls for rethinking the respective roles of those intimately involved in the agriculture knowledge information sub-system, namely research, extension, education and training. Fundamental questions raised by this evolving context include: how do farmers' specific demands for agricultural assistance impact biotechnology research and delivery?, what should be the goal of the extension services (e.g. production, transfer of new technologies, linking farmers to markets or helping farmers organize themselves into special interest groups around marketable products)?; and what should the government do to coordinate institutions that provide extension services (FAO, 2009d).

Specific national agricultural extension policies have been drawn up in a number of developing countries in recent years. China and India are two countries where major extension policy changes have occurred (FAO, 2008b; FAO 2009d). Common features of the extension changes in these and other countries are:

- progressive transition from public technology transfer to the private sector;
- enabling problem solving skills of farmers through an inter-disciplinary approach;
- public funds for private extension;

- provision for cost recovery and co-financing of extension via farmer organizations;
- reduction in the number of village level workers;
- use of para-extension workers and farmer interest groups for extension;
- employing more subject matter specialists;
- preparation of strategic research extension plans;
- improving the research-extension-farmer interface;
- skill development of extension agents;
- improving women's access to technology;
- linkage with agro-processors; and
- government as a facilitator and creator of an enabling environment.

The changes to extension systems and the new opportunities from biotechnology call for bringing researchers, extension agents, and smallholder producers and their organizations closer together. They also call for upgrading the skills of extension staff so they are both more capable of understanding the implications of biotechnology and of facilitating interactions between farmers and others involved in the agricultural knowledge information system.

D. References

Adams, S. & Henson-Apollonio, V. 2002. Defensive publishing: A strategy for maintaining intellectual property as public goods. *ISNAR Briefing Paper No. 53.* IFPRI, Washington DC. (available at www.cas-ip.org/publications/bp-53.pdf)

Alston, J., Norton, G. & Pardey, P. 1998. *Science under scarcity: principles and practice for agricultural research evaluation and priority setting*. CAB International, Wallingford, U.K.

Alston, J.M., Pardey, P.G. & Piggott, R.R. 2006. *Agricultural R&D in the developing world: too little, too late? In* P. G. Pardey, J. M. Alston & R. Piggott, eds. IFPRI, Washington, DC. (available at www.ifpri.org/sites/default/files/publications/oc51.pdf).

Anandajayasekeram, P., Rukuni, M., Babu, S., Liebenberg, F. & Keswani, C.L. 2007. *Impact of science on African agriculture and food security*. CAB International. London and Washington, DC.

Atanassov, A., Bahieldin, A., Brink, J., Burachik, M., Cohen, J.I., Dhawan, V., Ebora, R.V., Falck-Zepeda, J., Herrera-Estrella, L., Komen, J., Low, Fee Chon, Omaliko, E., Odhiambo, B., Quemada,H., Peng, Y., Sampaio, M.S., Sithole-Niang, I., Sittenfeld, A., Smale, M., Sutrisno, Valyasevi, R., Zafar, Y. & Zambrano, P. 2004. To reach the poor: results from the ISNAR-IFPRI next harvest study on genetically modified crops, public research and policy implications. *EPTD Discussion Paper No. 116.* IFPRI, Washington DC. (available at www.ifpri.org/sites/default/files/publications/eptdp116.pdf).

Beintema, N. M. & Stads, G-J. 2008a. Measuring agricultural research investments: a revised global picture. *ASTI Background Note*. IFPRI, Washington DC. (available at www.egfar.org/egfar/digitalAssets/1329_Global_revision_final.pdf).

Beintema, N. M. & Stads, G-J. 2008b**.** *Diversity in agricultural research resources in the Asia and Pacific region*. IFPRI and APAARI, IFPRI, Washington, DC. (available at www.apaari.org/wp-content/uploads/2009/05/asti-publication.pdf).

Bennett, A. B. 2007**.** Reservation of rights for humanitarian uses. *In IP Management in Health & Agricultural Innovation: A Handbook of Best IP Practices*, Chapter No. 2.1. (available at www.iphandbook.org/handbook/ch02/p01/).

Bijker, W.E. 2007. Science and technology policies through policy dialogue. *In* L. Box & R. Engelhard, eds. *Science and technology policy for development: dialogue at the interface*. London, UK, Anthem Press.

Binnenbaum, E., Nottenburg, C., Pardey, P.G., Wright, B.D. & Zambrano, P. 2000. South-North trade, intellectual property jurisdictions and freedom to operate in agricultural research on staple crops. *EPTD Discussion paper No. 70*. IFPRI. Washington, DC. (available at www.ifpri.org/sites/default/files/publications/eptdp70.pdf).

Biotecsur. 2008. *Catalogue of biotechnology patents in the MERCOSUR*. Biotecsur, Buenos Aires. (available at http://docs.biotecsur.org/informes/en/inventario/9_patentes_ms.pdf).

Birner, R. & Linacre, N. 2008. Regional biotechnology regulations: design options and implications for good governance. *IFPRI Discussion Paper 00753*. IFPRI, Washington, DC. (available at www.ifpri.org/sites/default/files/publications/ifpridp00753.pdf).

Boerse, J.E., Bunders, J.F. & Loeber, A.M. 1995. The interactive bottom-up approach to analysis as a strategy for facilitating the generation of appropriate technology: experiences in Zimbabwe. *Organization Environment* 9: 49-76.

Bovine HAPMAP Consortium 2009. The genetic history of cattle. *Science* 324: 529–532.

Bragdon, S. 2004. International law of relevance to plant genetic resources: a practical review for scientists and other professionals working with plant genetic resources. *Issues in Genetic Resources 10*. IPGRI, Rome. (available at www.bioversityinternational.org/fileadmin/bioversity/publications/pdfs/937.pdf).

Braunschweig, T. 2000. Priority setting in agricultural biotechnology research: supporting public decisions in developing countries with the analytic hierarchy process. *ISNAR Research Report No. 16.* ISNAR, The Hague. (available at www.sfiar.ch/documents/2001_markets/braunschweig.pdf).

Brookes, G. & Barfoot, P. 2005. GM crops: the global economic and environmental impact—the first nine years 1996–2004. *AgBioForum* 8: 187-196. (available at www.agbioforum.org/v9n3/v9n3a02-brookes.pdf).

Burachik, M., & Traynor, P.L. 2002. Analysis of a national biosafety system: regulatory policies and procedures in Argentina. *ISNAR Country Report 63.* IFPRI, Washington, DC. (available at ftp://ftp.cgiar.org/isnar/Publicat/cr63.pdf).

Byerlee, D. & Alex, G. 2003. National agricultural research systems: recent developments and key challenges. *Note prepared for the interim Science Council of the CGIAR*. FAO, Rome. (available at www.rimisp.org/isc/thinkpieces/individual/DerekByerlee.pdf).

Byerlee, D., Diao, X. & Jackson, C. 2005. Agriculture, rural development and pro-poor growth: country experiences in the post-reform era. *Agriculture & Rural Development Discussion Paper 21*, The World Bank, Washington, DC. (available at http://siteresources.worldbank.org/INTARD/Resources/PPG_final.pdf).

Byerlee, D. & Fischer, K., 2001. Assessing modern science: policy and institutional options for agricultural biotechnology in developing countries. *IP Strategy Today*, 1: 1-27.

CBD. 2009a. *Ad hoc* technical expert group on risk assessment and risk management. First Meeting, April 2009. UNEP/CBD/BS/AHTEG-RA&RM/1/1/Add.1 (available at www.cbd.int/doc/meetings/bs/bsrarm-01/official/bsrarm-01-01-add1-en.doc

CBD. 2009b. Special Focus: public awareness and participation: experiences and lessons learned from recent experiences. Biosafety Protocol News, Issue 6. Secretariat of the CBD. Geneva and Nairobi. (available at www.cbd.int/doc/newsletters/bpn/bpn-06.pdf).

Chandra, A. 2007. Business incubation in Brazil: creating an environment for entrepreneurship. *Working Paper 25 Networks Financial Institute*, Indiana State University. (available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1058901

Chaturverdi, S. 2005. Dynamics of biotechnology research and for industry in India: statistics, perspectives and key policy issues. *STI Working Paper 2005/6*. OECD, Paris. (available at www.oecd.org/dataoecd/43/35/34947073.pdf).

