CHAPTER 7

TARGETING AGRICULTURAL BIOTECHNOLOGIES TO THE POOR

SUMMARY

Designing and implementing policies for targeting agricultural biotechnologies to the poor requires holistic or "joined up" analyses of proposed interventions to identify their possible direct and indirect, immediate and longer-term ramifications and to foster coherence with overarching national policies for economic and social development, including agriculture and food security, as well as for science and technology (S&T). Doing so requires taking account of the institutional arrangements for developing new agricultural technologies into tangible products and the social contexts that influence the incentives for farmers and markets to adopt these, and fostering collective and transparent processes for decision-making. Policies for agriculture itself now have to deal with a multitude of new and emerging issues, and decision-making is further complicated by influential legally-binding instruments negotiated globally, regionally and bi-nationally. This plethora of cross-cutting considerations cannot be tackled effectively by an individual ministry and different interests will drive negotiations towards particular outcomes and priorities. Competing economic and social interests do not favour targeting biotechnologies in food and agriculture (BFA) towards small-scale and often poor farmers living in resource-challenged areas – only strong and persistent political commitment can achieve this.

This Chapter begins by outlining some of the broader considerations within which national agricultural and wider rural development policies and policy-making operate nowadays, and some principles that should be followed for formulating a national policy or strategy for BFA – including the critical issue of deciding on the distribution of benefits from introducing technological change through biotechnologies (i.e. direct and indirect effects).

A rationale is provided for establishing a national biotechnology policy/strategy (NBS) framework – something which few countries actually have in place – as well as

some principles and examples of how some countries have gone about planning and implementing biotechnology applications. The Chapter describes the type of analytical work that should underpin preparation of the NBS; the essentiality of ensuring the widest possible engagement with the public, including with representatives of farmer/producer organizations, private companies, non-governmental organizations (NGOs), civil society organizations (CSOs) etc., the ultimate aim being "participatory decision-making". In addition, the Chapter makes suggestions for content, based on a consideration of core government roles and responsibilities as well as on the assignment of roles and responsibilities for its implementation. It recommends that notwithstanding the need to develop policies, strategies and programmes that are aligned with those existing for the agricultural sector and its sub-sectors and tailored to meet the requirements of BFA, the governance of agricultural biotechnologies at national level should be horizontal. It also deals with the question of NBS approval, providing examples of options available.

Coordination – across government ministries, across government departments (within ministries), with sub-national governance structures and with other governments via bilateral, regional and multilateral mechanisms – is a key issue in designing and following through on policies for BFA. Horizontal as well as vertical coordination are therefore essential for comprehensive and balanced biotechnology policies and several options are outlined for achieving this between and within individual ministries. Important issues to be resolved here include the "reach" of such mechanisms where working at the policy and at the operational levels has to be clarified, as does how to involve others who may not be "at the table", e.g. NGOs, the business community and other partners from civil society. A further consideration is securing independent advice, and several principles and options are provided for countries and institutions wishing to obtain such input.

The Chapter includes an analysis of the NBS documents that have been developed and approved by 15 selected developing countries. Few of the countries analysed have formal structures to oversee development of agricultural biotechnologies and in even fewer do these appear to involve collective government. The option chosen was to assign responsibility for implementation as an "add on" to the ministry assigned to lead development of the framework (normally the Ministry of S&T), with no indication given about delegation of responsibility for specific areas such as BFA or for bringing policy issues to the "top table" for discussion and decision-making. A further gap seems to exist in countries with federal and local systems of governance, i.e. the lack of a specific national forum for coordinating policy, raising the distinct danger of, e.g. policy and funding overlaps and production and trade distortions.

Priority-setting for biotechnologies in general and specifically for BFA is arguably the biggest challenge faced by government and sector-level policy-makers, particularly if the goal is to tackle hunger and poverty in rural areas. Options to aid decision-making include establishing a national system of biotechnology statistics and indicators; setting up systems of biotechnology foresight; and introducing instruments that encourage research and development (R&D) institutional transformation with a premium placed on multi-disciplinarity and networking (i.e. "innovation systems" approaches). Also, policy-makers have to decide on public sector research entry points – the appropriate balance between basic/fundamental and applied research, and between crops, livestock, aquaculture and forestry; the breadth of the R&D portfolio; and the division of labour, i.e. which technologies can or will be developed exclusively by, or in partnership with, local or international private sector companies. Here, it should be recognized that for the most part, the role of private sector R&D and delivery systems will remain limited without significant government inducements, particularly for small-scale/subsistence farmers in marginal areas. Irrespective of whether one or a number of ministries is responsible for "Agriculture", a collective decision-making forum for priority-setting and resource allocation for R&D within or between the ministries involved would seem appropriate. As noted in Chapter 8, a number of countries are beginning to establish such mechanisms for dealing with regulatory issues, but no country seemed to have a similar forum for biotechnology priority-setting across the agricultural sector as a whole.

The potential for R&D to improve productivity and reduce hunger and poverty will be strongly influenced by the types of farms and production systems, and by the strength of the research, extension and higher education institutions available. Its focus should be directed at areas where the largest number of poor people live and respond to their vulnerabilities and livelihood strategies. This type of information needs to feed into a process that considers all the technical options available for dealing with the issue(s) in question. This in turn may require expertise in *ex ante* impact assessment supported where possible by *ex post* assessments to assess whether a particular biotechnology "adds value" to more conventional and probably lower-cost and technically less demanding R&D approaches for improving livelihoods through productivity or quality enhancements, the effectiveness of government or private services and the returns on government investments. For some biotechnologies, assessment should take account of socio-economic issues like intellectual property rights (IPR), the associated costs and assumptions concerning user and consumer acceptability nationally and internationally for commodities earmarked for trade, and the skills and infrastructure needed to cover possible R&D as well as post-release costs of biosafety and food/feed safety regulations. Other priority-setting considerations include: the current status and likely future strength of the national breeding, management and disease/pest control programmes; the delivery systems for the technology in question and their sustainability; and the national and international S&T landscape.

