CHAPTER 9

ENSURING ACCESS TO THE BENEFITS OF R&D

SUMMARY

This Chapter covers three subjects of importance to applications of biotechnologies in food and agriculture (BFA): intellectual property rights (IPR) and genetic resources; public awareness and participation; and agricultural extension. Like its two companion Chapters 7 and 8, the Chapter also provides an analysis of 15 selected developing countries to illustrate some of the options available to countries.

Analysis of the national biotechnology policy/strategy (NBS) documents of these 15 countries indicates that most countries mentioned IPR and the importance of their genetic resources. However, very few (1) indicated the need to change their existing, or introduce new, intellectual property (IP) legislation, regulations and other polices to cater for the specific challenges posed in particular by modern biotechnology, (2) described how their research institutions intended to go about accessing, or sharing with others, the research tools, gene constructs or genetic resources needed for research and development (R&D) or any end products arising from such efforts nationally or in other countries. None mentioned the role of research funding bodies in influencing the policies and behaviour of their national research communities.

IP protection systems in developing countries must consider both the structure and multifunctional roles of the agrifood sector and be consistent with the minimum requirements laid down in a number of international IP agreements, which differ in terms of eligibility and scope of protection. Other factors to be considered include: the inter-relationships between these IP agreements and the goal of national food security as well as the core aims of the Convention on Biological Diversity (CBD) and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). Costs and benefits of implementing

national IP legislation for BFA innovations consistent with international rules are further considerations. No single IP system will suit the needs and goals of all countries or serve all agricultural systems within an individual country. Consequently, in the process of designing IP legislation and related policies, countries wishing to use IP as an "enabler" of BFA should make realistic projections about the future role of biotechnologies in helping to meet their national agricultural and wider food security and poverty reduction goals, and make maximum use of the flexibility inherent in internationally agreed rules. Countries should also be aware that there are options outside of IPR instruments to protect developers and suppliers of plant, animal and microbial materials.

Requirements and mechanisms for establishing IP laws, and responsibilities for undertaking the related regulatory and administrative tasks assigned to particular institutions, raise daunting technical, legal, judicial, administrative and financial challenges. The needs for training and capacity building to deal with the wide scope, complexity and interplay between all the issues involved in ways that ensure public sector R&D remains focused on the social needs of the many, rather than the financial interests of the few, must remain paramount if BFA is to deliver on a pro-poor agenda. Consultative mechanisms therefore need to be established to reach agreement and strike compromises between groups both within and outside the agrifood sector on a number of fundamental issues. These include the extent to which, and in what forms, IP protection should be available; ownership of agreed IPR; institutions to identify and manage technologies and knowledge to be accessed and protected; and enforcement of legislation.

In response to changes in their laws that allow commercialization of inventions from publicly-funded R&D, a few agricultural ministries and research organizations in developing countries have established technology transfer offices (TTOs), working under various levels of decentralized authority. Policy-makers should be aware of the pros and cons of establishing such offices for BFA and, in general, of the potential issues regarding commercializing IP assets within the public sector. They should also not dismiss the option of exploiting the IP of their research institutes by publicly disclosing details of innovations though "defensive publication".

The IP and tangible property rights (e.g. germplasm, clones, expression vectors, computer software, and equipment) surrounding BFA can be highly complex. Unravelling this complexity by deconstructing each component and method followed by identifying all the potential patents, plant breeders' rights and licenses relating to each for conducting a product clearance analysis and determining freedom to operate (FTO) requires considerable IP management skills. The strategic IP management choices open to public organizations to access biotechnology tools and technologies for research, development and diffusion will depend on factors such as R&D capacity, objectives, cost, conditions and public acceptance.

Research institutes in developing countries can access them without seeking the owner's permission using gaps in patent and protected variety jurisdictions or using research and experimental use exemptions in national legislation, although both options have potential drawbacks. They can also access them with the owner's permission and several options are available, including material transfer agreements (MTAs), licensing agreements, purchasing outright, patent pools, open source licensing, public sector partnerships and public-private partnerships (PPPs). The pros and cons of each are described. Particular consideration is given to PPPs since such instruments are features of government policy in an increasing number of developing countries, supported in many cases by the donor community. Options to promote partnerships between public entities and the private sector in both research and commercial undertakings on pro-poor BFA without, or with limited, complications arising from IPR, include negotiating royalty-free access to proprietary genes, genetic constructs and germplasm, and using the services of third party brokers. Although promising, convincing evidence is still generally lacking about the success of such PPPs in BFA in terms of products in widespread field or commercial use.

Policy options are provided for consideration by national and international research funding and development agencies when dealing with technology and knowledge transfer. They include encouraging the free exchange of materials and data; ensuring that grant applicants include in their proposals an explanation of their stewardship plans, as well as plans for the sharing and dissemination of research results; and encouraging non-exclusive licensing.

The current plethora of "participatory" planning and implementation of R&D projects and extension services attests to how policies have been transformed within many governments and funding bodies for organizing these services. Nevertheless, such policies have not replaced the more traditional "top-down" (and often "supply-driven") option and both approaches are needed to provide balance, objectivity and transparency to government, ministerial or institutional decision-making. Challenges to participatory "bottom-up" approaches to biotechnology R&D are described, and examples from Kenya and Bolivia illustrate options for priority-setting which can be suitably adapted to include biotechnology.

Although rarely articulated in the NBS documents and not mentioned in any national biosafety or regulatory framework examined for the 15 selected developing countries, participation – as well as awareness and education – are important dimensions in national policy-making on biotechnology. They also carry the weight of law in countries acceding to international environmental instruments which either require or encourage inclusion in national laws and regulations. The Chapter outlines the many challenges involved and the instruments and options available to countries for dealing with information-sharing, education and communication between the public and national planning and implementing agencies with respect to BFA decision-making and regulation. What is essential is that poor

people have a voice, that decisions on biotechnology do not further marginalize those already marginalized, and that citizens of developing countries are able to make their own choices rather than having these defined for them by donors.

The role of agricultural extension in enabling access to the products of biotechnology R&D and necessary policy changes to facilitate that role, are almost totally neglected in the NBS documents of the 15 countries. Despite reforms, government policy remains significant within agricultural extension services. The changes to extension systems and the new opportunities from BFA call for policies to bring researchers, extension agents, and smallholder producers and their organizations closer together. They also call for upgrading the skills of extension staff so they are both more capable of understanding the implications of BFA and of facilitating interactions between farmers and others involved in the agricultural knowledge information system.

9.1 INTRODUCTION

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

Against this background, it is instructive to examine how the same 15 developing countries surveyed in the companion Chapters 7 and 8 intended to deal with the IP and (related or unrelated) genetic resources/biodiversity issues associated with BFA. It is also useful to highlight the principal considerations that need to be taken into account by countries in designing and managing IP policies that balance their needs to generate and access biotechnology tools and techniques and the genetic materials for research and producing tangible products, while promoting the diffusion of these products to small-

scale and resource-poor farmers. Topics covered here include: establishment of laws and institutions, and IP policy options and mechanisms for accessing biotechnology tools and products by research institutes and national and international research funding and development agencies. These issues are covered in Part 9.2 of the Chapter.