Chen, S. & Ravallion, M. 2008. The developing world is poorer than we thought, but no less successful in the fight against poverty. *Policy Research Working Paper 4703.* The World Bank, Washington DC. (available at http://go.worldbank.org/O47FIKM3Y0).

COGEM. 2008. *The new GMO debate: the clash between legislations*. Proceedings of a Symposium, 2 October, The Hague, The Netherlands.

Cohen, J.I. 2005. Poor nations turn to publically developed GM crops. *Nature Biotechnology* 23: 27-33.

Cohen, J.I., Falconi, C. & Komen, J. 1998. Strategic decisions for biotechnology: synthesis of four policy seminars. *ISNAR Briefing Paper No. 38.* IFPRI, Washington DC.

Cohen, J.I. & Paarlberg, R. 2002. Explaining the restricted approval and availability of GM crops in developing countries. *AgBiotechNet* 4: October, ABN 497. (available at http://joelcohen.org/pdf/RestrictedApproval.pdf).

Dargie, J.D. 2007. Marker-assisted selection: policy considerations and options for developing countries. *In* E.P. Guimarães, J. Ruane, B.D. Scherf, A. Sonnino, J. Dargie, eds. *Marker-assisted selection: current status and future perspectives in crops, livestock, forestry and fish*, Chapter 22. FAO, Rome. (available at www.fao.org/docrep/010/a1120e/a1120e00.htm).

da Silveira, J.M.F.J. & de Carvalho Borges, I. 2005. *An overview of the current state of agricultural biotechnology in Brazil*. Paper presented at a workshop held at Bella Villagio, Bellagio, Italy.

Day-Rubenstein, K.D., & Heisey, P. W. 2005. Can technology transfer help public sector researchers do more with less? The case of the USDA's Agricultural Research Service. *AgBioForum* 8: 134-142. (available at www.agbioforum.org/v8n23/v8n23a10-heisey.pdf).

de Janvry, A., Graff, G., Sadoulet, E. & Zilberman, D. 1999. *Agricultural biotechnology and poverty: Can the potential be made a reality?* Paper prepared for a conference on the shape of the coming agricultural biotechnology transformation: strategic investment and policy approaches from an economic perspective. University of Rome "Tor Vergata", Rome. (available at http://are.berkeley.edu/~sadoulet/papers/Biotech995.pdf).

Dhlamini, Z., Spillane, C., Moss, J.P., Ruane J., Urquia N. & Sonnino, A. 2002. *Status of research and application of crop biotechnologies in developing countries: preliminary assessment*. FAO, Rome. (available at www.fao.org/docrep/008/y5800e/Y5800E00.htm).

Dorward, A., Fan, S., Kydd, J., Lofgren, H., Morrison, J., Poulton, C., Rao, N., Smith, L., Tchale, H., Thorat, S., Urey, I. & Wobst, P. 2004. Rethinking agricultural policies for pro-poor growth. *Natural Resources Perspectives* 94: 1-4.

Echeverria, R.G. & Beintema, N. M. 2009. *Mobilizing financial resources for agricultural research in developing countries, trends and mechanisms*. GFAR, Rome. (available at www.egfar.org/egfar/website/gcard/updates/documents?contentId=2670&)

Falck Zepeda, J., Cohen, J. & Komen, J. 2003. *Assessing agricultural biotechnology in developing and emerging economies: the sustainable livelihoods approach*. *In:* Assessing agricultural biotechnologies in emerging economies. Proceedings of a Workshop on Biotechnology. OECD, Paris. (available at www.oecd.org/dataoecd/27/8/2955798.pdf).

FAO. 2001a. *Agricultural biotechnology for developing countries - results of an electronic forum*, by J. Ruane & M. Zimmermann. FAO Research and Technology Paper No. 8. Rome. (available at www.fao.org/DOCREP/004/Y2729E/Y2729E00.HTM).

FAO 2001b. *Genetically modified organisms, consumers, food safety and the environment*. FAO Ethics Series 2. FAO, Rome. (available at www.fao.org/DOCREP/003/X9601E/X9601E00.HTM).

FAO. 2002. Public agricultural research: the impact of IPRs on biotechnology in developing countries. In *Report of an Expert Workshop*. (available at www.fao.org/biotech/docs/torvergatareport.htm).

FAO. 2005. Public participation in decision-making regarding GMOs in developing countries: how to effectively involve rural people. E-mail conference. (available at www.fao.org/biotech/logs/C12/summary.htm)

FAO. 2006. A global plant breeding initiative. *Agriculture 21*. (available at www.fao.org/Ag/magazine/pdf/0606-1.pdf)

FAO. 2007. *FAO biosecurity toolkit*. (available at www.fao.org/docrep/010/a1140e/a1140e00.HTM)

FAO. 2008a. *The state of food insecurity in the world 2008*. (available at ftp://ftp.fao.org/docrep/fao/011/i0291e/i0291e00.pdf).

FAO, 2008b. *Global review of good agricultural extension and advisory service practices.* (available at ftp://ftp.fao.org/docrep/fao/011/i0261e/i0261e00.pdf

FAO. 2009a. *The contribution of technology*. Issues Brief for World Summit on Food Security. (available at www.fao.org/fileadmin/templates/wsfs/Summit/WSFS_Issues_papers/WSFS_tech_E.pdf).

FAO. 2009b. *GM food safety assessment: tools for trainers*. (available at ftp://ftp.fao.org/docrep/fao/012/i0110e/i0110e.pdf).

FAO, 2009c. *Learning from the past: successes and failures with agricultural biotechnologies in developing countries over the last 20 years*. Conference 16 of the FAO Biotechnology Forum (8 June to 8 July 2009). (available at www.fao.org/biotech/conf16.htm).

FAO, 2009d. *Agricultural extension in transition worldwide: policies and strategies for reform.* CD-ROM. (available at www.fao.org/nr/research/t-manuals/en/).

Fingleton, J. 2005. Funding options for agricultural development: the case for special purpose levies. *FAO Legal Papers Online 44.* FAO, Rome. (available at www.fao.org/legal/prs-ol/lpo44.pdf).

Foltz, J.D. 2007. *Economic analysis to support priority setting for investment in agricultural biotechnology for West Africa*. USAID. (available at http://pdf.usaid.gov/pdf_docs/PNADM978.pdf).

Fransen, L., La Vina, A., Dayrit, F., Gatlabayan, L., Santosa, D. A., & Adiwibowo, S. 2003. Integrating socio-economic considerations into biosafety decisions. World Resources Institute, Washington, DC. (available at http://pdf.wri.org/fransen_lavina_biosafetywhitepaper.pdf).

Gamborg, C., Gjerris, M., Gunning, J., Hartlev, M., Meyer, G., Sandoe, P. & Tveit, G. 2006. Regulating farm animal cloning. Final Report. Danish Centre of Bioethics and Risj Assessment. (available at www.bioethics.kvl.dk/tekster/CeBRAreport15.pdf).

Gehl Sampath, P. & Tarasofsky, R.G. 2002. The inter-relationship between intellectual property rights and conservation of genetic resources. Final report prepared for the European Commission. Institute for International and European Environmental Policy, Berlin. (available at www.cbd.int/doc/meetings/abs/abswg-02/information/abswg-02-inf-ext-en.pdf).

Gepts, P. 2004. Who owns biodiversity, and how should the owners be compensated? *Plant Physiology* 134: 1295-1307. (available at www.plantphysiol.org/cgi/content/full/134/4/1295).

Giannakas, K. 2003. Infringement of intellectual property rights: developing countries, agricultural biotechnology and the TRIPS Agreement. *Biotechnology and Genetic Resources Policies Brief 5*. IFPRI, Washington, DC. (available at www.ifpri.org/sites/default/files/publications/biotechbr5.pdf).

Glover, D. 2003. Public participation in national biotechnology policy and biosafety regulation. *IDS Working Paper 198*, Brighton IDS. (available at www.ids.ac.uk/download.cfm?file=wp198.pdf).

Glover, D., Keeley, J., McGee, R., Newell, P., Da Costa, P., Ortega, A.R., Loureiro, M. & Lin, L.L., 2003, *Public participation in National Biosafety Frameworks: a report for UNEP-GEF and DFID*. Brighton: Institute of Development Studies. (available at www.steps-centre.org/ourresearch/gmpolitics.html).