A summary is provided of methods for conducting impact (mostly economic) assessments, the majority of which feed into top-down approaches. Some, however, like the sustainable livelihoods approach can be adapted to bottom-up mechanisms although in general the associated data requirements are substantial. Impact assessment should be part and parcel of priority-setting processes and overall research evaluation and management systems within research organizations and therefore should be institutionalized throughout.

Priority-setting ultimately comes down to assessing the appropriateness of the technological packages being considered i.e. their technical feasibility, economic viability, social acceptability, environmental friendliness, relevance to the needs of farmers, consumers etc. – issues that inevitably vary over time and space. Assessing appropriateness requires capacity to identify and make hard choices among the many critical problems facing rural communities that can be addressed better with agricultural biotechnologies than by taking other approaches. This, in turn, depends on the quality of the background information available, the methods used, and who participates and how, in informing decision-making. The results will always be speculative, open to uncertainties and different interpretations and certainly cannot reliably be extrapolated from one country to another or even from one location to another within a country. It is therefore important to review results against studies from other countries with similar and different socio-economic conditions.

Government-level policy-makers should encourage the introduction within their national agricultural research systems (NARS) of more rigorous and participatory mechanisms and methods to inform decision-making on these matters, including allocation of resources through specific programmes, projects and activities. However, new approaches are needed to assess, and compare with conventional approaches, the likely impacts – social as well as economic, immediate and long-term, positive and negative – of all major modern biotechnologies used in food and agriculture, particularly for smallholders in disadvantaged areas.

7.1 INTRODUCTION

ABDC-10 takes place against the backdrop of global food, energy and financial crises, and a number of worrying statistics and trends concerning hunger, food insecurity, the state of the world's climate, and its resources of land, water and biodiversity upon which everyone ultimately depends for their livelihood and very existence. It benefits from the comprehensive and thought-provoking insights provided by the World Development Report on agriculture for development (World Bank, 2007), the International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD, 2009) and the State of Food Insecurity in the World (FAO, 2008) into the challenges faced and the opportunities available through agriculture at regional and global levels for meeting hunger and wider sustainable development objectives, such as reducing poverty, food insecurity and environmental degradation.

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

The vast majority of the world's hungry people live and work in rural areas as do three-quarters of the 1.4 billion living on less than US$ 1.25 per day (Chen and Ravallion, 2008), and most depend on agriculture for their livelihood both directly and indirectly through rural off-farm activities. Addressing food insecurity therefore requires policies, strategies and programmes that (1) stimulate widespread and long-term increases in the production of staple foods and other products through enhanced productivity, (2) doing so in ways that protect the environment, conserve and use agricultural and wider biodiversity sustainably, (3) ensure food safety and quality to protect the health of consumers, and (4) promote fair trade.

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

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

This Chapter (along with its companion Chapters 8 and 9), deals with policy[1] options for strengthening national capacities to make informed choices about using BFA. The Chapters recognize that views vary widely among countries, institutions and individuals about the contributions that biotechnologies, particularly advanced biotechnologies like genetic modification, can make to improve agricultural productivity and food security in developing countries, and whether, for example, strengthened intellectual property regimes are necessary to achieve these goals. Beneficial or regrettable, both are facts of life, and the Chapters do not advocate the use or avoidance of any particular biotechnology or approach towards their development and application, although each one highlights some key and unique issues that should be taken into account when considering its application.

The three Chapters also analyse the national biotechnology policy/strategy (NBS) documents that have been developed and approved by 15 selected developing countries (Table 1), as well as other relevant documents and policies from the same countries. These NBS documents may evolve and be revised by governments over time. However, by analysing the documentation from these 15 countries together with many peer-reviewed papers and global assessments, these Chapters set out to describe the range of policy/strategy roadmaps that have actually been prepared by a spectrum of developing countries from different regions for exploiting BFA, as well as to provide some additional options that may be considered by these and other countries.

The three Chapters are closely inter-connected because they include an analysis of the same 15 countries and by the reality that a national "biotechnology policy" covers the pursuit of many inter-linked policy objectives and strategies at any given point of time while striving for the best possible coherence among them to maximize benefits.

This Chapter therefore attempts to "paint the broad picture", covering some of the foundations and principles for countries to consider when targeting biotechnologies to the poor. Chapters 8 and 9 on the other hand – while not losing sight of these target end-user/beneficiary groups – emphasize policy options for dealing with the more specific technical, legal, regulatory and socio-economic dimensions of BFA for fostering their pro-poor development and diffusion.

This Chapter is divided into four main Parts, with Part 7.2 providing the broad context (national and international) within which agricultural policies operate, and stressing the essentiality of ensuring that biotechnology policy contributes to wider policies for agricultural and overall national development. Against some background of the key issues surrounding agricultural biotechnologies, Part 7.3 deals with the "why, what and how"

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

of developing, approving and implementing a NBS framework, including a list of the key policy issues that should be addressed at the governmental level. Part 7.4 provides options for the governance of BFA, dealing with both its structural and organizational aspects (e.g. leadership, coordination and options for independent advice), while Part 7.5 covers the all-important issue of R&D priority-setting at government, ministerial and research institution levels, including the "division of labour" between the public and private sectors. The Annex, in Part 7.6, provides concrete examples of processes and procedures followed by 15 selected developing countries.