A further, and not entirely unrelated, route to ensuring access to the benefits of biotechnology R&D is through improving public awareness and opportunities for participating in decision-making, and this topic is covered in Part 9.3. Decision-making about technology still remains largely in the hands of national agricultural research systems (NARS) working with their specific society groups – farmers, farmer cooperatives etc. However, there is increasing realization that agricultural biotechnologies (traditional and modern) will only fulfil their full potential if all relevant stakeholders have the opportunity to provide input to decision-making processes concerning their use. To make choices, societies have to be informed and educated about the pros and cons of particular decisions, and they will only accept biotechnologies if they consider they are "good" for them.

In addition to IPR and GRFA, this Chapter covers the issue of public awareness and participation from the standpoints of engaging wider society (1) in planning, implementing and assessing biotechnology R&D and extension, and (2) in the regulation of biotechnology. It provides options for dealing with both, including for implementing commitments laid down in international agreements and by international standard-setting bodies in relation to regulation. In common with other strategic policy issues relating to BFA, it describes how the 15 selected developing countries (see Table 1 of Chapter 7) proposed to deal with participation in their NBS documents[1] and/or regulatory frameworks.

The third topic, covered in Part 9.4, is agricultural extension. National agricultural extension systems have been in transition worldwide for some time, and reforms have already impacted, and will continue to impact, the agriculture knowledge information sub-system and thereby access to the fruits of BFA. Since the role of government and government policy in agricultural extension remains significant, it is relevant here to highlight the potential roles of extension in enabling access to BFA.

9.2 INTELLECTUAL PROPERTY RIGHTS AND GENETIC RESOURCES

9.2.1 Coverage in national biotechnology policy/strategy documents

From an analysis of selected developing countries in the Annex (Part 9.5), it is noteworthy that while most countries did indeed mention IPR and the importance of their genetic resources, very few indicated the existence of a national IP strategy or the need to change

[1] Most of the NBS documents of the selected developing countries are available at www.fao.org/biotech/country.asp

their existing, or introduce new, IP legislation, regulations and other policies to cater for the specific challenges posed in particular by modern biotechnologies and how these would be harmonized with the global IP and genetic resources/biodiversity legislative architecture. Also, few described how their research institutions intended to go about accessing, or sharing with others, the research tools, gene constructs or genetic resources needed for R&D or any end products arising from such efforts nationally or in other countries. None of them mentioned the role of their research funding bodies in influencing the related policies and behaviour of their national research communities.

9.2.2 The global context

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

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

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

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

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

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

Fundamental questions raised include the criteria for patentability of gene fragments or mutations (e.g. in some jurisdictions, expressed sequence tags [ESTs] and single nucleotide polymorphisms [SNPs] may be patentable subject matters even in the absence of proven utility/industrial application, although the rules on this have recently been tightened in industrialized countries); the role of IP protection in stimulating agricultural R&D and bringing new innovations to market, and in fostering the transfer and diffusion of techniques,

processes, products and information within and between the public and private sectors and between developed and developing countries. The feeling often expressed by the scientific community is that access to key platform technologies and even research tools and data has become increasingly limited and threatens to slow progress in both the fundamental and applied biosciences (e.g. Chapter 6 in FAO, 2001a).

Against this background, all countries should develop IP policies that carefully balance their needs to generate and access the basic tools, techniques, breeding lines and varieties for both research and the production of seeds and other tangible products, while promoting diffusion of these products to small-scale and particularly resource-poor farmers. These are particularly important for those developing countries where the entire agricultural "value chain" running from R&D through to the production, distribution and oversight in using biological inputs remains largely a public responsibility rather than a series of commercial operations.

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

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

- the 1961 International Convention for the Protection of New Varieties of Plants (the "UPOV Convention") and its revised Acts of 1972, 1978 and 1991. There are currently 68 country members, mostly from the Northern hemisphere but increasingly also from Latin America;
- the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) which had 153 members as of July 2008. Particularly relevant here is Article 27.3(b). Although not referring specifically to biotechnology, this contains provisions concerning patentability that are relevant to it and offers countries three options for protecting plant and animal inventions, i.e. (1) through patents, the

criteria for which are novelty, involve an inventive step and usefulness/capable of industrial application (2) a system created specifically for the purpose ("*sui generis*") which may or may not conform with one of the UPOV Acts but must be "effective" or (3) a combination of the two. Such flexibility is also available for essentially biological processes for producing new germplasm and varieties of plants and animals.

These Agreements differ in terms of eligibility and scope of protection, and it is beyond the scope of this Chapter to deal with these differences in detail or to dwell on the many "creative interpretations" by individuals concerning definitions, commitments (or lack thereof) and inter-relationships. See Tansey and Rajotte (2008) for more details.

In designing and managing national IPR systems, countries should be aware of a number of key issues. One is that the core assumptions of the TRIPS Agreement, and indeed of the UPOV Acts, are that IPR will stimulate international transfer of technology and therefore (bio) technology-related R&D in developing countries as well as the wider exchange of improved breeding lines and varieties. However, the relationship between the strength of IP protection and all these factors is highly complex and, as noted by FAO (2003a) and others in relation to biotechnology, IP is only one factor influencing technological innovation, transfer and diffusion. Others include S&T capacity and wider infrastructure, structure of the agricultural sector, potential market size, ecological similarities between countries, the subject matter of protection (e.g. hybrid or open pollinated crops; poultry, pigs or cattle), national policies concerning foreign direct investment, trade, and the macroeconomic environment.

Another issue is the inter-relationships between international IP agreements (specifically the UPOV Acts and TRIPS Agreement) and (1) the core aims of the CBD and the ITPGRFA – namely, access to and fair and equitable sharing of benefits from using genetic resources, conservation and sustainable use of GRFA, and preservation of and respect for knowledge, innovations and practices of indigenous and local communities/farmers' rights and (2) the goal of national food security.

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

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

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

A fourth issue is the costs and benefits of implementing national IP legislation for BFA innovations consistent with international rules. These are simply unknown, but will certainly be country-specific and depend, for example, on the status of current legislation, technical and administrative capacities, and subject matter eligibility criteria such as the number of plant species protected. Costs of implementing patent administrative systems will certainly be higher than for *sui generis* PVP systems, while potential benefits (with many underlying caveats) include contributions to greater productivity, trade, incomes and food security. Developing countries intent on building strong breeding capacity involving biotechnology should nevertheless be aware that granting patents for gene constructs and genetically modified organisms (GMOs) will increase the price of seeds, propagating materials and other products because of the IP-related "technology fees" charged by patent owners. On the other hand, higher input prices must be balanced against potential yield, quality and other benefits and costs, all of which have to be factored in when assessing uptake and distribution of economic and social benefits (see Chapter 7).

The principal policy goal of these international agreements is to provide incentives to biotechnologists and breeders to develop new products that are useful to the agrifood sector and for seed, breed/brood stock and food and other input supply companies and government support services to market or use these nationally and/or through international trade. One complication is that they cover what might be termed "conventional" IPR. Since the main driver for developing IPR policies and using IP systems is the strength of the domestic science and (bio) technology capacities within the public and private sectors of a country, where these capacities are weak the IP system will be used primarily to protect imported technologies. This reality is clearly illustrated with respect to modern BFA applications in both Brazil and Argentina where non-residents are responsible for about 90 percent of BFA patents (Biotecsur, 2008). In South Africa, almost 60 percent of the protected plant varieties are not owned by South Africans (Van der Walt and Koster, 2005).