Glowka, L. 2003. Law and modern biotechnology. *FAO Legislative Study 78*. FAO, Rome. (available at ftp://ftp.fao.org/docrep/fao/006/y4839e/y4839e00.pdf).

Goodman, M. 2004. Plant breeding requirements for applied molecular biology. *In* Symposium on genomics and plant breeding: the experience of the initiative for future agricultural and food systems. *Crop Science* 44: 1913-1914. (available at http://crop.scijournals.org/cgi/content/full/44/6/1893).

Gowda, C.L.L., Reddy, B.V.S., Rai, K.N., Saxena, K.B. & H.C. Sharma. 2004. *Public-private sector partnership–a novel institution building for supporting agricultural research and enhancing impacts*. Proceedings for the 4th International Crop Science Congress, Brisbane,

Australia, 26 September – 1 October 2004. (available at www.cropscience.org.au/icsc2004/poster/4/6/1012_gowda.htm).

Graff, G.D. 2007**.** Echoes of Bayh-Dole? : a survey of IP and technology transfer policies in emerging and developing economies**.** *In* IP Management in Health &Agricultural Innovation: A Handbook of Best IP Practices. Chapter No. 3.3. (available at www.iphandbook.org/handbook/ch03/p03/).

Gruère, G.P. & Sengupta, D. 2008. Biosafety at the crossroads: an analysis of South Africa's marketing and trade policies for genetically modified products. *IFPRI Discussion paper 00796.* IFPRI, Washington DC. (available at www.ifpri.org/sites/default/files/publications/ifpridp00796.pdf).

Guei, R.G., Somado, E.A. & Larinde, M. 2008. Improving the seed delivery system in sub-Saharan Africa, In, E. A. Somado, R. G. Guei & S. O. Keya eds. NERICA: the new rice for Africa – a compendium, WARDA, Cotonou, Benin, pp 98-105. (available at www.warda.org/publications/nerica-comp/module%2010_Low.pdf).

Hall, A., Janssen W., Pehu, E. & Rajalahti, R. 2006. *Enhancing agricultural innovation: how to go beyond the strengthening of research systems.* The World Bank, Washington, DC. (available at http://siteresources.worldbank.org/INTARD/Resources/Enhancing_Ag_Innovation.pdf).

Hartwich, F., Gonzalez, C., & Vieira, L-F. 2005. Public-private partnerships for innovation- led growth in agrichains: a useful tool for development in Latin America? *ISNAR Discussion Paper 1*. IFPRI, Washington, DC. (available at www.ifpri.org/sites/default/files/publications/isnarbr01.pdf).

Hartwich, F. & Jansen, H-G. 2007. The role of government in agricultural innovation. Lessons from Bolivia. *Research Brief No 8*, IFPRI, Washington, DC. (available at www.ifpri.org/sites/default/files/publications/rb08.pdf).

Hazell, P. 2008. *An assessment of the impact of agricultural research in South Asia since the green revolution.* CGIAR Science Council, FAO, Rome. (available at ftp://ftp.fao.org/docrep/fao/011/i0279e/i0279e.pdf).

Hazell, P. & Haddad, L. J. 2001. Agricultural research and poverty reduction. *Food, Agriculture and the Environment Discussion Paper 34*, IFPRI, Washington DC. (available at www.ifpri.org/sites/default/files/publications/2020dp34.pdf).

Hazell, P., Poulton, C., Wiggins, S. & Dorward, A. 2007. *The future of small farms for poverty reduction and growth*. IFPRI, Washington DC. (available at www.ifpri.org/sites/default/files/publications/vp42.pdf).

Helfer, L.R. 2002. Intellectual property rights in plant varieties: an overview with options for national governments. *FAO Legal Papers Online #31.* FAO, Rome. (available at www.fao.org/legal/prs-ol/lpo31-2.pdf).

Henson-Apollonio, V. 2007. Impacts of intellectual property rights on marker-assisted selection research and application for agriculture in developing countries. *In* E.P. Guimaraes, J. Ruane, A. Sonnino, B.D. Scherf, & J. Dargie, eds. *Marker-assisted selection: current status and future perspectives in crops, livestock, forestry and fish*, Chapter 20. FAO, Rome. (available at www.fao.org/docrep/010/a1120e/a1120e00.htm).

Huang, J., & Wang, Q. 2002. Agricultural biotechnology development and policy in China. *AgBioForum* 5: 122-135. (available at www.agbioforum.org/v5n4/v5n4a01-huang.pdf).

IAASTD. 2009. *Agriculture at a crossroads: global report*. Island Press, Washington Covelo, London. (available at www.agassessment.org/).

Inter-American Development Bank. 2006. *The politics of policies: economic and social progress in Latin America.* Inter-American Development Bank, Washington DC. (available at www.iadb.org/res/ipes/2006/part_I.cfm?Language=English).

IPGRI 1999. *Key questions for decision – makers. Protection of plant varieties under the WTO Agreement on Trade –Related Aspects of Intellectual Property Rights.* IPGRI, Rome. (available at www.bioversityinternational.org/fileadmin/bioversity/publications/pdfs/41.pdf).

Janssen, W., Falconi, C. & Komen, J. 2000. The role of NARS in providing biotechnology access to the poor: grassroots or an ivory tower? pp. 357-380. *In* M. Qaim, A. Krattingert and J. von Braun, Eds. *Agricultural biotechnology in developing countries: towards optimizing the benefits for the poor*. Kluwer Academic Publishers, Boston.

Jayaraman, K. 2008. India partners to fast track biotech. *Nature Biotechnology* 26: 1201. (available at www.nature.com/nbt/journal/v26/n11/full/nbt1108-1202.html).

Jepson, P. C. 2007. Challenges to the design and implementation of effective monitoring for GM crop impacts: lessons from conventional agriculture, pp.33-56. *In* K. Ghosh and P. C. Jepson, eds. *Genetically modified organisms in crop production and their effects on the environment: methodologies for monitoring and the way ahead*. FAO, Rome (available at ftp://ftp.fao.org/docrep/fao/008/ae738e/ae738e00.pdf

Juma, C. & Seragelden, I. 2007. *Freedom to innovate: biotechnology in Africa's development. A report of the high level African panel on modern biotechnology.* African Union and New Partnership for Africa's Development, Addis Ababa and Pretoria. (available at www.nepadst.org/doclibrary/pdfs/biotech_africarep_2007.pdf).

Kalaitzandonakes, N., Alston, J.M. & Zilberman, D. 2007. Compliance costs for regulatory approval of new biotech crops. *Nature Biotechnology* 25: 509-511. (available at www.nature.com/nbt/journal/v25/n5/full/nbt0507-509.html).

Kowalski, S.P., Ebora, R.V., Kryder, R. D. & Potter, R.H. 2002. Transgenic crops, biotechnology and ownership rights: what scientists need to know. *The Plant Journal* 31: 407-421.

Kryder, R.D., Kowalski, S.P. & Krattinger, A.F. 2000. The intellectual and technical property components of pro-vitamin A rice (GoldenRiceTM): a preliminary freedom-to-operate review. ISAAA, Ithaca, New York. (available at www.isaaa.org/resources/publications/briefs/20/download/isaaa-brief-20-2000.pdf).

Kuiper, H.A., Kok, E.J. & Engel, K.H. 2003. Exploitation of molecular profiling techniques for GM food safety assessment. *Current Opinion in Biotechnology*, 14: 238-243.

Leeuwis, C. 2004. Communication for rural innovation. Blackwell, Oxford, UK.

Lofgren, H., Harris, R.L. & Robinson, S. 2002. A standard computable general equilibrium (CGE) model in GAMS. *Microcomputers in Policy Research 5***.** IFPRI, Washington DC.

Mackenzie, R., Burhenne-Guilmin, F., La Viña, A.G.M., & Werksman, J.D. 2003. An explanatory guide to the Cartagena Protocol on Biosafety. *IUCN Environmental and Policy Law Paper No. 456.* International Union for Conservation of Nature and Natural Resources, Gland, Switzerland and Cambridge, UK. (available at http://cmsdata.iucn.org/downloads/biosafety_guide_1__2.pdf).

Manalo, A.J. & Ramon, G. P. 2007. The cost of product development of *Bt* corn event MON810 in the Philippines. *AgBioForum* 10: 19-32. (available at www.agbioforum.org/v10n1/v10n1a03-manalo.htm).