7.2 AGRICULTURAL AND NATIONAL DEVELOPMENT POLICY CONTEXTS

Agricultural policies that address a single issue (e.g. BFA) in a piecemeal manner without considering the totality of its dimensions will not contribute positively to meeting the challenges faced by the sector or the people whose livelihoods depend directly and indirectly upon it. This is because each policy initiative (e.g. using semen or embryos to upgrade livestock as

TABLE 1

NATIONAL BIOTECHNOLOGY POLICY/STRATEGY (NBS) FRAMEWORKS OF 15 SELECTED DEVELOPING COUNTRIES

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

part of a dairy development programme) can have enormous knock-on effects – positive and negative – on others, e.g. the people involved in small-scale integrated crop-livestock production systems and the suppliers of feeds and veterinary services.

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

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

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

7.2.1 National and international dimensions of agricultural policy-making and policies

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

These cross-cutting issues cannot be tackled effectively by an individual ministry and clearly different interests will drive negotiations towards particular outcomes and priorities. Also, agriculture has to compete for treasury appropriations against other commercial and social sectors such as manufacturing, infrastructure, education and health, a task made increasingly demanding in the face of rapid urbanization and in nations where agriculture is no longer the backbone of economies, e.g. in countries characterized as "transforming" and "urbanized" (World Bank, 2007). In addition, within agriculture itself, small-scale subsistence-oriented farms, farmers and their organizations have to compete with larger, more commercial and possibly export-oriented systems and their better-organized representatives at the tables of decision-making regarding levels, locations and orientation of government policy and direct and indirect financial support. None of this favours targeting biotechnologies towards the poor – only strong and persistent political commitment can achieve this.

National agricultural policies, and the legal and regulatory frameworks that support them, are also increasingly influenced by legally-binding instruments negotiated globally, regionally and/or bi-nationally. While countries may choose not to take part in one or more of these international agreements, they increasingly set the scene e.g. for global trade, and their influence cannot be ignored. As discussed in Chapters 8 and 9, of particular relevance to biotechnology are the global rules that:

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

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

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

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

7.2.2 Towards comprehensive agricultural development policies and strategies

From the foregoing, it is clear that now and in the future, agriculture needs to contribute to a much more complex set of outcomes than simply producing more food and other primary products. There can therefore be no single strategy for putting all the pieces together for achieving sustainable food security and wider development objectives through national agricultural and food policies and there will be many potential entry points. For a start, policy-makers rarely begin with a clean sheet – they have a baseline of knowledge and experience which evolves over time, and it is a well-known maxim that "each policy

[2] The CPB uses the term living modified organism (LMO), defined as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology", where modern biotechnology is defined as "the application of in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection". Technically, there are differences between a GMO and an LMO but for the purposes here the more commonly used term "GMO" is used, although reference may be made to an LMO. It is also questionable technically, whether some products referred to as GMOs are in fact GMOs since processing has removed all traces of the organism from which the product was obtained. Clear definitions are, however, essential when making laws and regulations transparent and predictable, and differences in these can lead also to misunderstandings between nations; this aspect is not expanded upon further here.

has its own politics" (IDB, 2006). Also, given the tremendous diversity of the agricultural and wider productive and socio-economic sectors across countries and within and even between sectors, and in the cultures of the institutions and individuals that make and implement policies or regulatory standards, it should not be surprising that the processes of reaching agreement nationally, and more particularly internationally, on a particular issue are inevitably protracted with many twists and turns.

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

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

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

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

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

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

7.3 NATIONAL BIOTECHNOLOGY POLICY/STRATEGY FRAMEWORKS

7.3.1 Biotechnology issues from a policy perspective

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

In addressing these and other questions, a number of pertinent issues should be considered. Firstly, contrary to the impression given by the popular and scientific press, biotechnology is much more than GMOs. The first five Chapters document the fact that biotechnology represents a broad collection of tools that are being used for a variety of different purposes in food and agriculture in developing countries. Notable examples include: genetic improvement of plant varieties and animal populations to increase their yields or efficiency; genetic characterization and conservation of genetic resources; plant and animal disease diagnosis; vaccines to protect livestock and fish from disease; and improvement of feeds. There are therefore many potentially useful tools included in BFA – both "traditional" and "modern" – to be considered by policy-makers for contributing to the "technological mix" needed to advance sustainable agriculture and rural development, and which will continue to offer wide choice in the types of agriculture being pursued. GMOs also have potential. However, their development and use, as well as the use of products derived from them, require attention to scientific, legal, regulatory, financial and other considerations that are not generally encountered with other biotechnologies (see below and Chapters 8 and 9).

In addition, at its “top end”, biotechnology is best described as a “platform” or generic technology, embracing applications of genomics and bioinformatics, microarray technologies, high-throughput DNA sequencing, genotyping, polymerase chain reaction (PCR), transgenesis, robotics, mass spectrometry etc., across sectors and biological boundaries, i.e. it is both sector- and scientifically cross-cutting and requires the determined pursuit of multi-disciplinarity. Policies and strategies for research involving the wider application of modern biotechnologies should therefore be developed in ways that maximize the opportunities arising from their cross-fertilization features. This requires strong inter-ministerial coordination and collaboration.