Another consideration is that these agreements do not have provisions for rewarding farmers, local communities and indigenous peoples for their roles in conserving and providing the genetic resources used by scientists and breeders to develop the new IP-protected varieties and other products using agricultural biotechnologies or other means. Neither do

they protect farmer-bred varieties (i.e. "traditional" and more informal communal systems of innovation by farmers and indigenous communities). These are concepts covered under multilateral biodiversity agreements (the CBD, particularly Articles 12 and 16, and the ITPGRFA), and which countries have to address in ways that are both consistent with international trade agreements and between different pieces of legislation. How they do this – through biodiversity or PVP laws or other instruments – is also a matter of some controversy, but is outside the scope of this Chapter. Details are provided by Bragdon (2004) and Stannard *et al.* (2004).

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

Inevitably, no single IP system will suit the needs and goals of all countries or serve all agricultural systems within an individual country. Consequently, in the process of designing IP legislation and related policies, countries wishing to use IP as an "enabler" of BFA should (1) make realistic projections about the future role of biotechnologies in helping to meet their national agricultural and wider food security and poverty reduction goals, and (2) make maximum use of the flexibility inherent in internationally agreed rules. Because of the "minimum standards" framework of both the UPOV Acts and the TRIPS Agreement, national governments have considerable discretion in interpreting and applying their provisions. For example, the discretion offered by the TRIPS Agreement to protect plant varieties through three distinct approaches allows its members to balance the protection offered to breeders against other important (and possibly competing) development goals, including those found, e.g. in the CBD and the ITPGRFA.

Nevertheless, in pursuing biotechnology, an important consideration is how to avoid overlaps and contradictions between national patent and *sui generis* PVP systems, and thereby balance incentives for plant breeding using biotechnology and traditional breeding. Here, it should be borne in mind that the TRIPS Agreement does not prevent patent laws being modified or *sui generis* systems being created to include exemptions for farmers and/or breeders, and it does not define the scope of protection of patents for biological material

and biotechnology processes. In other words, countries, for example, can include genes but not the plant in which the gene is contained, i.e. limit the scope of protection of a gene patent so that it does not "carry through" to plants into which the gene has been inserted.

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

9.2.3 Establishing laws and institutions

Principles, requirements and mechanisms for reviewing, updating and possibly introducing legislation to meet international obligations and establish complementary policies, and mechanisms and responsibilities for undertaking the related regulatory and administrative tasks assigned to particular institutions were described earlier in relation to agricultural and biosafety policies (Chapter 8). These apply equally to coverage of IPR and related biodiversity issues and are therefore not repeated here.

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

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

Using the principles outlined earlier, consultative mechanisms therefore need to be established to reach agreement and strike compromises between groups, within and outside the agrifood sector, which invariably will have widely different perspectives on a number of fundamental questions (particularly with respect to patents) concerning legislation, its implementation and enforcement. These include to what extent, and in what forms, should IP protection be available? who can, or should, own those agreed property rights?; how

will legislation be enforced?; and what institutions will be put in place and how will they be resourced (staffed, equipped) to identify and manage technologies to be accessed and protected? Graff (2007) provides an excellent account of the laws and institutions established by Argentina, Brazil, Chile, China, India, Kenya, Malaysia, South Africa and Uganda at central and decentralized levels to deal with IPR issues.

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

9.2.4 Intellectual property management: Options for research institutes

9.2.4.1 Accessing proprietary biotechnology tools and products

IPR allow holders to exclude others from making, using, selling and distributing their technology. However, this right is not absolute. One restriction is the national jurisdiction of protection. Another, present in all UPOV Acts and many national patent laws, is the so-called "research" or "experimental use exemption". Article 30 of the TRIPS Agreement also describes exceptions to the rights conferred, i.e. "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties".

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

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

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

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

To use proprietary tools and products, research institutes in developing countries may or may not request the permission of the owner. For each of these alternatives, they can use different options.

a) Without seeking the owner's permission

Using gaps in patent and protected variety jurisdictions

Patents are only valid in countries in which they are registered. Under *sui generis* laws, plant varieties are only protected in the country issuing the PVP certificate or PBR and in other countries that are members of the same UPOV Act. One option therefore is to use the research tool or technology (e.g. a transformation or selection tool, specific transgene, molecular marker or novel variety) without seeking the owner's permission. This option is legal in those countries where the particular patent or plant variety is not registered. Many current and important biotechnologies (both research tools and finished technologies) appear to be unprotected in all but a relatively small number of developing countries. Major exceptions in the countries covered here would be large producers and/or exporters of cotton, maize and soybeans and derived products, such as Argentina, Brazil, China, India and South Africa, i.e. countries with Type I NARS, but also some of those with Type II NARS (Byerlee and Fischer, 2001).

There are, however, legal and technical caveats to this option. First, that the use of the material in laboratory, greenhouse and/or field settings and/or products derived from biotechnology (plant, animal or micro-organism, food and feed products) is not covered

by other relevant national laws (e.g. seed, environmental/biosafety/plant protection, animal health and/or food safety). Second, that any product derived from the proprietary technology is not exported to a country where the invention is protected (i.e. establishing "freedom to trade" is also important). This would require systems to segregate production and these may be logistically impossible in many situations. Third, that even where a technology is not legally protected in a particular jurisdiction, if a patent or PBR has been granted on a tool, technology or variety that means it is under IP protection in the owner's country.

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

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

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

Regarding the trade dimension, Binenbaum *et al.* (2000) examined the production and trade patterns between 168 developing countries and 29 developed countries for the 15 staple crops that are most important for food security in the developing world. Their analysis revealed that exports from developing to developed countries constituted less than 5 percent of the total production and consumption in developing countries. Also, it

showed that the value of these exports was concentrated in only four crops, i.e. bananas, soybeans, rice and coconuts, and that these came from very few countries (Costa Rica and Ecuador for dessert bananas, Brazil and Argentina for soybeans, Thailand for rice, and the Philippines for coconuts). Further, the bulk of these exports was to Western Europe (64 percent) followed by the United States (16 percent) and Japan (11 percent). The data also showed that for other crops covered by the CGIAR centres, the share of developed country imports originating from developing countries varied from around 90 percent (in the case of cassava, chickpeas and groundnuts) to figures ranging from 5–40 percent for wheat, maize, barley, sorghum, millet, lentils and beans.

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

Using the research and experimental use exemption within national legislation

The generality of the criteria and the vagueness regarding the scope and nature of exceptions in IP laws for using other peoples' proprietary technologies, make it difficult to interpret rights and obligations. For example, defining the scope of a "research tool" or the cut-off between "basic" and "applied" research or between "research" and "development" is fraught with difficulties. A rice line with resistance to a bacterial pathogen is a research tool. It can be used as a breeding tool by some, but to biotechnologists it is source material for mapping, sequencing and cloning the gene coding for the resistance trait, and subsequently for the grant of a patent on the gene sequence. Through an exclusive license negotiated with the patent owner to a company it then becomes a research tool for a commercial company to develop pest-resistant GM crops (and to gain access to the gene, the developers of the original rice-resistant line would have to negotiate conditions for using the gene sequence for furthering their own applied research).