Manzella, M. & Vapnek, J. 2007. Development of an analytical tool to assess biosecurity legislation. *FAO Legislative Study 96*. FAO, Rome. (available at www.fao.org/docrep/010/a1453e/a1453e00.htm).

McLean, M.A., Frederick, R. J., Traynor, P., Cohen, J.I. & Komen, J. 2002. A conceptual framework for implementing biosafety: linking policy, capacity and regulation**.** *ISNAR Briefing Paper No. 47*. IFPRI, Washington, DC.

Meinzen-Dick, R., Adato, M., Haddad, L. & Hazell, P. 2004. Science and poverty: an interdisciplinary assessment of the impact of agricultural research. IFPRI, Washington, DC. (available at www.ifpri.org/sites/default/files/publications/pr16.pdf).

Melo, A. & Rodríguez-Clare, A. 2006. Productive development policies and supporting institutions in Latin America and the Caribbean. *Inter-American Development Bank Competitive Studies Series*, Washington, DC. Inter-American Development Bank. (available at www.iadb.org/res/publications/pubfiles/pubC-106.pdf).

Michiels, A. & Koo, B. 2008. Publish or patent? : knowledge dissemination in agricultural biotechnology. *IFPRI Discussion Paper 00795*. IFPRI, Washington, DC. (available at www.ifpri.org/sites/default/files/publications/ifpridp00795.pdf).

Millstone, E., Brunner, E. & Meyer, S. 1999. Beyond substantial equivalence. *Nature* 401: 521-526. (available at www.nature.com/nature/journal/v401/n6753/full/401525a0.html).

Nadolnyak, D.A. & Sheldon, I.M. 2002. Valuation of international patent rights for agricultural biotechnology: a real options approach. *Paper for presentation at the Annual Meetings of the American Agricultural Economics Association, Montreal, 2003.* (available at www.docstoc.com/docs/8825162/).

Narrod, C.A., Pray, C.E. & Tiangco, M. 2008. Technology transfer, policies, and the role of the private sector in the global poultry revolution. *IFPRI Discussion Paper 00841*. IFPRI, Washington DC. (available at www.ifpri.org/sites/default/files/publications/ifpridp00841.pdf).

Naseem, A., Were Omamo, S. & Spielman, D.J. 2006. The private sector in agricultural R&D: policies and institutions to foster its growth in developing countries. *ISNAR Discussion Paper 6*. IFPRI, Washington, DC. (available at www.ifpri.org/sites/default/files/publications/isnardp06.pdf).

National Research Council. 2002. *Environmental effects of transgenic plants: the scope and adequacy of regulation.* Committee on Environmental Impacts Associated with Commercialization of Transgenic Plants, Board on Agriculture and Natural Resources**,** National Academies Press, Washington DC. (available at www.nap.edu/catalog.php?record_id=10258).

National Research Council. 2008. *Genetically engineered organisms, wildlife and habitat: a workshop summary*. National Academies Press, Washington, DC.

Neuchatel Group. 2007. Common framework on agricultural extension. Neuchatel Group, Lindau, Switzerland. (available at www.neuchatelinitiative.net/english/content_ressources.htm)

Neuchatel Group. 2008. Common framework on market-oriented agricultural advisory services. Neuchatel Group, Lindau, Switzerland. (available at www.neuchatelinitiative.net/english/content_ressources.htm)

Nightingale, P., & Martin, P. 2004. The myth of the biotech revolution. *Trends in Biotechnology* 22: 564-569.

Nottenburg, C., Pardey, P.G. & Wright, P.D. 2001. Accessing other peoples technology: do non-profit agencies need it? How to obtain it. *EPTD discussion paper No. 79*. IFPRI, Washington, DC. (available at www.ifpri.org/sites/default/files/publications/eptdp79.pdf).

OECD. 2005**.** An introduction to the biosafety consensus documents of OECD'S Working Group for Harmonization in Biotechnology. *Number 32 in OECD Series on Harmonisation of Regulatory Oversight in Biotechnology*. OECD, Paris. (available at http://appli1.oecd.org/olis/2005doc.nsf/linkto/env-jm-mono(2005)5).

Pardey, P.G. & Beintema, N.M. 2001. Slow magic: agricultural R&D a century after Mendel. *IFPRI Food Policy Report*, IFPRI, Washington DC. (available at www.ifpri.org/sites/default/files/publications/fps36.pdf).

Pardey, P.G. & Beintema, N.M., Dehmer, S. & Wood, S. 2006**.** *Agricultural research: a growing global divide?* IFPRI, Washington, DC: (available at www.ifpri.org/sites/default/files/publications/pr17.pdf).

Pray, C.E., & Naseem, A. 2003. Biotechnology R&D: policy options to ensure access and benefits for the poor. *ESA Working Paper No. 03-08*. FAO, Rome. (available at ftp://ftp.fao.org/docrep/fao/007/ae041e/ae041e00.pdf).

ProsperAr. 2008. *Biotechnology in Argentina: knowledge and innovation to meet global market needs*. ProsperAR. (available at www.argentina.gov.ar/argentina/portal/popups/biotechnology-opportunities.pdf).

Puente-Rodríguez, D. 2007. Redesigning the production of the *Bacillus thuriengensis* biopesticide within the context of subsistence agriculture in Andhra Pradesh, India. *Asian Biotechnology and Development Review* 9: 57-83.

Raney, T. & Pingali, P. 2004. Private research and public goods: Implications of biotechnology for biodiversity. *ESA Working Paper No. 04-07*, FAO, Rome. (available at ftp://ftp.fao.org/docrep/fao/007/ae062e/ae062e00.pdf).

Rangnekar, D. 2002. Access to genetic resources, gene-based inventions and agriculture. *Commission on Intellectual Property Rights Study Paper 3a*. UK Commission on Intellectual Property Rights, London. (available at www.iprcommission.org/papers/pdfs/study_papers/sp3a_rangnekar_study.pdf).

Rothschild, M.F., Plastow, G. & Newman, S. 2003. Patenting in animal breeding and genetics. *WAAP Book of the Year 2003:* 269-278. (available at www.psas-web.net/documents/Info/3.5%20Rothschild.pdf).

Rozelle, S., **Jin, S., Pray, C. & Huang, J.** 1999. Commercializing agricultural research, fungible government investment, and poverty: lessons from China. Paper presented at Poverty Assessment Workshop, San Jose, Costa Rica. (available at http://ciat-library.ciat.cgiar.org/paper_pobreza/074.pdf).

Sengooba, T., Mugoya, C., Traynor, P.L. & Komen, J. 2005. *Analysis of the biosafety system in Uganda: regulatory framework, policies and procedures*. East African Regional Programme and Research Network for Biotechnology, Biosafety and Biotechnology Policy Development (BIO-EARN), Kampala, Uganda. (available at http://programs.ifpri.org/pbs/pdf/pbsugandacountrystudy.pdf).

Sharma, M., Charak, K.S. & Ramanaich, T. V. 2003, Agricultural biotechnology research in India: status and policies. *Current Science* 84: 297-302

Smale, M., Zambrano, P. & Cartel, M. 2006. Bales and balance: a review of the methods used to assess the economic impact of *Bt* cotton on farmers in developing countries. *AgBioForum* 9: 195-212. (available at www.agbioforum.org/v9n3/v9n3a06-zambrano.htm).

Smale, M., Zambrano, P., Gruère, G., Falck-Zepeda, J., Matuschke, I., Horma, D., Nagarajan, L., Yerramareddy, I. & Jones, H. 2009. Measuring the economic impact of transgenic crops in developing agriculture during the first decade: approaches, findings and future directions. *IFPRI Food Policy Reviews 10*. IFPRI, Washington, DC. (available at www.ifpri.org/sites/default/files/publications/pv10.pdf).

Spielman, D.J., & Birner, R. 2008. How innovative is your agriculture? Using innovation indicators and benchmarks to strengthen national agricultural innovation systems. *ARD Discussion Paper 41*. World Bank, Washington DC. (available at http://siteresources.worldbank.org/INTARD/Resources/InnovationIndicatorsWeb.pdf)

Spielman, D.J., Cohen, J. I. & Zambrano, P. 2006. Will agbiotech applications reach marginalized farmers? Evidence from developing countries. *AgBioForum* 9: 23-30. (available at www.agbioforum.org/v9n1/v9n1a03-spielman.pdf).