Biotechnology approaches to agricultural research are not alternatives to conventional technologies but are complementary. However, whereas developments in conventional technologies are generally driven from within applied science research settings, modern biotechnology evolves from discoveries, knowledge and innovations coming from the basic sciences. There is therefore an institutional “disconnect” between these two research environments, e.g. between institutions involved in mapping, isolating and discovering the function of genes and producing gene constructs and those using genetic markers, gene constructs, and strands of DNA to characterize or provide improved germplasm, vaccines, diagnostic tests etc. Even at the more downstream end of modern biotechnology (e.g. using validated molecular markers, diagnostic reagents, tissue culture and micropropagation), biotechnology R&D comes at additional cost. Working further upstream (e.g. in structural and functional genomics, basic immunology and cell biology, bioinformatics and genetic transformation) increases both start-up and maintenance costs considerably. This is particularly so in the veterinary field or when dealing with diseases transferred from livestock to man (zoonotic diseases) where laboratories and animal facilities with high levels of physical containment may be required.

Another consideration is that biotechnology R&D needs physical facilities, expensive and sophisticated equipment and a critical mass of scientists with new skills to complement existing expertise in the traditional agricultural specialities like plant and animal breeding, disease management etc. Shortcomings in either these new or conventional knowledge arenas (arising from quantitative or qualitative deficiencies in school and tertiary education, opportunities for continuous learning and funding of more traditional research including monitoring the status and trends in agricultural and wider biodiversity and the environment) will seriously limit the potential of BFA.

Realizing the full potential of agricultural biotechnologies takes more than laboratory-based research. Innovations from upstream research need to be developed and scaled up through further innovations into tangible products (e.g. seeds, plantlets, diagnostic kits, vaccines, batches of enzymes, foods) that are useful, affordable and acceptable to farmers, to diagnostic and other support and input providers, and to consumers. Of course, to be useful, these products have to be delivered to them. Assuming regulatory requirements are satisfied (see Chapters 8 and 9), these critically important aspects – development/scaling up and delivery – are invariably the major "missing links" or stumbling blocks to deploying most technologies, including biotechnologies, in developing countries i.e. the capacity to "commercialize" biotechnology through the creation or support of demand-driven private sector firms or public-private enterprises that can deliver to end users is key for success. Underpinning the success of such firms and arrangements is the availability of entrepreneurial and business management skills and financial capital.

An additional issue to consider is that the international legal and regulatory framework surrounding biotechnology R&D and the diffusion of some of its products are complex and constantly evolving. They also add significantly to the cost of innovations and to uncertainty about returns on investments. While certainly not restricted to GMOs, the following should be noted:

- Research involving, and products derived from recombinant DNA (rDNA) techniques, need to satisfy additional scientific and other requirements for ensuring the safe use of laboratory techniques and field testing of new products before they are released for general use, i.e. biosafety[3] (Chapter 8; see also National Research Council, 2002 and 2008). Products may also require environmental monitoring after commercial release and restrictions may be placed on how and where they are cultivated or used (National Research Council, 2002; FAO, 2007b). Products entering food and feed chains also have to meet safety regulations. Meeting regulatory requirements requires additional legal and scientific skills and laboratory, administrative and management infrastructures. Ideally, these should be independent from those available within public and private research and product development institutions;
- GMOs and products derived from them and other evolving technologies (e.g. animal cloning) can potentially come up against trade restrictions due to national differences in approaches to, interpretation of, or enforcement of laws and regulations (e.g. labelling and IPR), as well as asynchronous approvals (Chapter 8). These differences may increase if, as expected, new products with additional features come to market, but they may also decrease if adoption of the technology and products becomes more widespread;

[3] The CPB does not define biosafety. Judging by the scope of their primary laws and regulations on biotechnology, countries surveyed for Chapters 7-9 employed the term variously in relation to protecting agricultural or agricultural and wild biodiversity, or the "environment" as a whole (i.e. both the biotic and abiotic components of landscapes or ecosystems); they may or may not include human health in all its dimensions or one particular aspect e.g. food safety. For the purposes of these Chapters, the term biosafety refers to assessing and managing the potential risks to the environment and human health, including food and feed safety arising from R&D, use (contained and not contained), and marketing for food and feed uses of GM products and the processed materials derived from them.

- Related to the above, there are many social and economic issues surrounding the use of modern BFA. These require more complex ways of organizing the interplay between science, decision-making and society to address public concerns about risks and benefits. In any event, a number of international instruments, such as the CPB, specifically address the issue of public awareness and participation regarding GMOs (Chapter 9).
- Many of the tools and much of the biological information used for some of the biotechnologies considered at ABDC-10 have intellectual property and tangible property (IP/IT) protection (Chapter 9). Also, access to some genetic resources (particularly animals, micro-organisms and from plant and tree species not covered by the ITPGRFA) will inevitably be subject to bilateral access and benefit-sharing arrangements. In addition to private sector companies, public sector universities and research institutes as well as the international research centres of the Consultative Group on International Agricultural Research (CGIAR) increasingly seek IP/IT protection for the fruits of their research. All of these increase substantially the complexity of R&D management, can restrict "freedom to operate" and can be barriers to technology transfer and diffusion. As shown in Chapter 9, a range of options, including public-private partnerships, are available that may be useful for reducing such barriers.