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

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

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

Appropriate courses of action to follow for building and retaining trust (as well as funding) within national scientific, breeding and commercial establishments could therefore include 1) for governments to ensure an appropriate exemption for research directed towards providing public goods (e.g. for crops, micro-organisms and traits important to small-scale subsistence farmers) 2) for research funding organizations and implementing institutions to be aware of their legal rights and to develop general and specific policies, strategies and operating procedures that set the conditions and obligations for both protecting (and sharing) their own IP and for using technologies and resources developed by others and 3) as a "rule of thumb", for those working in the BFA arena at both R&D and commercial levels, to determine whether the permission of the owner is needed to use the material in question, i.e. whether there is FTO.

b) With the owner's permission

A number of different options are available to the public sector wishing to access proprietary tools and technologies with the owner's permission (Byerlee and Fischer, 2001). Seven potential options are considered here.

Material transfer agreements (MTAs)

These are likely to remain the main mechanism for accessing (and providing) BFA for non-commercial uses. Nevertheless, researchers seeking access to genetic resources in another country (and sometimes also in their own country) may have to contact the National Biodiversity Authority to obtain the agreement of the provider on the transfer, and clarify

the conditions under which the transfer and use are authorized. The MTA may include provisions on whether IPR can be sought and under what conditions, i.e. joint ownership of rights arising from inventions derived from the resources, preferential access to any technology developed, or monetary or non-monetary benefit-sharing arising from their use.

Licensing agreements

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

Purchasing outright

This needs skills in technology valuation. Although there are models available for valuing some BFA (Nadolnyak and Sheldon, 2003), the high volatility in returns from marketing many biotechnologies renders this option less appropriate than MTAs and licensing agreements for obtaining tools and products, especially for smallholder farming situations.

Patent pools

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

Open source licensing

The Biological Innovation for Open Society (BIOS)[2] initiative developed by the Centre for the Application of Molecular Biology to International Agriculture (CAMBIA) provides open source licensing. It is based on the idea of a protected commons for making and using improvements to licensed technology for research or commercial purposes through a web-based meeting place for scientists. Anyone can obtain a free license to the technology, but they have to agree to put any improvements back into the licensing pool. Examples of technologies developed through this approach are Trans-Bacter, a technique for transferring genes to plants using a plasmid containing a new T-DNA sequence that allows gene transfer into bacterial strains other than *Agrobacterium tumefaciens*, and GUSPlus, a new reporter gene for sensitive visualization of gene transfer events.

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

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

Public sector partnerships

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

Possibly the best example of a purely national effort leading to commercialization of products is the Bt cotton varieties developed using a modified Bt fusion gene (Cry 1ab and Cry 1Ac) by the Chinese Academy of Agricultural Sciences. This organization has also now developed Bt hybrid cotton which is distributed through state-owned county, prefectural and provincial seed companies and has also recently been approved for cultivation in India.

[2] www.bios.net/daisy/bios/home.html

The second type of institutional constellation is best illustrated by the CGIAR's Generation Challenge Programme[3], which brings traditional and advanced biotechnologies to bear on 12 target crops and seven crop-trait combinations (with a major focus on drought tolerance) for developing tools and technologies that help plant breeders in the developing world to produce better crop varieties for resource-poor farmers. It uses a network of over 170 institutes in all regions of the world, and a cornerstone of the Consortium Agreement and project contracts is the provisions on IP requiring outputs to be released as public goods, enabling scientists in developing countries to readily use elite genetic stocks and new marker technologies in their breeding programmes. However, a recent review of the programme has shown that these terms are not always respected, and that ways need to be found to compel compliance to the contractual documents, including ultimately requiring reimbursement of funds from partners who fail to live up to their obligations (Woolley *et al.,* 2009).

The CGIAR's Harvest Plus Challenge Programme[4] operates along similar lines, but different IP arrangements. It involves a consortium of donors and over 200 agricultural and nutrition scientists in the task of developing (through conventional breeding) staple crops like beans, cassava, maize, pearl millet, rice and sweet potato which are biofortified with vitamin A, zinc and iron. In this programme, individual research partners can take out patents on their own discoveries, but they must make their results freely available in the public domain for use in developing countries.

The FAO/IAEA coordinated research projects[5], organized and funded through FAO's Joint Programme with the IAEA, are other examples of public sector partnerships. They bring together public sector research institutes in developing and industrialized countries to develop and validate BFA tools and products needed to improve understanding or solve particular constraints to agricultural development. Prominent examples of technologies developed or validated and subsequently widely applied in developing countries include mutations, using radiation and targeting induced local lesions in genomes (TILLING), combined with molecular markers to develop new varieties of food and industrial crops, and immunoassay and molecular diagnostic tests for rinderpest, foot-and-mouth disease and brucellosis. Here again, contributors to these projects agreed to release products and other information without IPR restrictions.

In line with its mandate, the International Centre for Genetic Engineering and Biotechnology (ICGEB) has adopted IP policy guidelines. These state that "access to IPR concerning the results emanating from the research work of the Centre shall be granted to members and to developing countries that are not members of the Centre in accordance with

3 www.generationcp.org/
4 www.harvestplus.org/content/about-harvestplus
5 www-naweb.iaea.org/nafa/index.html

applicable international conventions" with the objectives of (1) promoting the development, production and wide application of biotechnology in the interests of developing countries, (2) promoting the transfer of technology and know-how to its member countries, and (3) overcoming the difficulties encountered by developing countries in fostering innovation, ownership and in-house application.

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

Public-private partnerships (PPPs)

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

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

A flavour of the wide range of relevant ongoing PPPs is available from presentations at the recent Crawford Fund Annual Conference[6] that explored ways in which the private sector

[6] www.crawfordfund.org/conference/2009.html

can engage in international agricultural research, development and extension to the benefit of the rural poor. One of these is dedicated to the Hybrid Parents Research Consortium (HPRC) that was initiated in 2000 by the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) and private sector seed companies as a R&D partnership for improving the availability of seeds of high yielding cultivars. It was the first PPP arrangement in the CGIAR system, and ICRISAT has now partnered with many private sector seed companies in India, Indonesia, Egypt and Mexico through the HPRC to deliver its improved sorghum, pearl millet and pigeonpea hybrids to poor farmers. As a member of the CGIAR, ICRISAT adheres to policies concerning the transfer of germplasm in line with the CBD and with the agreement between the CGIAR centres and FAO by which designated germplasm held in-trust for the world community is made freely available through the standard MTA under the ITPGRFA (Gowda *et al.,* 2004).

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

(a) Negotiating royalty-free access to proprietary genes, genetic constructs, and germplasm

There is increasing evidence of the willingness of MNCs to donate proprietary biotechnology with no, or limited, restrictions on FTO. This should be recognized as a step in the right direction. Recent examples include Syngenta, which has committed to provide its technology royalty-free to benefit subsistence farmers in developing countries. It has also stated that it will not pursue patent protection for any plant biotechnology or seeds invention for private and non-commercial use in least developed countries. Furthermore, IPR related to the rice genome will not be enforced in least developed countries for non-commercial use by subsistence farmers[7]. Monsanto and Syngenta have also provided royalty-free licenses to the Golden Rice Humanitarian Board for technologies that can help further the development of pro-vitamin A (beta carotene) enhanced rice.

