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

Guadalajara, Mexico, 1 – 4 March 2010

Synthesis: Policy options for agricultural biotechnologies in developing countries

Introduction

One billion people – nearly one sixth of the world's population – now go to bed hungry. Business as usual will not reduce that number because the underlying causes of the increase in food prices and in the numbers of hungry people over the past two years remain. The world's population is continuing to rise, but as people in developing countries are becoming better off, demand for agricultural products, particularly for meat, will increase even more. At the same time, new land for increasing production is becoming increasingly scarce, as are water supplies in many countries. Biofuels are increasingly competing with food crops for available land, and climate change is emerging as one of the main threats to food security in developing countries. While not neglecting the importance of larger-scale and/or high-input commercial agriculture that is practised in more favourable environments, significantly cutting poverty and hunger will require empowering the 1.3 billion or so smallholders and landless workers who constitute the backbone of rural communities to produce and sell more food and other agricultural products, and create a more resilient food supply for everyone.

New technologies that sustainably increase agricultural productivity, provide "added value" and facilitate the marketing of products, can be powerful forces for reducing hunger, food insecurity, poverty and environmental degradation. Agricultural biotechnologies, the theme of this FAO international technical ABDC-10 conference, represent one of the technological approaches used in present-day agriculture. Other background documents prepared by FAO for ABDC-10 describe the main scientific and technological advances that the different biotechnologies in food and agriculture (BFA) have to offer. The present document looks at issues of public policy, investment and the adoption of technologies such as biotechnologies, all of which require governments to carefully consider an array of costs and benefits – a task that can be challenging for all countries.

The present document synthesizes the key elements of ABDC-10/8.1 and deals with public policy options for strengthening national capacities to make informed choices about applying BFA in developing countries. It is based on an analysis of information available from 15 developing countries and from a wide variety of other global assessments and peer-reviewed papers. The document is divided into three broad sections. The first section provides a framework for targeting biotechnologies to the poor. It emphasizes the importance of placing biotechnologies in the context of wider policies for national agricultural and rural development and science and technology (S&T) while also stressing the international dimensions of these policies and the importance of priority-setting. The second section deals with public policies for fostering appropriate applications of BFA, including: scientific and technical capacity-building for research, development and diffusion; approaches to and mechanisms for planning and funding; and requirements to ensure the safe use of BFA through environmental and food/feed safety regulation. The third section elaborates on the opportunities available to developing countries for gaining access to the benefits of agricultural biotechnologies. The section covers key aspects including intellectual property rights (IPR), public awareness and stakeholder participation, and the roles of extension services.

1. Targeting Agricultural Biotechnologies to the Poor

(a) Key considerations about agricultural biotechnologies

Government and agricultural policymakers have to make hard choices amongst the many legitimate demands made on public finances. In considering their options, they will inevitably be confronted with questions such as: Why focus on agricultural biotechnologies? Which agricultural biotechnologies should be used and for which purpose? What are their relative advantages and disadvantages, costs and benefits?

In addressing these and other questions, they should consider the following:

- Biotechnology is much more than genetically modified organisms (GMOs);

- At its “top end”, biotechnology is a “platform” or generic technology applicable across sectors and biological boundaries, i.e. it is both sectorally and scientifically cross-cutting, and requires the determined pursuit of multidisciplinarity. Policies and strategies for research involving advanced biotechnologies should therefore be developed in ways that maximize the opportunities arising from its cross-fertilization features. This requires strong interministerial coordination and collaboration;

- Biotechnology approaches to agricultural research are not alternatives to conventional technologies but, rather, complementary to them;

- Even at the downstream end of advanced biotechnologies (e.g. using validated molecular markers, diagnostics, tissue culture and micropropagation), biotechnology research and development (R&D) comes at additional cost. Working further upstream (e.g. in structural and functional genomics, basic immunology and genetic modification) increases both start-up and maintenance costs considerably;

- Biotechnology R&D needs physical facilities, expensive and sophisticated equipment and a critical mass of scientists with new skills to complement existing expertise in the traditional agricultural specialities such as plant and animal breeding and disease management. Shortcomings either in these new or in conventional knowledge arenas will seriously limit the potential of BFA;