Spillane, C., Engels, J., Fassil, H., Withers, L. & Cooper, D. 1999. Strengthening national programmes for plant genetic resources for food and agriculture: planning and coordination. *Issues in Genetic Resources No. 8*. IPGRI, Rome.

Spreij, M. 2007. The SPS Agreement and Biosafety. *FAO Legal Papers Online # 65*. FAO, Rome. (available at www.fao.org/Legal/prs-ol/lpo65.pdf).

Stads, G-J. & Beintema, N. M. 2009. Public agricultural research in Latin America and the Caribbean: investment and capacity trends. *ASTI Synthesis Report*. (available at www.asti.cgiar.org/pdf/LAC_Syn_Report.pdf).

Stads, G-J., Hartwich, F., Rodríguez, D. & Enciso, F. 2008. *Agricultural R & D in Central America: policy, investments and institutional profile*. IFPRI and Inter-American Institute for Cooperation in Agriculture (available at www.asti.cgiar.org/pdf/ASTICentralAmerica-En.pdf).

Stein, A. J. & Rodríguez-Cerezo, E. 2009. The global pipeline of new GM crops: implications of asynchronous approval for international trade. *JRC Scientific and Technical Reports*, Institute for Prospective Technological Studies. European Commission, Seville. (available at http://ftp.jrc.es/EURdoc/JRC51799.pdf).

Stannard, C., van der Graaff, N., Randell, A., Lallas, P. & Kenmore, P. 2004. Agricultural biological diversity for food security: shaping international initiatives to help agriculture and the environment. *Howard Law Journal* 48: 397-430.

Stone, G.D. 2007. Agricultural deskilling and the spread of genetically modified cotton in Warangal. *Current Anthropology* 48: 67-103. (available at http://artsci.wustl.edu/~anthro/research/stone/stone480102.web.pdf).

Tansey, G. & Rajotte, T. 2008. *The future control of food: a guide to international negotiations and rules on intellectual property, biodiversity and food security*. Earthscan, London. (available at www.idrc.ca/openebooks/397-3/).

Texeira, F. G.de M. 2008. Innovation in agribusiness: the Embrapa's case. (available at www.anodaciencia.com.br/multimidia/multimidia_20080318162958.pdf).

The Royal Society. 2003. Keeping science open: the effects of intellectual property policy on the conduct of science. The Royal Society, London.

UNCTAD 2008. *Economic development in Africa: export performance following trade liberalization: some patterns and policy perspectives*. UNCTAD, Paris. (available at www.unctad.org/en/docs/aldcafrica2008_en.pdf).

UNCTAD-ICTSD 2003. Intellectual property rights: implications for development. *Policy Discussion Paper*. UNCTAD and ICTSD, Geneva. (available at www.iprsonline.org/unctadictsd/policyDpaper.htm.

UNEP-GEF. 2006. *A comparative analysis of experiences and lessons from the UNEP-GEF Biosafety projects*. Nairobi, Kenya and Washington, DC. (available at www.unep.org/Biosafety/Documents/UNEPGEFBiosafety_comp_analysisDec2006.pdf).

UN Millennium Project. 2005. *Task Force on Science, Technology and Innovation. Innovation: applying knowledge in development* UNDP. Earthscan, London and Sterling, Virginia. (available at www.unmillenniumproject.org/documents/Science-complete.pdf).

UNU-IAS. 2008. *Internationally Funded Training in Biosafety and Biotechnology - Is it Bridging the Biotech Divide?* UNU, Yokohama, Japan.

Van Beuzekom, B. & Arundel, A. 2009. *OECD Biotechnology Statistics 2009*. OECD, Paris.

Van der Walt, W.J. & Kloster, B. 2005. An overview of plant variety protection in South Africa. *IP Strategy Today* 13: 18-28.

Vitale, J. & Boyer, T. 2007. The economic impacts of introducing Bt technology in smallholder cotton production systems in west Africa: a case study from Mali. *AgBioForum*, 10: 71-84. (available at www.agbioforum.org/v10n2/v10n2a02-vitale.htm).

Wagner, C.S., Brahmakulam, I., Jackson, B., Wong, A., & Yoda, T. 2001. *Science and technology collaboration: building capacity in developing countries?* RAND, Pittsburg.(available at www.rand.org/pubs/monograph_reports/2005/MR1357.0.pdf).

Walsh, J.P., Arora, A. & Cohen, W. M. 2003. Effects of research tool patents and licensing on biomedical innovations. *In* W. A. Cohen and S. A. Merrill eds. *Patents in the knowledge based economy.* Committee on Intellectual Property Rights in the Knowledge-Based Economy, National Research Council National Academies Press, Washington, DC. (available at www.nap.edu/catalog.php?record_id=10770).

Woolley, J., Ribaut, J-M., Bouis, H. & Adekunle, A. 2009. The CGIAR's Challenge Program experiences: a critical analysis. Document prepared by staff of the four Challenge Programs..

World Bank 2004. Intellectual property rights: designing regimes to support plant breeding in developing countries. Report No. 35517-GLB World Bank, Washington, D.C. (available at http://siteresources.worldbank.org/INTARD/Resources/IPR_ESW).

World Bank. 2007. *World Development Report, 2008: Agriculture for Development*. The World Bank, Washington DC. (available at http://go.worldbank.org/LBJZD6HWZ0.

World Bank. 2008. National agricultural research project- phase II. *Project performance assessment report. Republic of Kenya.* The World Bank, Washington DC.

Zarrilli, S. 2005. International trade in GMOs and GM products: national and multilateral legal frameworks. Policy Issues in International Trade and Commodities *Study Series No. 29*. UNCTAD, UN, New York and Geneva. (available at www.unctad.org/en/docs/itcdtab30_en.pdf).

E. Annexes

Annex 1. The processes of developing, approving and overseeing biotechnology policy/strategy frameworks and of providing independent advice

1. Development and approval

National frameworks

Leadership*: In some countries, the process was led "from the top"* i.e. by the Prime Minister and/or through setting up a "high level" i.e. interministerial coordination mechanism (Team, Council or Committee) involving a lead minister or permanent secretary (normally for S&T) with participation of Ministers/Secretaries for Agriculture, Health, Education, Environment, Finance, Trade, and in some cases Foreign Affairs and Justice. This was done by Brazil, Chile, India, Malaysia, and Thailand.

In the other countries, there appeared to be no formal interministerial coordination. Rather, the process was assigned to the Ministry of S&T or similar and from there to one of its constituent entities e.g. National Council for Science/Research Council. Examples of this approach include Kenya and Uganda.

In most countries, the NBS was prepared only very recently, but some national biotechnology policies go back many years and have been updated as the technology evolved. *In the case of China*, biotechnology first emerged in 1977 through the declaration of the Four Modernizations as its State policy. Here, biotechnology was a focal point of the country's S&T development programme and agricultural biotechnology perhaps the most important component. The first policy document on the subject (the National Biotechnology Development Policy Outline) was prepared in 1985 and revised in 1986 at the beginning of the "7th. Five-year Plan" under the leadership of the Ministry of Science and Technology (MOST) and the State Development and Planning Commission (SDPC) and approved by the State Council in 1988 (Huang and Wang, 2002).

In the case of India (see Chaturvedi, 2005), originally a National Biotechnology Board (NBTB) was set up chaired by a Science Member of the Indian Planning Commission with representation from almost all the S&T agencies in the country. It produced a Long Term Plan in Biotechnology for India in 1983 outlining priorities for achieving national development objectives. Later, NBTB graduated to the Department of Biotechnology within the Ministry for S&T and together with other agencies it coordinated development of the current National Biotechnology Development Strategy.

Developing the Draft Policy/Strategy: In countries that set up an interministerial mechanism, *responsibility for drafting the policy/strategy was assigned to a 10-20 person Task Force, Advisory/ Steering Committee, Consultative Group or Expert Panel* with representatives from key departments within ministries, universities, research institutions, science funding bodies, private foundations, industry, and in some instances civil society and consumer groups. In some cases, separate working groups were established to lead consultations and report on specific topics (e.g. R&D, communication) and sectors (e.g. agriculture, health, environment, industry). For example, in Thailand six sub-committees were established under the National Biotechnology Policy Committee to obtain inputs and draft the document, and a further sub-committee dealt specifically with genetic modification and biosafety policy development.