In addition, Monsanto and BASF are partners in a large project on water efficient maize for Africa (WEMA), funded by the Bill and Melinda Gates and Howard Buffet Foundations, with the participation of the International Maize and Wheat Improvement Center (CIMMYT) and a number of NARS in Africa[8]. These companies will provide

[7] www2.syngenta.com/en/media/positionstatements_full.html#ip

[8] www.aatf-africa.org/wema

proprietary germplasm, transgenes and advanced breeding tools without royalties for research, and any products developed will likewise be made available to small-scale farmers without royalties. The agricultural biotechnology company Arcadia Biosciences Inc. has also agreed to provide compensation-free technology for the development of nitrogen use efficient and salt tolerant rice for Africa.

(b) Using the services of third party brokers

A number of organizations and advanced research institutions work to facilitate the transfer of proprietary tools and technologies and related knowledge from private companies to public sector institutes with a focus on Africa, pro-poor crops and livestock diseases. Well known examples include the African Agricultural Technology Foundation (AATF), based in Kenya, which was set up to facilitate and promote PPPs for accessing and delivering appropriate proprietary agricultural technologies for use by resource-poor smallholder farmers in sub-Saharan Africa[9]. It is a "one-stop-shop" that provides expertise and know-how to facilitate the identification, access, development, delivery and use of proprietary agricultural technologies. It is backed by a number of donors, including the Rockefeller Foundation, the UK Department for International Development (DFID), the United States Agency for International Development, the Bill and Melinda Gates Foundation and the Buffett Foundation. It engages actively with CGIAR centres, NARS, local and international seed and biotechnology companies, and is involved in most of the African initiatives on PPPs described above.

Another example is the International Service for the Acquisition of Agri-biotech Applications (ISAAA), which was established to deliver the benefits of new agricultural biotechnologies to the poor in developing countries[10]. Best known for its annual report on the global status of commercialized GM crops, this organization also facilitates the transfer of proprietary technologies from the private sector in industrial countries for the benefit of subsistence farmers and the poor. It has been particularly active in the area of tissue culture for bananas and cassava in East Africa.

The Public Intellectual Property Resource for Agriculture (PIPRA)[11] also assists developing countries to access new technologies by reducing IP barriers to cooperation among public sector institutes for improving staple and speciality crops, and facilitating the transfer and adoption of their technologies by resource-poor farmers. A final example is GALVmed[12], an alliance of public, private and government partners, which was established

9 http://aatf-africa.org/
10 www.isaaa.org/
11 www.pipra.org/
12 www.galvmed.org/

in 2005 to make livestock vaccines, diagnostics and medicines accessible and affordable to developing countries, primarily in Africa, funded by the Bill and Melinda Gates Foundation and DFID. It is part of a task force led by the African Union-Interafrican Bureau for Animal Resources (AU-IBAR) to facilitate the registration and commercialization of a tissue culture-derived vaccine for East Coast fever that is presently produced by the International Livestock Research Institute (ILRI) and to transfer vaccine manufacture and distribution to the private sector.

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

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

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

Virtually all research institutes and universities in industrialized countries dealing with BFA have established technology transfer offices (TTOs). These are staffed by people trained in advising on, and processing, IP applications and with the negotiation and business skills for securing agreements with third parties seeking access to the products in question or holding IP on products considered relevant to furthering the research or commercial interests of the institution housing the TTO. These offices also deal with

non-proprietary assets, e.g. textbooks, training manuals, software, audio-visual material etc. In some cases, public institutions have allowed/encouraged their staff to engage in the creation of spin-off companies.

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

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

Both EMBRAPA and ICAR have legal authority to manage their own IP portfolios and technology transfers (relating mainly to both patents and *sui generis* PVP and copyrights) in conformity with existing national IP laws and other related laws/rules. ICAR even registers its own patents and PVP certificates. In the case of the ARC, IP is managed through its Intellectual Property Management Office (IPMO) which works under the umbrella of a National IPMO which was set up to harmonize IP management across all institutes supported through public funds and which deals with patent applications from these institutes.

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

Irrespective of the above, policy-makers should be aware of the following potential issues regarding commercializing IP assets within the public sector. First, there is the risk that the focus of BFA research shifts to private research interests at the expense of tackling issues with a predominant "public goods" value (i.e. from more upstream to near-market, and from species and traits important to small-scale and resource-poor farmers to those of interest to export and commercially-oriented operations). It is important, therefore, that the principles for seeking protection and for managing biotechnology IP and wider assets further the mission of the institute, i.e. foster access to, and diffusion of, their proprietary and non-proprietary assets to the poor and food insecure.

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

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

Third, the main benefits of licensing proprietary technology are (1) the potential to facilitate technology transfer when a private partner is needed, while reserving the rights of the public sector to deliver that technology to farmers who otherwise could not afford it, i.e. as a means of market segmentation, (2) as a "bargaining chip" to access technologies owned by others, and (3) as an entry point into global or regional research consortia, often involving the sharing of research tools for non-commercial purposes.

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

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

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

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

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

Principles also have to be developed for engaging in collaborative and contract research compatible with the mission of each party. In the case of PPPs, they should take account of the level of private funding and maximize the commercial and socio-economic impact

of the research, maintaining an IP position that allows further academic and collaborative research and avoids impeding the dissemination of the R&D results.

For public sector research institutes whose mission is pro-poor agricultural development, the policy statements published by some of the CGIAR centres are good guides for informing their own scientists, stakeholders and the public at large on their position concerning the protection and use of their intellectual assets[13].

Few developing countries have scientists, patent attorneys or agents who are sufficiently knowledgeable to bring the required depth and breadth of understanding in biotechnology, agriculture and law to the complexity and variety of tasks required for effective filing and management of modern biotechnology-related patents. Most do so by contracting this work out to third party management companies and centres, especially for the needed specialized legal and business skills. For example, the biotechnology incubators and parks described in Chapter 8 have established technology transfer and commercialization offices which take on consultancy work for public sector institutions, in addition to undertaking IP work for companies situated within the hub.

9.2.5 Options for national and international research funding and development agencies

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

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

Administrators in many funding agencies, research institutes and universities and many scientists themselves have noted the increasing complexity of the patent landscape and the burden that this is placing on the scientific endeavour in the fields of structural and

[13] For example, for CIMMYT at www.cimmyt.org/en/about-us/policies/cimmyt-intellectual-property-policy

functional genomics (proteomics, metabolomics etc.) through patents on gene sequences, their protein products and methods to detect, produce, study or manipulate genes or proteins (Royal Society, 2003).