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

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

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

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

7.3.2 Purpose and content of biotechnology frameworks

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

As noted earlier, biotechnology cuts across several sectors and is of interest to a wide spectrum of stakeholders. Therefore, notwithstanding the need to develop policies, strategies and programmes that are aligned with those existing for the agricultural sector and tailored to meet the requirements of BFA, the governance of biotechnology at national level should be horizontal.

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

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

Putting all this together is a formidable challenge, requiring much effort to collect and analyse national baseline data and information, as well as information on how other countries have approached the issues in question. In addition to close interministerial coordination at scientific, technical, legal, administrative and financial levels, it requires the widest possible engagement with the public, including with representatives of farmer/producer organizations, private companies, NGOs, CSOs etc., the ultimate aim being "participatory decision-making" (Chapter 9). Bijker (2007) provides an excellent description of the key criteria for building policies via a policy dialogue and a methodology for carrying out a diagnostic study, emphasizing the importance of ensuring that the policies and strategies identified support institutional reforms, including greater cooperation at national, regional and international levels; strengthen national capacities; and identify new funding mechanisms.

7.3.3 Developing and approving national frameworks

The institutions involved in developing and approving the frameworks in the 15 selected countries analysed for this Chapter are shown in Table 1. Key features regarding the development and approval of these frameworks, as well as of those from the two countries that have prepared strategies specifically for BFA, are described in the Annex (Part 7.6.1). Most national biotechnology policy documents are available from the FAO biotechnology website[4] while other information was obtained from ISAAA's AfriCenter and from other Internet sources.

While there were several commonalities to the mechanisms established to develop these frameworks, the Annex indicates that there were also significant differences between the 15 countries – particularly with respect to the level and degree of cross-ministerial engagement, but even more noticeably in terms of involving or consulting non-ministerial and non-scientific entities in the process. For most countries, the process could be described as "top down" and lacking involvement of both industry and civil society groups. For most countries also, the NBS was directed at modern biotechnology and particularly at

4 www.fao.org/biotech/country.asp

the governance of R&D and diffusion of GMOs and their products. Moreover, within that context, virtually every country stressed as a fundamental principle the importance or essentiality of protecting health and sustaining the environment as pre-conditions for success in applying biotechnology. Many also mentioned precaution, liability and redress, and labelling of GMOs and their products as important regulatory principles, with one country placing a moratorium on the use of genetic use restriction technologies (GURTs). Others emphasized the importance of integrating and protecting indigenous knowledge, resources and practices, and of benefit-sharing.

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

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

7.3.4 Issues for policy consideration

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

- coordination nationally, regionally and globally;
- strengthening the scientific knowledge base and scientific infrastructure;
- encouraging investment in commercial development (particularly Argentina, Brazil, Chile, China, Malaysia, Peru, Thailand and South Africa);
- providing strategic investments and other incentives to foster partnerships between universities, public research institutions and commercial companies (Argentina, Brazil, China, India, Malaysia, Peru, Thailand and South Africa);
- providing a regulatory system that is both transparent and effectively assesses and manages the risks from developing and introducing new and modified products while allowing innovation (all countries);
- introducing, reviewing and/or, if necessary, proposing amendments to laws and regulations concerning intellectual property and access to and benefit sharing from plant and other biological resources (all countries with reference to GMOs);

- fostering community understanding about biotechnology by improving access to understandable information and providing the means by which citizens can express their views;
- providing opportunities for considering cultural and ethical issues (some countries).

How the countries concerned proposed to deal, or have actually dealt, with each of these issues forms the basis of much of the remainder of this Chapter and the two following Chapters. An attempt has also been made to identify "gaps" or "areas in need of further attention" within each of these themes both nationally and internationally (regionally and globally). However, although many countries have established biosafety frameworks (see Chapter 8), very few countries have actually prepared NBS frameworks and even fewer have done so for BFA, leaving considerable scope for the remainder to consider their options on both fronts.

7.4 GOVERNANCE STRUCTURES AND ORGANIZATION

7.4.1 Leadership and coordination: principles and options

Because of its inherently science-driven character and with applications across a range of sectors and activities being undertaken within different jurisdictions, successful governance of biotechnology requires policies and strategies that address all stages of the innovation chain, i.e. from fundamental through to adaptive research, from there to the development of tangible products and then on to their diffusion to end users, i.e. both farmers and consumers. This, as well as related trade issues, requires coordination across governments, across government departments, with sub-national governance structures as well as with other governments via bilateral, regional and multilateral mechanisms.

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

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

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

Horizontal coordination

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

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

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

While countries have the option of separating these roles and responsibilities, a fully functioning horizontal coordinating mechanism should be able to develop, support and advance both policy and operational elements of the government's NBS framework. This makes the structural challenge all the more demanding since the coordinating body needs to be able to accommodate and bridge distinct but overlapping policy and operational activities even though these may be organized in different ways in the relevant offices by different nations (for example, when "agriculture" is covered by separate Ministries for Agriculture, Livestock, Fisheries and Forestry and, as noted earlier, when Ministries of Environment, Trade, Natural Resources etc. engage on specific issues).

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

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

Vertical coordination

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

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

Analysis of the 15 selected developing countries (Annex, Part 7.6.2) shows that while all governments recognized that no single ministry could hold all responsibilities in moving their national agendas forward, and therefore the need for effective inter- and intra-ministerial coordination and decision-making, in only a few cases have new formal structures been established or proposed to oversee biotechnology's development and in very few cases do these appear to involve collective government.