Some countries (e.g. Malaysia, Malawi, South Africa and Zambia) brought in outside consultancy organizations, development partners or individuals to assist the process. Others (e.g. Argentina, Brazil, India, and Uganda) provided opportunities for consultations at state, regional or provincial levels, while some countries (notably India) also solicited public comments by placing their draft strategies on the internet, and Chile sought the views of parliamentarians and experts.

In other countries (Kenya, Uganda, Namibia, Jamaica) the tasks of both coordinating inputs and drafting the document were undertaken by the National S&T/Research Council or similar.

***Scope*:** While some countries (e.g. Jamaica, Kenya, Malawi, Uganda), emphasized that the policy/strategy applied to both conventional and modern biotechnologies, in the majority of cases, and although not specifically stated except in the case of Namibia and Peru, *the thrust was clearly toward modern biotechnology and particularly the governance of R&D and diffusion of GMOs and their products.*

Content: Despite the wide differences between the countries in terms of population, economic strength, scientific and technological capabilities and cultures, there was *a remarkable consistency to their vision* of biotechnology contributing to social and economic development by improving productivity, creating jobs, promoting health and a better environment. However, a specific vision statement was provided by only five countries, namely India, Malawi, Malaysia, Thailand and Uganda.

In terms of *overarching principles***,** virtually every country stressed the importance or essentiality of protecting health and sustaining the environment as pre-conditions for success in applying biotechnology, and many stressed public participation; Malaysia stressed the importance of strong IPR protection while the precautionary principle or approach was mentioned as a cornerstone to regulation by many countries as was liability and redress (e.g. Malawi, Namibia, Uganda, Zambia). Many included labelling of GMOs and their products (e.g. Malawi, Thailand), and Namibia put a moratorium on the use of GURTs. Brazil, Kenya, Peru and Uganda mentioned the importance of integrating and protecting indigenous knowledge, resources and practices and of benefit-sharing. The *priority sectors* identified by the majority of the countries reviewed were: health, agriculture, industry (and trade) and the environment.

Cross-cutting themes included by all countries were R&D and communication, many countries included bio-resources (specifically biodiversity in only a few), education (also of the general public), and ethical, cultural and socio-economic issues although little or no detail was provided by any country as to how exactly such considerations would be included in decision-making and what mechanisms would be set up to address them. Promoting gender equality was essentially a non-issue in all documents, except in the case of Uganda.

With respect to agriculture itself, most countries dealt with the sector in an integrated "across the board" manner (i.e. covered crops, livestock, forestry, aquaculture) while some emphasized particular areas of interest (e.g. aquaculture, fruits and forestry in Chile), crops resistant or adapted to drought, pests, diseases and climate change (Brazil, India and Kenya), livestock vaccines, diagnostics, feeds, drugs and reproductive technologies (Argentina, Brazil, India and Kenya), biopesticides and biofertilizers (Kenya), and the creation of bio-industries from crop and animal by-products (Argentina, Brazil and India).

Apart from the national BFA strategy documents developed specifically by Argentina, and India (see below), it is noteworthy that the plans outlined by Kenya, Uganda and Malawi are also almost exclusively or heavily directed towards BFA and related issues. Kenya's strategy, for example, covers the crop, livestock and fish/aquaculture sub-sectors, while those of Uganda and Zambia have a heavy bias towards crops and towards micropropagation (and particularly GM crops in Uganda), although both Kenya and Uganda also include the development of industries using biotechnology using their rich resources of biological diversity.

The Zambian document (entitled "National Biotechnology and Biosafety Policy") and particularly the Namibian policy document (entitled "Enabling the Safe Use of Biotechnology") are heavily oriented towards biosafety, while the documents e.g. from Brazil, Chile, Kenya, Malawi and Peru deal equally with "promotion" and "regulation". Documents of China, India, Thailand, South Africa and particularly Malaysia are oriented towards "promotion", with limited or no reference to regulation.

***Approval of NBS Frameworks*:** Countries took, or intended to take, one of three routes for approving their policy/ strategy documents:

- *Creating new primary legislation that embraced substantial elements of the entire document* (including the creation of new financial and/or regulatory institutions and mechanisms and/or additional roles and responsibilities of existing institutions, financing arrangements etc). The legislatures of China, Brazil, Peru and Chile (in progress) passed decrees/laws covering the policy/strategy documents prepared by government authorities;
- Obtaining full government approval for the NBS and separately creating primary or secondary laws and regulations to cover specific aspects e.g. on biosafety; IPR, establishment of funding instruments etc. This was the path chosen by the vast majority of countries reviewed; and
- Obtaining approval from the ministry given the lead responsibility for the issue and creating non-binding guidelines for specific matters. Based on available information, this was the path chosen by essentially all countries initially and has been retained by many for particular aspects.

While the advantages of the first option include wider debate, greater political and possibly financial commitment and level of enforcement, and "up front" agreement on the roles and responsibilities of governments and legislatures, one disadvantage would be the significantly longer timeframe between preparation and initiating implementation. The second option would lead to earlier implementation of activities requiring regulatory action and oversight, but in some jurisdictions it may not have the same level of enforcement, while the third would most likely be ineffective and even counter productive in terms of moving forward, particularly on the many regulatory matters associated with some modern biotechnologies.

Strategy frameworks for biotechnology in food and agriculture

Two developing countries (Argentina and India) have prepared comprehensive BFA policy/strategy papers although, as described in more detail elsewhere, these and most other countries have developed laws and regulations on GMOs. In *Argentina* the strategy was developed under the leadership of the Secretariat of Agriculture, Livestock, Fisheries and Food (SAGPyA). Its development involved many stakeholders, including the offices of Senators and Deputies, the Secretariats of Industry, Sustainable Development, Science & Technology, Ministry of Foreign Affairs, all the main universities, funding bodies, industry and civil society groups and individual companies, including multinationals. In *India*, the Department of Agriculture and Cooperation within the Ministry of Agriculture set up a Task Force to formulate a draft long-term policy on applications of biotechnology in agriculture, including suggestions to streamline/harmonies decision-making under various ministries/organizations. The strategy covers the crop, livestock, forestry, and fish sectors. It also deals with related issues like genetic resource conservation and use, food safety, co-existence of organic, conventional and GM agriculture, regulation, public participation and commercialization etc. Five working groups were set up to examine, report on and provide recommendations on the various issues, culminating after eleven meetings and interactions with a wide variety of stakeholders in a comprehensive report issued in 2004.

Sub-national biotechnology policy and strategy frameworks

A comparatively recent development in an increasing number of countries is the initiative taken by sub-national (e.g. state and provincial) governments to develop biotechnology policies and strategies. In *India*, for example, the governments of Andhra Pradesh, Maharashtra, Karnataka and Tamil Nadu have each come out with their own policy and strategy documents. It is outside the scope of this paper to deal further with this subject, but *an important policy issue for countries that have moved, or are moving, towards de-centralized decision- making is the extent to which powers are invested in sub-national governments and agencies* to make laws or regulations with respect to R&D, technology diffusion, local and international markets and any risks to these markets associated with the introduction of e.g. GMOs. Failure to do so has already lead to inter-jurisdictional competition for investment from both federal and foreign sources, and although they

may have the same or similar regulatory approaches to those promulgated by national authorities, sub-national bodies have interpreted these in an inconsistent manner leading e.g. to production and trade inconsistencies within countries.

Supra-national frameworks

The *African Union strategy* was produced by a High Level African Panel with two Chairs and 12 Panel Members assisted by a Secretariat and a Research Team. The report (Juma and Serageldin, 2007) is based on many meetings, submissions from all types of stakeholders, requests for comments on the web and feedback from workshops and conferences in Africa and elsewhere. It too, covers the topic in a cross-sectoral manner detailing current status, describing sector priorities (with heavy emphasis on agriculture, including on biofertilizers and biopesticides) and plans for moving forward.