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

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

- encourage the free exchange of materials and data; Nucleic acid sequences, including ESTs and SNPs, are fundamental for describing and understanding the structure, function, and development of agriculturally important plants, animals and micro-organisms. Although private industry retains sequence data relating to many agriculturally important organisms in proprietary databases, these firms should be encouraged, and public sector institutions required, to place such sequences in public data banks.
- ensure that grant applicants include in their proposals an explanation of their stewardship plans, as well as plans for the sharing and dissemination of research results;
- monitor the actions of grantees and contractors with regard to data and material sharing and, if necessary, require grantees and contractors to comply with their approved IP and data sharing plans;
- extend the "Bermuda Rules" that were agreed for the human genome project to the sequencing of genomes of organisms that are essential for agricultural production in developing countries. This means releasing within 24 hours all DNA sequences longer than say 1 000 base pairs to a public database and issuing a directive against patenting newly discovered DNA;

- foster responsible patenting and licensing strategies. Whenever possible, non-exclusive licensing should be used when technologies owned or funded by public sector institutions are transferred to the commercial sector. This facilitates making broad enabling technologies and research uses of inventions widely available and accessible to the scientific community. Options include:
- ensure that proprietary or exclusive means of dissemination are pursued by recipients of grants and contracts only when there is a compelling need. Also, whenever possible, licenses should be limited to relatively narrow and specific commercial application rather than as blanket exclusive licenses for uses that cannot be anticipated at the moment;
- because of the complexity in determining FTO and the fact that most developing countries have little experience in managing IP, industrialized countries donating proprietary technology should conscientiously supply products that are "clean" with respect to intellectual and tangible property (Kowalski *et al.*, 2002);
- introduce explicit reservations of rights in commercial technology licenses to protect their own institutional objectives and support humanitarian applications (Bennett, 2007).

9.2.6 Final considerations

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

9.3 PUBLIC AWARENESS AND PARTICIPATION

9.3.1 Participatory biotechnology R&D and extension

The farmer and technology development "participatory" paradigm of planning and, in some cases, implementing and assessing the benefits of particular courses of action came from the recognition that those targeted as potential beneficiaries of R&D projects should have a say in, and influence, priorities and strategies. Other terms used are "bottom-up" and "demand-driven". Combined with similar approaches to providing extension services, these were designed to encourage scientists and extension agents to work with small-scale farmers when defining problems and finding solutions – in effect to make R&D and extension more responsive to their needs and priorities. The current plethora of "participatory" planning

and implementation of R&D projects and extension services (which now cover topics ranging from plant breeding, integrated pest management, soil and water management, gender planning, assessment of organic agriculture, risk assessment for animal diseases like bird flu etc.), attests to how policies within many governments and funding bodies for organizing these services have been transformed.

Such policies have not, of course, replaced the more traditional "top-down" (and often "supply-driven") option. Here, a committee (chaired perhaps by the Permanent Secretary of the Ministry of Agriculture) is normally set up composed of senior ministry officials, research leaders within NARS and relevant universities including those located regionally, and key private sector bodies and non-governmental organizations (NGOs). Other ministries (particularly of S&T, Rural Development and Economic Planning) would also be appropriate participants, the aim being to optimize the match between technical and wider policy considerations. Ideally, both approaches are needed (and in fact, are usually practised) to provide balance, objectivity and transparency to government, ministerial or institutional decision-making.

Several constellations are possible for "participatory/bottom-up" approaches (see e.g. Boerse, Bunders and Loeber, 1995 and Cohen, Falconi and Komen, 1998). Puente-Rodríguez (2007) presents a notable example of a "participatory" and self-organized "bottom-up" approach within the context of subsistence agriculture, for the control of the castor semilooper (*Achea janata*) pest in Andhra Pradesh, India. Their common features are that they involve farmers, extension services, scientists, local or national policy-makers and NGOs in identifying and prioritizing problems and finding solutions at the grassroots level that are amenable to R&D. Critical challenges include:

- establishing a multidisciplinary coordination team/steering committee with a wide policy, scientific and cultural background to support the process, which involves substantial dialogue to reach common ground;
- supporting the process with "evidence-based" data and information obtained through one or a combination of the methods described in Chapter 7;
- ensuring that the process goes beyond diagnosis and priority-setting by involving the communities concerned, e.g. in farm or village experiments to test new technology.

Another challenge with all these approaches is deciding who participates and the manner and extent of their involvement. In setting up participatory priority-setting, decision-makers have to establish criteria. These should be guided by research objectives and proposed target groups which, in turn, will depend on whether the exercise is purely national or part of a wider regional or global programme with involvement of one or a number of regional research organizations, CGIAR centres, bilateral donors, banks and philanthropic organizations. In

such cases, agreement has to be reached between the government or responsible ministry on participatory principles and administrative arrangements. It is important here to retain national ownership and identity.

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

Kenya (World Bank, 2008) and Bolivia (Hartwich and Jansen, 2007) provide examples of options for pursuing priority-setting which can be suitably adapted to include biotechnology. In the case of Kenya, the Kenyan Agricultural Research Institute (KARI) has an Annual Research Forum to set the national strategic research agenda and a number of Research Coordination Committees to approve proposals, as well as Centre Research Advisory Committees to screen proposals at the national and regional research centres. The KARI Biennial Science Conference is where agricultural policy-makers, researchers and the private sector participate and provide feedback on on-going research activities and identify emerging issues. The national and regional research centres identify research topics in consultation with various stakeholders in their districts, including district agricultural officers, farmer groups and scientists in local universities and, after technical review meetings, their recommendations are submitted to KARI headquarters. KARI is also now establishing a monitoring and evaluation system.

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

9.3.2 Participatory policies for regulation of biotechnology

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

The importance of public participation in decision-making was recognized by policy-makers through Principle 10 of the Rio Declaration on Environment and Development, adopted by over 170 countries in 1992. It states that: "Environmental issues are best handled with the participation of all concerned citizens, at the relevant level. At the national level, each individual shall have appropriate access to information concerning the environment that is held by public authorities, including information on hazardous materials and activities in their communities, and the opportunity to participate in decision-making processes. States shall facilitate and encourage public awareness and participation by making information widely available. Effective access to judicial and administrative proceedings, including redress and remedy, shall be provided".

The Rio Declaration is not legally binding. A number of legally binding international instruments have, however, been adopted that are relevant to public participation and awareness in biotechnology matters (see Mackenzie *et al.,* 2003 for more details). One is the CBD, which through Article 14.1 promotes notification, exchange of information and consultation on activities that are likely to have significant adverse effects on biological diversity. The Cartagena Protocol on Biosafety (CPB), a supplementary agreement to the CBD, deals specifically with public awareness and participation regarding living modified organisms (LMOs) in Article 23. This Article states that Parties to the CPB shall promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of LMOs in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health; endeavour to ensure that public awareness and education encompass access to information on LMOs identified in accordance with this Protocol that may be imported; in accordance with their respective laws and regulations, consult the public in the decision-making process regarding LMOs and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21; endeavour to inform its public about the means of public access to the Biosafety Clearing-House.

The Aarhus Convention[14] is the most recent and comprehensive international agreement relating to public participation, adding much "meat" to government obligations. Its full title is the United Nations Economic Commission for Europe's (UNECE) Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (where the UNECE is one of five regional commissions of the UN, with 55 Member countries from North America, Western, Central and Eastern Europe and Central Asia). Although a UNECE Convention, it has a global significance as it is also open to all non-UNECE States that are members of the UN.

[14] www.unece.org/env/pp/treatytext.htm

At their 2nd Meeting in Kazakhstan in 2005, Parties to the Convention adopted an amendment aiming to strengthen the rights of the public to participate in decision-making on GMOs. This amendment enters into force when it has been ratified by three fourths of the Parties and would require the Parties to inform and consult the public in decision-making on the deliberate release and placing on the market of GMOs. The public would have the right to submit comments and the public authorities would be expected to take these into account in the decision-making process. Once made, the decision taken should be publicly available together with the reasons and considerations upon which it is based. Except for cases of commercial confidentiality, information associated with GMO decisions would be made available to the public i.e. Parties could not withhold as confidential, information on the intended uses of the release or on the assessment of environmental risk[15]. The amendment requires that the provisions made by Parties be complementary and mutually supportive with their approaches for meeting the objectives of the CPB.