- Realizing the full potential of biotechnology takes more than laboratory-based research. Development/scaling up and delivery are invariably the major “missing links” to deploying most biotechnologies in developing countries. Incentives to create or support demand-driven private sector firms or public-private enterprises are key for success;

- The success of private sector firms or public-private enterprises depends on the availability of entrepreneurial and business management skills and financial capital;

- The international legal and regulatory framework surrounding some modern biotechnology R&D and the diffusion of, including trade in, some products is complex and constantly evolving; it also adds significantly to the cost of innovations and to uncertainty about return on investments;

- Many of the tools and much of the biological information used for many biotechnologies have intellectual and tangible property protection.

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

Countries have many options for tackling these challenges through public policy. The instruments they choose will be determined by the prevailing macroeconomic environment, the structure of the sector, the legal and regulatory environment within which it operates, and the strength of the innovation systems (scientific, technological, marketing), including the regional and global links that support it. However, there must be realistic matching of technological opportunities with context. Policies aimed at fostering biotechnology for improving the livelihoods of small-scale/subsistence farmers will neither help them nor promote their interests without prior consideration of the constraints facing productivity of the plant and animal species used within the specific farming systems in which they are currently engaged. Holistic or "joined-up" analyses of proposed interventions are therefore not just sensible, they are essential – in the first place, for identifying the possible direct and indirect, immediate and longer-term ramifications of the intervention itself and, secondly, for designing and implementing policies and practices that will give a "pro-poor" direction to intended improvements in national agricultural and rural development and food supplies.

(b) Frameworks for action: National biotechnology policies/strategies

BFA should foster collective and transparent national ownership and an outcome consistent with the country's priorities for economic and social development in general. Given the multiple players and interests in BFA, its governance through policies, institutions and technologies will be most appropriately effected through a comprehensive national biotechnology policy/strategy (NBS). This should be informed by an inventory and analysis of existing national capacities for S&T and biotechnology generally, and for agricultural S&T and BFA in particular, and it should be coherent with the country's overarching policies for agriculture and food security. While there are many options open to countries for developing a NBS, certain principles are recommended for attracting widespread legitimacy and "buy-in". In particular, the mechanisms for developing an NBS framework for action should have the following overlapping features:

- They should be both forward- and outward-looking, e.g. based on information available about each subsector and stakeholder group potentially involved in BFA (crops, livestock, aquaculture, forestry and research, industry, the general public and farmers etc.). The information on each subsector should be evidence-based i.e. it should come from a wide range of sources that are transparent, take account of past lessons and consider a range of costed and appraised options, and be based on information that can be validated;

- They should be inclusive, i.e. involve key stakeholders directly and meet the needs and/or take account of the impact of the policy on all groups directly or indirectly affected by it;

- They should take a holistic or "joined-up" view, looking beyond subsector and institutional boundaries to ensure that the sum of the contributions of agriculture to the nation's strategic sustainable development objectives is greater than the parts contributed by its different subsectors;

- They should be balanced, i.e. they should consider both scientific and social and economic issues, as well as cultural and ethical dimensions. Consideration should also be given to how the policy will be communicated to the public, and how it will be reviewed and evaluated;

- The anticipated outcomes should improve, or at least not disproportionately harm, the sustainability of agriculture or the livelihoods of the most vulnerable groups contributing directly to, or affected by, the sector.

Developing these frameworks requires consideration and prioritization of many different policy options – inevitably a very difficult call with many caveats and trade-offs since the potential contribution of BFA to pro-poor growth will vary with the stage of development of the country and also between locations within countries, the key determinant being the existing conditions. Possibly the most fundamental policy issue faced by governments, however, is deciding on the types and levels of public support that should be directed towards small and large farms for reducing hunger and poverty through introducing technological change via biotechnologies. Since the benefits of BFA can be direct (through improving the incomes and food security of poor farmer households), and indirect (through lowering the price of food for net food-buying smallholders, labourers, non-agricultural rural and urban poor), there may be trade-offs between using that technology to reduce smallholder poverty and food insecurity at the expense of increasing aggregate farm productivity, food insecurity and poverty. On the other hand, even in areas where significant and widespread increases in productivity cannot be achieved (e.g. with poor resources and high population pressure), agriculture still has an essential role in protecting livelihoods and the natural resource base. The policy dilemma, therefore, is whether to invest in technology and other services or to provide safety nets and help people out of farming. Thus, while few would question the need to substantially re-direct public investments to rural areas, policies concerning technologies and other means of support for smallholders need to be tailored to context, in particular to location and resource endowments.