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

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

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

7.4.2 Independent advice: Principles and options

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

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

Options for advisory structures include:

- an individual acting as chief scientific advisor to the Head of State or to the government and chairing a broad-based panel of well-respected individuals;

- establishing permanent advisory committees within sectoral ministries;
- dealing with specific/emerging issues through *ad hoc* committees;
- engaging the expertise available within a national science academy or research council, one of whose roles is to ensure that the best possible evidence and advice are available to policy-makers.

While some of the 15 selected developing countries established an independent biotechnology advisory committee or council to provide strategic policy advice to government, more often the mechanism was set up to advise an individual ministry or department (see Annex, Part 7.6.3, for details). Concerning the representation of NGOs and CSOs in advisory mechanisms, there was no evidence for this having been done or intended in any of the countries reviewed. Only Argentina appeared to have set up an advisory mechanism to cater specifically for food and agriculture, the remaining countries relying on a broad-based/horizontal mechanism reporting to government or more often to the Ministry for S&T. Other countries should consider their options for obtaining more focused advice relating to BFA rather than leaving this up to "generalists".

7.5 SETTING PRIORITIES FOR R&D

7.5.1 At the level of government

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

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

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

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

A number of approaches can be considered. One is to establish a national system of biotechnology statistics and indicators to inform policy actions, bearing in mind that this should include more than data about biotechnology R&D (e.g. funds allocated, number of researchers involved). Data on, e.g. productivity improvements, environmental impacts and socio-economic benefits are also required. The first step in this process is to define the term biotechnology, a list-based definition being probably the most useful when the policy interest relates to benefits (e.g. Van Beuzekom and Arundel, 2009).

Another strategic direction is to set up reliable systems for biotechnology foresight, to monitor and assess the relevance for national agricultural and rural development of global patterns of technological change as well as demand from both home and export markets for biotechnology products including market potential, acceptability by users and consumers, and pricing. This helps guide formulation of technology policies and strategies. Currently, only some industrialized countries appear to have such systems in place.

A third approach is to introduce instruments that encourage the transformation of traditional research institutions and related higher education centres from "silos" of often pure discipline-oriented activity into innovation systems that put a premium on multi-disciplinarity and networking and a much greater number and diversity of actors. Of the developing countries reviewed, only Argentina, Brazil, China, India and South Africa signalled their intention to move in this direction and, as illustrated in Chapter 8, have actually done so. Other countries were silent on such initiatives.

7.5.2 For biotechnologies in food and agriculture

7.5.2.1 Strategic considerations

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

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

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

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

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

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

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

The reasons for this include the strengthening of IPR on biological innovations (Chapter 9), and because private R&D investments will be largely directed at medium- and large-scale commercial agriculture (especially export crops, fruits, vegetables, flowers, aquaculture and livestock products) and food processing. Also, some technologies – particularly the key platform technologies employed in genetic modification, disease diagnosis and molecular analysis which are needed for downstream and adaptive research – are controlled by private firms. Most of these are not applied to the crop or animal-trait or disease combinations important to small-scale and resource-poor farmers, and therefore there is substantial "space" for the public sector to engage in pro-poor biotechnology R&D by complementing and not duplicating or substituting for private initiatives and filling gaps relevant to the poor who cannot pay. It does, however, mean that the NARS are going to have to largely "go it alone". This reality has substantial policy implications for governments, not least of which is the need to decide on the emphasis to be placed on "home grown" production/self-sufficiency of particular commodities, and on the proposed beneficiaries of R&D investments.

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

This pressure is both political and, in some situations, justified on the grounds that the combination of market liberalization and private sector investment is already reducing the need for continued public sector research investment (e.g. in areas most relevant to commercial farmers). Are these issues being factored into national and international R&D priority-setting processes? For example, in addition to the small number of well-known major global crops such as maize, rice, wheat and cotton, many more crops are regionally and nutritionally as important (if not more so) for poor farmers and households (examples include sorghum, millets, bananas and plantains, roots and tubers like cassava and yams, groundnuts and indigenous crops like tef and quinoa). These under-researched "orphan" crops are nutritious, well adapted to harsh environments, and genetically diverse and have great potential for improving food security, livelihoods, cropping system stability and genetic diversity. Is the biotechnology being considered targeting the crops and animals of small-scale and poorer farmers and their traits of interest?

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

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

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

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

7.5.2.2 Assessing impact

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

- **Precedence**: uses previous funding levels as the basis for the next programme cycle; quick, not to be recommended, but all too common;
- **Congruence**: ranks alternative themes on the basis of a single criterion; quick, demands very little data, questionable rigour;
- **Weighted scoring**: ranks alternative programmes and projects by identifying and weighting multiple criteria; easy, does not require advanced quantitative skills, relatively transparent, promotes multi-disciplinarity and stakeholder involvement. The analytical hierarchy process (Braunschweig, 2000) is one variation of this. It involves breaking the decision problem down into a number of more easily understood sub-problems. These elements are then played off against each other in pairs using both evidence-based and subjective data, and with uncertainty in cost, benefit etc. The essence of the approach is that human judgements and not just hard factual data are used to inform decision-making;
- **Cost-benefit analysis methods**: widely used, the simplest involving examining the streams of both costs and benefits of a particular technology in financial terms only. Another approach takes into account the costs of alternatives;
- **Economic surplus models**, such as the Dynamic Research Evaluation for Management (DREAM) model (Alston, Norton and Pardey, 1998), are also available to guide priority-setting based on the expected financial return to investments from research or uptake of a particular technology. The economic analysis by Foltz (2007), supporting priority-setting for investment in modern biotechnologies to deal with biotic and abiotic constraints to crop production in countries in West and Central Africa, is an excellent example of this approach. Similarly, Vitale *et al.* (2007) have employed the approach to assess the economic impacts of introducing Bt technology in smallholder cotton/maize production systems in Mali, concluding that the use of the technology in cotton would have a much higher priority than in maize due to the price differentials between these crops, and the fact that farmers spray cotton but not maize for controlling insect pests – a conclusion consistent with studies conducted elsewhere (Brookes and Barfoot, 2005). This approach requires a great deal of data, is done independently of stakeholder input and, while appropriate for ranking benefits from research or user uptake from particular commodities, it is not well suited to ranking upstream research or bringing in social issues.