From the aspect of food safety, the Codex Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (2003) appear particularly relevant from the standpoint of public awareness and participation. On risk communication, they state that: "Effective risk communication is essential at all phases of risk assessment and risk management. It is an interactive process involving all interested parties, including government, industry, academia, media and consumers. Risk communication should include transparent safety assessment and risk management decision-making processes. These processes should be fully documented at all stages and open to public scrutiny whilst respecting legitimate concerns to safeguard the confidentiality of commercial and industrial information. In particular, reports prepared on the safety assessments and other aspects of the decision-making process should be made available to all interested parties. Effective risk communication should include responsive consultation processes. Consultation processes should be interactive. The views of all interested parties should be sought and relevant food safety and nutritional issues that are raised during consultation should be addressed during the risk analysis process". Since Codex standards and guidelines are reference points for national implementation of the Sanitary and Phytosanitary (SPS) Agreement, this suggests a clear linkage between public awareness and participation and this WTO agreement.

As noted in Chapter 7, governments have two roles: (1) fostering community understanding/awareness about biotechnology including by improving access to understandable information, and (2) providing means by which citizens can express their views. This doesn't mean that they should "go it alone", but rather that they create the environment/provide the incentives for others, e.g. schools, universities, extension services, farmer and business

[15] www.unece.org/press/pr2005/05env_p06e.htm

organizations, NGOs, civil society organizations (CSOs) etc. to take initiatives. Because biotechnology needs horizontal governance, this should include developing a "top level" strategy to which all ministries commit through a shared programme of work that includes agreement on the combination of mechanisms that can realistically be applied and financed in the light of national circumstances.

Since biotechnology is also a very broad topic with intersecting thematic areas that include biosafety, food and feed safety, consumer protection, intellectual property, seed certification, bio-ethics, as well as access to genetic resources and benefit-sharing, national capacity for fostering public awareness needs to extend to these topics. In the resource-constrained environments within which all developing countries operate, and given the reality that resources for enhancing public empowerment need to compete for scarce funding, decisions may have to be made as to whether communicating, e.g. to small-scale farmers about the merits of using biotechnology to improve crop or animal productivity should take priority over communicating to urban consumers about the merits of consuming food derived from these crops.

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

9.3.3 Coverage in national biotechnology policy/strategy documents and regulatory frameworks

9.3.3.1 In NBS documents

The survey of NBS documents of selected developing countries showed that scientific and technical capacity building in biotechnology from undergraduate through to PhD levels was a key element of essentially all national plans, and that in a few countries efforts would be made to initiate awareness-building among schoolchildren. But apart from that,

more than half of the NBS surveyed were either silent on public education/awareness and participation, or made only short generic statements to the effect that "civil society would be engaged", "public information/ education programmes would be set up" etc.

It is noteworthy that all NBS documents that raised the issue of public awareness/participation were either vague or silent on the rationale for involving the public at all. Also, none defined whether such involvement would be (1) used for developing wider policies, (2) confined to regulatory aspects, (3) purely advisory or entail involvement in decision-making, and (4) if the latter, whether this would be "arms reach" participation, e.g. providing comments in writing or verbally which would then be fed into decision-making by people traditionally considered to be better qualified to make judgements, e.g. scientists, regulators etc., or actually sitting at "the top table" and being directly involved.

Only three countries were more specific. Chile made public participation one of its "Flagship Initiatives" with thrusts to include ensuring dissemination of accurate and reliable information, particularly on regulatory matters, decisions based on ethical values as well as scientific principles, and a commitment to respect the value of considering different societal options. South Africa, in recognizing the critical importance of public understanding of biotechnology, outlined a number of specific initiatives. First, the government would articulate a single vision of biotechnology so that it is not confronted with different opinions from different ministries and departments. Second, public education campaigns on biotechnology would be initiated to give accurate information based on the inputs of various ministries/public sector agencies. Third, biotechnology issues would be included in high school curricula to encourage debate on potential benefits, risks, and ethical and environmental issues. Also, the media would be provided with information representing all sides of debates and encouraged to convey biotechnology issues to the public in a responsible manner. Only Peru provided any insight into the government or public sector structures that would be involved in leading or coordinating national initiatives in these areas. In this case, a National Forum on Biotechnology (FONABIO) would be established to connect citizens with up-to-date information on biotechnology, receive and respond to feedback and thereby create an environment of consultation and educated opinion. There would also be a Committee on Ethics to discuss, review and make recommendations to its regulatory authority on all aspects related to the promotion and development of modern biotechnology.

9.3.3.2 In national regulatory frameworks

Analysis of national regulatory frameworks provided little further insight on these issues. As noted in Chapter 8, in the majority of countries the main link between public awareness/information and biosafety lies in the reference by many countries to labelling

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

Noteworthy also were the confidentiality provisions in most of the national instruments (see Chapter 8) but again, these were stated in generic terms and it was not possible to determine how countries would use them and whether they would restrict the public's access to relevant information for policy or regulatory decision-making.

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

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

Finally, making laws and regulations is one thing – implementing them is quite another. The extent to which public awareness and participation are actually facilitated or exist in a country is impossible to determine from a simple review of the country's biotechnology-related legislative instruments. Fine legally-expressed words may not translate into actual participation if, as is clear for many of the national instruments examined, additional criteria

are not provided on the form public participation may take. Also, the best public participation provisions may not be used if the public does not have the capacity to participate effectively.

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

Similar conclusions were reached through an e-mail conference organized by FAO on public participation in decision-making regarding GMOs in developing countries, which focused on how to effectively involve rural people (FAO, 2005). While there was broad agreement that citizens including rural people should be involved in decision-making when it is likely to impact on them, opinions on the degree and nature of the suggested participation differed, although many contributors felt that in many cases participation of the rural people could usually be indirect, i.e. through their chosen representatives. It was also felt that effective participation depended on access to unbiased and comprehensive information on the nature and consequences of GMOs, and that this information would have to be adapted to the needs and capacities of different groups of rural people and their representatives in order for it to be helpful, and that it would have to be communicated effectively, e.g. through extension services and radio. Use of local languages was particularly emphasized. Many participants complained that misinformation abounded (both for and against GMOs) and some were quite sceptical that a real public participation exercise might take place on this issue and, if it did, that its outcomes would have any impact. Interestingly, international agreements were regarded as being useful, but concern was expressed that commitments to these agreements might compromise the outcomes of an eventual national debate on GMOs – a point that also emerged from the analysis of Glover (2003).

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

9.4 AGRICULTURAL EXTENSION

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

In this dynamic situation, a shift of power may take place in some countries, but the role of government and government policy still remain significant. When and if the decision is made to reform agricultural extension, the government is faced with significant policy and strategy choices that will also indirectly impact the issue of farmers' access to the fruits of biotechnology R&D. As highlighted in Chapter 7, the paradigm now in vogue for describing the process of agriculture development is that of an agricultural "innovation system". It calls for rethinking the respective roles of those intimately involved in the agriculture knowledge information sub-system, namely research, extension, education and training. Fundamental questions raised by this evolving context include: how do farmers' specific demands for agricultural assistance impact biotechnology research and delivery?; what should be the goal of the extension services (e.g. production, transfer of new technologies, linking farmers to markets or helping farmers organize themselves into special interest groups around marketable products)?; and what should the government do to coordinate institutions that provide extension services (FAO, 2009).