2. Oversight

- *Brazil* established a high level National Biotechnology Ministerial Council/Committee (NBC) within the Prime Minister's/President's office to coordinate implementation of their strategy/ law;
- *India set up a Department of Biotechnology* within its Ministry of Science & Technology to promote and coordinate all aspects of biotechnology development in the country;
- *Malaysia established a Biotechnology Corporation* overseen by an Implementation Council and advised by an international Advisory Panel both under the leadership of the Prime Minister;
- *Peru established an Interministerial Commission* to harmonies sectoral policies, and a National Executive Committee on Biotechnology (CONEBIO) within its National Council for Science, Technology and Innovation Technology (CONCYTEC) to deal specifically with biotechnology;
- In *Thailand, the National Biotechnology Policy Committee* was chaired by the Prime Minister and assisted by seven sub-committees including one dealing with genetic engineering and biosafety policy development ; and
- *Kenya proposed the setting up of a National Biotechnology Enterprise Programme* consisting of a *National Commission* to oversee implementation of the policy framework and a *National Education Centre* to coordinate and facilitate training, develop databases and a national culture collection, but whether an interministerial mechanism will be created to oversee these initiatives is unclear.

3. Independent advice

Among the countries analysed, various mechanisms have been used:

- *South Africa's* biotechnology advisory committee (BAC) is a sub-committee of the National Advisory Council on Innovation which assists the Minister for Science and Technology;

- *Argentina set up a National Advisory Commission* on agri-biotechnology to advise its Secretariat on technical and biosafety requirements. Public and private organizations with competencies in BFA are represented;

- *Chile established a Commission for the Development of Biotechnology* and plans to set up an independent Biotechnology Forum to be consulted on issues and charged with promoting public debate;

- *In India, the Department of Biotechnology set up a Scientific Advisory Committee and an international Standing Advisory Committee*;

- *In the case of Malawi, a National Biotechnology Commission* with representatives from academia, R&D, education and commerce is proposed to advise the National Research Council;

- *Peru established a National Advisory Committee for Biotechnology R&D* within CONEBIO to advise on non-regulatory issues ; and
- *AU/NEPAD has a High Level Panel on Modern Biotechnology* to provide independent strategic advice on developments in modern biotechnology and their implications for agriculture, health and the environment.

Annex 2. Science & technology systems in developing countries: Challenges and opportunities

The traditional developers and disseminators of agricultural technology (the NARES) are highly diverse in size, in scientific and technical strength, and in the way 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, 2008b and Stads and Beintema, 2009 for detailed studies of the Asia-Pacific and Latin American-Caribbean regions), 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, 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, while 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, whereas in India the main government agency is 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 research and development, 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 of the Americas for Agricultural Research and Technological Development (FORAGRO), and specifically for biotechnology, the Technological Cooperation Network on Plant Biotechnology for Latin America and the Caribbean (REDBIO) and, of course, the advanced research institutes (ARIs) in developed countries. At international levels, the research centres belonging to the CGIAR, the ICGEB and their NARES partners continue to enhance agricultural knowledge, science and technology (AKST) 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 AKST, including through BFA. The recent granting of US$ 3 million to ICGEB to strengthen sub-Saharan African regulatory regimes in biosafety

(www.icgeb.org/~bsafesrv/pdffiles/%20ICGEB_Gates.pdf) and of US$ 10.4 million to NEPAD's African Biosafety Network of Expertise (www.nepadst.org/newsroom/pdfs/news_brs.pdf) 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 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* (the traditional suppliers of knowledge and technology for which 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, AKST 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, 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. the UK Commission on Intellectual Property Rights (www.iprcommission.org/). This issue is discussed in Section C;
- 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 NARES) is fast becoming obsolete. The numerous technologies that "sit on the shelf" attest to this reality and to the need to complement the traditional with the more horizontal *"national innovation system"*(NIS) approach 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;

- changed norms for accessing and sharing the benefits of biodiversity in general, and particularly for plant genetic resources in food and agriculture, is yet another driving force for change;
- national biotechnology policies, like S&T policies in general, are framed horizontally; the scope for independent action by Ministries for 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; and
- the agricultural sector must increasingly compete with other sectors in determining the types of courses offered, research conducted and other services offered 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 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 (see Sections A4 and C).

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 document which now focuses on direct policy options for enhancing the role of biotechnologies in agricultural development.

Annex 3: Building and funding biotechnology R&D and innovation capacities

Training and capacity-building

India now directly supports institutions providing undergraduate training in life science and biotechnology to achieve the status of "Star Colleges" by improving teacher skills and knowledge and providing equipment and reagents and running summer schools that expose students to platform biotechnologies (www.pscst.com/en/about/sum_ann_report.htm). It has also established a 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 (www.fundacionredbio.org/popup.asp?Id=2).

In order to fulfil their complementary mission of knowledge production and training of skilled human resources for biotechnology, all 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 with a PhD increasing in China from two percent in 1986 to more than 20 percent in 2000 (Huang and Wang, 2002), India currently offering 18 MSc. courses in BFA at various universities and with many universities in Argentina creating the Licenciatura en Biotecnología (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 of Argentina and Brazil that work on specific biotechnology research projects that have 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 Ministry of Science, Technology and Productive Innovation in Argentina (CONICET) and the Spanish Ministry of Education & 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 policymaking 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 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 eight years by FAO, other UN agencies/bodies and the CGIAR centres regarding biotechnologies in food and agriculture in developing countries is available from FAO-BiotechNews (www.fao.org/biotech/archive.asp).

Countries that have created new institutions or "re-branded" existing institutions for biotechnology R&D include:

- *Argentina* which set up an Institute of Biotechnology and CEBIGEVE, a new Centre for Plant Genomics at the University of Rosario;
- *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 (CPMM), a National Centre for Plant Genome Research at various universities and institutions and a National Agrifood Biotechnology Institute (NABI) (Sharma, Charak and Ramanaich, 2003);
- *Malaysia* which created a National Institute of Agrobiotechnology at its Agricultural Research & Development Institute (MARDI); and
- *Thailand* which set up a National Centre for Genetic Engineering & 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, 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 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 bio processing, Malaysia (BioValley) and Thailand (the Thailand Science Park at Rangsit which emphasizes genetic engineering and other biotechnologies).

National funding policies and initiatives

Argentina: Through reforms to its S&T system, Argentina established a National Agency for the Promotion of Science and Technology 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 Fondo Tecnológica Argentina (FONTAR) which finance projects on a competitive basis ranging from basic research to improving competitiveness through technological innovation. A major part of these funds has been directed at BFA (ProsperAr, 2008).

Biotechnology also benefits from a 2007 Law for the Promotion of the Development and Production of Modern Biotechnology managed by the Ministry of Economy which is valid for 15 years (www.glin.gov/view.action?glinID=195363). This law created a Fund for the Stimulation of New Entrepreneurs in Modern Biotechnology which finances (at a subsidised 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 submit innovations that meet requirements for patentability

first to the National Institute 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 amortisation (for income tax purposes) of capital goods and special equipment purchased specifically to be used in the projects supported;

- 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; and

- special access to the "ANR Patentes PyMES," through which FONTAR finances the costs faced by SMEs to obtain patents for their innovations.

Brazil: Federal funds for financing S&T including BFA come from the Ministry for Science and Technology's National Fund for Scientific and Technological Development (FNDCP) which is channelled through its Science Council (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 EMBRAPA and universities have been funded to develop the Brazilian agricultural system. 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 (www.fapesp.br/). Its funds are guaranteed by the Constitution of the State of São Paulo, which ensures it a one percent share of the total tax revenue of the State. FINEP also has a venture capital programme called INOVAR, as well as a seed capital programme that provides funding for early stage growth. BNDES (Bank for Social Development) which used to support only large companies now has a support programme also for micro-enterprises.

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. IDB gives the incubator grant money of US$ 200,000 – US$ 1 million 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 $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 legislature passed a new Innovation Law in 2005 which allows researchers at federal universities to set up companies in their names; researchers can also leave the university for a period of time to work for a private company and then return to the university if they desire (www.wipo.int/sme/en/documents/brazil_innovation.htm).

India: The Biotechnology Industry Partnership Programme (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;

- 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 trial 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, good manufacturing practice (GMP) facilities for vaccines. Different financing and management models are foreseen for these facilities including e.g. 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, differential fees for public and private use; specialized facility for discovery and innovation, soft loan, differential fee for public and private users, 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 and Uganda: With joint funding from the Rockefeller Foundation and the Gatsby Charitable Foundation, the Maendelo Agricultural Technology Fund with an Advisory Panel of local experts and donor representatives was set up to transfer and adapt new agricultural technologies to smallholders. Supported by the Ministries for Agriculture and local governments and the NARES, this Trust provides grants on a competitive basis to projects identified through value chain priority-setting. In both countries, 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 that are of national importance to the Malaysian industry, BFA being a high priority. There are 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), the Malaysian Technology Development Corporation (MTDC) and others;

- 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), was set up to manage an approximately US$ 135 million fund in 2001 (www.mavcap.com/). Out of this, US$ 25 million has been allocated to biotechnology in the form of direct investment, and outsourced to smaller fund managers; and

- companies that have been 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 the expansion of 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 research and development (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 Commercialisation Office administering this fund also engages in strategy formulation, development of commercial routes to market, due diligence and deal-structuring; and

- 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.