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

Getting well grounded information and answers using one or a combination of these methods is important. Yet, the methods themselves should not drive the process – they should inform it. They should not be used to replace sound judgement, experience and ingenuity or to leave so little room for manoeuvre that freedom to explore new avenues is inhibited. Nevertheless, impact assessment should be part and parcel of priority-setting process and of the overall research evaluation and management systems within research organizations, and therefore should be institutionalized throughout. Further information on impact assessment for agricultural research is available elsewhere[5], while Anandajayasekeram *et al.* (2007) provide specific examples of using these methods in an African context.

7.5.2.3 Other considerations for R&D priority-setting

These include the current status and likely future strength of the national breeding, management and disease/pest control programmes for the crops, trees and animals in question and for processing their products, bearing in mind that the biotechnologies being considered would normally complement rather than fully replace the technological package available to the farmer or used by the plant protection and veterinary services; and in the case of improved genetic traits, that these would need to be "added on", singly or more likely combined, to local germplasm containing other agronomic traits valued by farmers and rural households (e.g. higher yield, tolerance to drought, resistance to other diseases or pests, high nutritional value, better cooking quality etc.) and not included in the new technology itself.

5 http://impact.cgiar.org/

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

Another consideration is the national and international "science and technology landscape", to decide, for example, whether to rely on spillovers from R&D conducted through other national or international initiatives or engage actively in the entire basic-applied-adaptive research continuum, the decision on which to choose being determined by the assumptions made about the "strings attached" to each (see Chapter 9). Information that has to be gathered here includes availability of the technology; who owns it; best guesses of the effort, time and costs to develop it from scratch or adapt it for local use; interest of, and conditions for, private sector investment in the required R&D, mechanisms of product delivery and skills in its use through partnership with the public sector and availability of policy instruments to encourage such partnerships (Chapter 8); and acceptability of the product to farmers and communities in terms of both price and cultural considerations.

In relation to costs of GM crop development, Manalo and Ramon (2007) estimated the cost of developing MON 810 Bt corn in the Philippines from the confined greenhouse stage at US$2.6 million. Costs in the United States which preceded the work in the Philippines (i.e. for gene discovery, making the gene construct, introgression of the gene, selection of transformed plants, laboratory and greenhouse testing, confined field trials, multi-location field trials) were US$29 million. Over 65 percent of the costs in the Philippines were for meeting government regulatory requirements. Other estimates of regulatory costs include those for virus resistant papaya and herbicide resistant soybeans in Brazil (US$700 000 and US$4 million respectively, in the latter case due to requirements for animal studies), and US$160 000 for insect resistant maize in Kenya (Atanassov *et al.,* 2004). Also, a study of regulatory costs in 10 countries concluded that the cost of introducing a GM trait can range from US$6–15 million (Kalaitzandonakes, Alston and Zilberman, 2007). These costs will, of course, be heavily dependent on national regulatory requirements (Chapter 8).

Also, the introduction of GM crops (whether obtained in the form of the owner's protected variety, by backcrossing this with a local well-adapted variety, or by introgressing an imported or local gene construct into a local variety), will inevitably involve charging farmers a "technology fee" – in effect, a higher price for the seed. The price at which this is set will influence both adoption rates and social welfare benefits and will vary with the profitability of the crop, in general being higher for industrial/export crops than for traditional subsistence crops (see, for example, Vitale *et al.,* 2007). At the same time, consideration needs to be given to the issue of collecting technology fees. Inability of technology owners to collect these at the time of seed sale due to lack of appropriate IP laws or their enforcement (see Chapter 9) could significantly affect estimates of social and economic benefits.

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

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

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

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

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

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

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

Government policy-makers should encourage the introduction within their NARS of more rigorous and participatory mechanisms and methods to inform decision-making on these matters, including allocation of resources through specific programmes, projects and activities. Possible mechanisms for doing so are presented in Chapter 8.

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

7.6 ANNEX: The processes of developing, approving and overseeing biotechnology policy/strategy frameworks and of providing independent advice in selected developing countries

7.6.1 Development and approval of NBS frameworks

7.6.1.1 National frameworks

Leadership

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

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

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

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

Developing the draft policy/strategy

In countries that set up an interministerial mechanism, responsibility for drafting the NBS was assigned to a 10–20 person task force, advisory/steering committee, consultative group or expert panel. This included representatives from key departments within ministries, universities, research institutions, science funding bodies, private foundations, industry and, in some instances, civil society and consumer groups. In some cases, separate working groups were established to lead consultations and report on specific topics (e.g. R&D, communication) and sectors (e.g. agriculture, health, environment, industry). For example, in Thailand, six sub-committees were established under the National Biotechnology Policy Committee to obtain inputs and draft the document, and a further sub-committee dealt specifically with genetic modification and biosafety policy development.