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

- progressive transition from public technology transfer to the private sector;
- enabling problem solving skills of farmers through an inter-disciplinary approach;
- public funds for private extension;
- providing for cost recovery and co-financing of extension via farmers' organizations;
- reducing the number of village level workers;
- using para-extension workers and farmer interest groups for extension;
- employing more subject matter specialists;
- preparing strategic research extension plans;
- improving the research-extension-farmer interface;
- skill development of extension agents;
- improving women's access to technology;
- linking with agro-processors; and
- government as a facilitator and creator of an enabling environment.

The changes to extension systems and the new opportunities from biotechnology call for bringing researchers, extension agents, smallholder producers and their organizations closer together. They also call for upgrading the skills of extension staff so they are both more capable of understanding the implications of biotechnology and of facilitating interactions between farmers and others involved in the agricultural knowledge information system. Yet, the role of agricultural extension in enabling access to the products of biotechnology and necessary policy changes to facilitate that role is almost totally neglected in the biotechnology policy/strategy documents of the 15 selected developing countries consulted.

Lack of information and skills is one of the main reasons for the gap between potential and actual productivity/profitability of smallholder farmer systems, constraining the adoption of available technologies and practices and reducing their efficiency if eventually adopted (World Bank, 2007). For example, Guei, Somado and Larinde (2008) noted that farmers in sub-Saharan Africa do not use improved seed because very often it is not available to them or they are not aware of its advantages. Good quality seed is also not accessible to smallholders because there is often a weak linkage between farmers, extension systems, research institutions and the market. In the e-mail conference organized as part of the build up to ABDC-10 (see Chapter 6), the weakness of the extension system was identified by participants as one of the reasons for the failure in adoption of biotechnologies like artificial insemination in developing countries. Indeed, one of the four main suggestions for increasing the success of agricultural biotechnologies in the future that emerged from cross-sectoral discussions during the e-mail conference was that extension systems should be strengthened, as they can ensure that relevant R&D results actually reach the farmer.

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

9.5 ANNEX: Coverage of IPR and genetic resources issues in national biotechnology policy/strategy frameworks of selected developing countries

The following summarizes the coverage given to these issues in NBS documents:

Brazil gave considerable attention to access to genetic resources, benefit-sharing and guaranteeing the rights of traditional communities and indigenous peoples. It intended therefore to improve its legislation concerning these aspects. At the same time, it would promote the strategic use of IP to make national biotechnology more competitive; increase the number of Brazilian-owned patents in Brazil and abroad; improve IP management capabilities within research, industry and the judiciary; harmonize IP practices within agencies that promote R&D; harmonize IP practices for recovery of traditional knowledge; review and strengthen national legislation for the protection of plant cultivars; strengthen breeders rights; and adopt mechanisms for protecting lines derived from animal breeding.

Chile intended to update and upgrade its IP system, design and implement a programme to train decision-makers on biotechnology-related IP issues, and encourage patenting in national research institutes.

India's National Biotechnology Development Strategy notes that a new bill on protection, utilization and regulation of IP for public funded R&D has been prepared through inter-ministerial consultation, its aim being to optimize the potential of public R&D, encourage innovation in SMEs, promote collaboration between government and non-government organizations and catalyze commercialization of IP generated through public R&D. The

strategy also includes building capacity in technology transfer and IPR by having national and regional centres linked to university departments for training personnel which would also be done overseas.

Jamaica's NBS included a number of key strategies, one of which was to protect IP. Here, the government would play a proactive role in creating awareness of the importance of IPR issues in research and innovation, and through the development of databases and assistance to scientists and entrepreneurs through the national IP Office.

Kenya's biotechnology policy document stated that biotechnology would be developed in cognizance with international agreements (TRIPS and UPOV), and noted that the country's rich species diversity and the traditional knowledge associated with it offered great opportunities for industrialization through biotechnology. It therefore intended to set up a database on species in different ecosystems and the knowledge associated with them, develop capacity for effective management of IP including training scientists, improve the accessibility of IP services and establish a government fund to support filing of patents from public research. It would also review its policies and legislation on protection of traditional knowledge and resources and align these with policies on royalties, patenting, access to information and benefit-sharing on products resulting from biotechnology.

Malawi proposed to use biotechnology to conserve and sustain the use of its biological diversity by enacting legislation to regulate access and benefit-sharing, setting up a national database on, and clearing house for, facilitating access and sharing of benefits, facilitating adherence to the terms of technology transfer agreements, providing copyright and patent protection in respect of all conventions to which it is a signatory. It noted that it did not have an IPR policy and that its present legislation dating back to 1948 did not address biotechnology and community rights. It intended therefore to establish an IPR policy and legislation that would conform to its international legal obligations without undermining national development opportunities, to strengthen domestic legislation to ensure that IPR protected indigenous knowledge systems and genetic resources while at the same time attracting investment and development in biotechnology. It would formulate regulations that protected biotechnology innovations through IPR by harmonizing national implementation of biotechnology, trade and IPR agreements, and it would develop *sui generis* legislation to protect farmers and community rights. It would also develop appropriate guidelines for accessing and sharing the benefits from the products of biotechnology and establish mechanisms to facilitate access by Malawians to IPR-protected products of modern biotechnology.

In the Foreword to **Malaysia**'s biotechnology policy, the Prime Minister highlighted the potential of the country to be a key player in biotechnology because of its wealth of biodiversity. Regarding IPR, the policy states that the country will develop a strong IP protection regime to support R&D and commercialization efforts.

Namibia stated that national legislation relating to community or individual IPR will include contractual arrangements to share financial and other benefits arising from biotechnology, and that the State would facilitate community access to advice for negotiating such agreements. No details were provided on roles, responsibilities or mechanisms.

Peru specifically provided for the granting of patents except for whole organisms or parts thereof that exist naturally or have been modified by modern biotechnology, and for IP certificates for plant varieties developed with or without modern biotechnology. It also expressly recognizes and protects the rights of indigenous peoples and local communities in furthering biotechnology.

South Africa noted that it had many Acts relevant to biotechnology but since these provide conflicting legislation they would be reviewed and harmonized. It intended to update its Plant Breeders Right Act to include DNA fingerprinting to distinguish between phenotypes and it would consider introducing legislation for animal breeders. It would also introduce a search and examination capacity into its IP Office and develop standard guidelines on IPR of inventors for science councils and universities.

Thailand stated its intention to strengthen IP management including competency in international negotiations for fair benefit-sharing and technology transfer. It also intended to establish "community business networks" to promote the conservation and use of indigenous resources and thereby provide incomes for local communities. Further details were not provided.

Uganda made no specific mention of IPR, but intended to integrate indigenous knowledge with modern biotechnology to develop a vibrant biotechnology-based industry while promoting equitable access and benefit-sharing of indigenous knowledge.

Zambia described the need to ensure fair and equitable access and benefit-sharing from using genetic resources and by transfer of technologies, taking account of all rights over these resources and technologies. The NBS document did not elaborate further on how this would be achieved.

9.6 REFERENCES

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