Annex 4. Coverage of regulation within national biotechnology policy/strategy frameworks

The following synthesizes the coverage of regulation within the NBS frameworks surveyed:

- *Argentina*, one of only two developing countries to develop a specific BFA strategy, mentioned the need to strengthen the legal and institutional framework through laws on regulation and development of a communication plan and system for engaging the public as priorities. 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, 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* policy gives high importance to the environmental and food safety aspects of GMOs and the need to take protective measures. In fact, of the 23 actions outlined in the policy, nearly half relate to an overall goal of establishing a regulatory framework that guarantees a safe, sustainable and responsible development of biotechnology. These include: recommendations to draft a framework law on biotechnology, provide training of staff in public institutions, develop regulations for foods derived from GMOs, labelling, procedures for release into the environment, certification of GMO products for export, including mechanisms of traceability, reviewing and where necessary amending legislation on the environment, agriculture, aquaculture and health as well as CONICYT's (Comision Nacional de Investigación Científica y Tecnológica) Manual on Biosecurity Standards which includes technical standards for laboratory safety. Other recommendations include the creation of a Committee on Biotechnological Regulations to ensure appropriate coordination between public regulatory authorities and review proposals for regulations 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 for risk assessment and management. It had established a National Biosafety Committee with multisectoral membership in 1997 through its Plants (Importation) Control Regulations of the same year under its National Commission on Science and Technology to monitor importation of GMOs for experimental use (transgenic papaya) and more recently, GM cotton. It has also been involved in sensitizing the public on biosafety issues, and other tasks include preparing guidelines, codes of conduct for relevant users of GMOs. Through UNEP-GEF funding, it had a NBF project 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 (a) 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", (b) an objective – to provide safety measures for the above and establish acceptable standards for risk assessment and management, and (c) 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 safety and health of workers; protecting human rights by guaranteeing consumer choice by: establishing thresholds for acceptance levels of specific biotechnology products; and 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 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 GURTs, the country would impose a 5-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 including, *inter alia*, its scope i.e. all GMOs and their products, all existing laboratory and field applications; the regulatory process 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, 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 Biosafety Advisory Council (NBAC) 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 there could be impacts on these.

- *Malaysia:* Its national biotechnology policy is underpinned by nine policy thrusts, one of which includes "creating 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; 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, 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 inspection of imported products; conduct research to collect scientific data needed for risk assessment of food and agricultural products for export; and enhance capability in inspecting and certifying food quality and safety standards.
- *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 government and 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 (IBCs) have been established in some institutes. All the same, it notes that the UNCST Act is inadequate to regulate 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 has 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 GMO(s), and products. The Biosafety Advisory Committee would advise the NBA on prohibitions, authorization and the exercise of necessary control of imports, on authorization or notification of contained uses, authorization of trials or general releases; and 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 for the safe 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 products thereof 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, combinations of GMOs and products thereof 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 products thereof; 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.

Annex 5: Coverage of intellectual property rights and genetic resources issues in national biotechnology policy/strategy frameworks

The following summarizes coverage of these issues in national biotechnology policies/strategies:

- *Brazil* gave considerable attention to access to genetic resources, benefit-sharing and guaranteeing the rights of traditional communities and indigenous peoples. It intended therefore to improve its legislation concerning these aspects. At the same time, it would promote the strategic use of IP to make national biotechnology more competitive, increase the number of Brazilian-owned patents in Brazil and abroad, improve IP management capabilities within research, industry and the judiciary, harmonies IP practices within agencies that promote R&D, harmonies IP practices for recovery of traditional knowledge, review and strengthen national legislation for the protection of plant cultivars, strengthen breeders rights and adopt mechanisms for protecting lines derived from animal breeding.
- *Chile* intended to update and upgrade its IP system, design and implement a programme to train decision-makers on biotechnology-related IP issues, and encourage patenting in national research institutes.
- *India's* Biotechnology Development Strategy includes a new Bill on protection, utilization and regulation of IP for public funded R&D, the aim being to optimize the potential of public R&D, encourage innovation in SMEs, promote collaboration between government and non-government organizations and catalyse commercialization of IP generated through public R&D. The strategy also includes building capacity in technology transfer and IPR by having national and regional centres linked to university departments for training personnel which would also be done overseas.
- *Jamaica* mentioned that the government would play a proactive role in creating awareness of the importance of IPR issues in research and innovation and through the development of databases and assistance to scientists and entrepreneurs through the national IP Office.
- *Kenya's* Biotechnology Policy document stated that biotechnology would be developed in cognisance with international agreements (TRIPS and UPOV), and noted that the country's rich species diversity and the traditional knowledge associated with it offered great opportunities for industrialization through biotechnology. It therefore intended to set up a database on species in different ecosystems and the knowledge associated with them, develop capacity for effective management of IP including training scientists, improve the accessibility of IP services and establish a government fund to support filing of patents from public research. It would also review its policies and legislation on protection of traditional knowledge and resources and align these with policies on royalties, patenting, access to information and benefit sharing on products resulting from biotechnology.
- *Malawi* proposed to use biotechnology to conserve and sustain the use of its biological diversity by enacting legislation to regulate access and benefit-sharing, setting up a national database on, and clearing house for, facilitating access and sharing of benefits, facilitating adherence to terms of technology transfer agreements, providing copyright and patent protection in respect of all conventions to which it is a signatory. It noted that it did not have an IPR policy and that its present legislation which dates back to 1948 did not address biotechnology and community rights. It intended therefore to establish an IPR policy and legislation that would conform to its international legal obligations without undermining national development opportunities, to strengthen domestic legislation to ensure that IPR protected indigenous knowledge systems and genetic resources while at the same time attracting investment and development in biotechnology. It would formulate regulations that protected biotechnology innovations through IPR by harmonizing national implementation of biotechnology, trade and IPR agreements, and developing *sui generis* legislation to protect farmers and community rights. It would also

develop appropriate guidelines for accessing and sharing the benefits from the products of biotechnology and establish mechanisms to facilitate access by Malawians to IPR–protected products of modern biotechnology.

- *Malaysia* described how it was one of the 12 mega diversity areas of the world and that it would develop a strong IP protection regime to support R&D and commercialization efforts to capitalize on this biodiversity for agriculture, health and industry. Further details were not provided.
- *Namibia s*tated that national legislation relating to community or individual IPR will include contractual arrangements to share financial and other benefits arising from biotechnology and that the State would facilitate community access to advice for negotiating such agreements. However, no further details were provided on roles, responsibilities or mechanisms.
- *Peru* specifically provided for the granting of patents, except for whole organisms or parts thereof that exist naturally or have been modified by modern biotechnology, and for IP certificates for plant varieties developed with or without modern biotechnology. It also expressly recognizes and protects the rights of indigenous peoples and local communities in furthering biotechnology.
- *South Africa* noted that it had many Acts relevant to biotechnology but since these provide conflicting legislation they would be reviewed and harmonized. It intended to update its Plant Breeders Right Act to include DNA fingerprinting to distinguish between phenotypes and it would consider introducing legislation for animal breeders. It would also introduce a search and examination capacity into its IP Office, and develop standard guidelines on IP rights of inventors for science councils and universities.
- *Thailand* stated its intention to strengthen IP management including competency in international negotiations for fair benefit sharing and technology transfer. It also intended to establish “community business networks” to promote the conservation and use of indigenous resources and thereby provide incomes for local communities. Further details were not provided.
- *Uganda* made no specific mention of IPR, but intended to integrate indigenous knowledge with modern biotechnology to develop a vibrant biotechnology- based industry while promoting equitable access and benefit-sharing of indigenous knowledge.
- *Zambia* described the need to ensure fair and equitable access and benefit-sharing from using genetic resources and by transfer of technologies, taking account of all rights over these resources and technologies. The document did not, however, elaborate further on how this would be achieved.