Some countries (e.g. Malaysia, Malawi, South Africa and Zambia) brought in outside consultancy organizations, development partners or individuals to assist the process. Others (e.g. Argentina, Brazil, India and Uganda) provided opportunities for consultations at state, regional or provincial levels, while some countries (notably India) also solicited public comments by placing their draft strategies on the Internet, while Chile sought the views of parliamentarians and experts. In other countries (Jamaica, Kenya, Namibia and Uganda), the tasks of both coordinating inputs and drafting the document were undertaken by the National S&T/Research Council or similar.

NBS scope

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

NBS content

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

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

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

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

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

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

Approval of NBS frameworks

Countries took, or intended to take, one of three routes for approving their NBS documents:

- creating new primary legislation that embraced substantial elements of the entire document (including the creation of new financial and/or regulatory institutions and mechanisms and/or additional roles and responsibilities of existing institutions, financing arrangements etc); The legislatures of China, Brazil, Peru and Chile (in progress) passed decrees/laws covering the policy/strategy documents prepared by government authorities;
- obtaining full government approval for the NBS and, separately, creating primary or secondary laws and regulations to cover specific aspects e.g. on biosafety, IPR, establishment of funding instruments etc; This was the path chosen by the vast majority of countries reviewed (see Table 1).

- obtaining approval from the ministry given the lead responsibility for the issue and creating non-binding guidelines for specific matters; Based on available information, this was the path chosen by essentially all countries initially and has been retained by many for particular aspects.

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

7.6.1.2 Strategy frameworks for BFA

Two of the countries (Argentina and India) prepared comprehensive BFA policy/strategy papers although, as described in more detail in Chapter 8, these and most other countries have also developed laws and regulations on GMOs. In Argentina, the strategy was developed under the leadership of the Secretariat of Agriculture, Livestock, Fisheries and Food (SAGPyA). Its development involved many stakeholders including the offices of Senators and Deputies, the Secretariats of Industry, Sustainable Development and S&T, the Ministry of Foreign Affairs, all the main universities, funding bodies, industry and civil society groups and individual companies, including multinationals. In India, the Department of Agriculture and Cooperation within the Ministry of Agriculture set up a Task Force to formulate a draft long-term policy on applications of biotechnology in agriculture, including suggestions to streamline/harmonize decision-making under various ministries/organizations. The strategy covers the crop, livestock, forestry and fish sectors. It also deals with related issues like genetic resource conservation and use, food safety, co-existence of organic, conventional and GM agriculture, regulation, public participation and commercialization. Five working groups were set up to examine, report on and provide recommendations on the various issues, culminating, after eleven meetings and interactions with a wide variety of stakeholders, in a comprehensive report issued in 2004.

7.6.1.3 Sub-national biotechnology policy and strategy frameworks

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

7.6.2 Oversight

- Brazil established a high level National Biotechnology Ministerial Council/Committee within the Prime Minister/President's office to coordinate implementation of their strategy/law;
- India set up a Department of Biotechnology within its Ministry of S&T to promote and coordinate all aspects of biotechnology development in the country;
- Malaysia established a Biotechnology Corporation overseen by an Implementation Council and advised by an international Advisory Panel, both under the leadership of the Prime Minister;
- Peru established an Interministerial Commission to harmonize sectoral policies, and a National Executive Committee on Biotechnology (CONEBIO) within its National Council for Science, Technology and Innovation Technology (CONCYTEC) to deal specifically with biotechnology;
- In Thailand, the National Biotechnology Policy Committee was chaired by the Prime Minister and assisted by seven sub-committees including one dealing with genetic engineering and biosafety policy development;
- Kenya proposed the setting up of a National Biotechnology Enterprise Programme consisting of a National Commission to oversee implementation of the policy framework and a National Education Centre to coordinate and facilitate training, develop databases and a national culture collection, but whether an interministerial mechanism will be created to oversee these initiatives is unclear.

7.6.3 Independent advice

Among the countries analysed, various mechanisms were used:

- South Africa's Biotechnology Advisory Committee is a sub-committee of the National Advisory Council on Innovation which assists the Minister for S&T;

- Argentina set up a National Advisory Commission on agri-biotechnology to advise its Secretariat on technical and biosafety requirements. Public and private organizations with competencies in BFA are represented;
- Chile established a Commission for the Development of Biotechnology and plans to set up an independent Biotechnology Forum to be consulted on issues and charged with promoting public debate;
- In India, the Department of Biotechnology set up a Scientific Advisory Committee and an international Standing Advisory Committee;
- In the case of Malawi, a National Biotechnology Commission with representatives from academia, R&D, education and commerce is proposed to advise the National Research Council;
- Peru established a National Advisory Committee for Biotechnology R&D within CONEBIO to advise on non-regulatory issues;
- The African Union (AU) and the New Partnership for Africa's Development (NEPAD) put together the High Level African Panel on Modern Biotechnology, whose specific remit was to "provide the AU and NEPAD with independent and strategic advice on developments in modern biotechnology and its implications for agriculture, health and the environment". The Panel, consisting of two co-chairs and 12 panel members assisted by a Secretariat and a Research Team, delivered a comprehensive report about biotechnology and the role it can play for development in Africa (Juma and Serageldin, 2007). The final report was based on many meetings, submissions from various stakeholders, requests for comments on the web and feedback from workshops and conferences in Africa and elsewhere. An Executive Summary of the draft report was submitted to the Ministers' Meeting of the extraordinary conference of the African Ministerial Council on Science and Technology in November 2006 and in their meeting Declaration, the Ministers endorsed the report.

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