An NBS framework should aim to deliver or maximize:
- The coordination of BFA policy development nationally, regionally and globally;
- The strengthening of the scientific knowledge base and scientific infrastructure;
- Investment in commercial development;
- Strategic investments and other incentives to foster partnerships between universities, public research institutions and commercial companies;
- A regulatory system that is both transparent and effectively assesses and manages the risks from developing and introducing new and modified products, while allowing innovation;
- Mechanisms for the access, use and regulation of BFA-related intellectual property (IP), including benefit sharing from genetic resources in food and agriculture;
- Fostering community understanding about biotechnology, including through improved access to understandable and balanced information and by providing means by which citizens can express their views;
- Opportunities for considering cultural and ethical issues.

(c) Governance of national BFA

Owing to the inherently science-driven character of BFA, which is applied across a range of sectors and involves activities in various different jurisdictions, the successful governance of biotechnology requires policies and strategies that address all stages of the innovation chain: from fundamental to adaptive research, and from the development of tangible products to their diffusion to end-users (farmers and consumers). This requirement, as well as related trade issues, necessitates government-wide coordination (between government departments and subnational governance structures) as well as coordination with other governments via bilateral, regional and multilateral mechanisms.

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

Coordination –horizontal and vertical, national and subnational – is therefore essential for a comprehensive and balanced biotechnology policy. Whatever approach is taken, it must be effective in achieving concrete objectives. Given that not all the relevant competencies and expertise will necessarily reside within government, there are important roles to be played by non-governmental organizations (NGOs), the business community and other partners from civil society within coordination mechanisms. The use of external expertise to provide independent advice also facilitates ownership and buy-in from externally affected parties.

(d) Priority setting for national BFA policy

BFA priority setting is arguably the biggest challenge faced by policy-makers at government and sectoral level, particularly if the goal is to tackle hunger and poverty in rural areas. Many countries do not seem to be prepared to make critical choices about investments in BFA, which reflects the absence of, or insufficient rigour in, priority setting, and perhaps the undue influence of donors and supporters of particular technologies. In setting priorities, government-level policy-makers should, *inter alia*:

- Set up reliable systems for biotechnology foresight to monitor and assess the relevance for national agricultural and rural development of global patterns of technological change as well as demand from both home and export markets for biotechnology products including market potential, acceptability by users and consumers, and pricing. This helps guide formulation of technology policies and strategies;

- Irrespective of whether one or several ministries are responsible for “agriculture”, establish a collective decision-making forum within or between the ministry(ies) for priority setting and R&D resource allocation. A number of countries are beginning to establish such mechanisms for dealing with regulatory issues;

- Ensure that research investments are closely aligned to national development priorities and that transparent and fair mechanisms are in place, not only for selecting, funding and monitoring research performance but also for improving priority setting;

- Decide on research entry points appropriate to different national objectives (e.g. basic/fundamental or applied research), bearing in mind that producing scientific knowledge is one thing but having it absorbed and appreciated by society is quite something else;

- Ensure that priorities for public sector engagement in R&D consider which biotechnologies can or will be developed exclusively by, or in partnership with, local or international private sector companies;

- Introduce instruments that encourage the transformation of traditional research institutions and related higher education centres from “silos” of often pure discipline-oriented activity into innovation systems that foster multidisciplinarity and networking and a much greater number and diversity of actors;

- Determine the appropriate balance between advanced biotechnologies and other technical approaches for addressing the constraints faced by farmers, especially smallholders;

- Undertake cost/benefit assessments (particularly for R&D), bearing in mind that these methods should not themselves drive the process, but rather inform it, nor should they be used to replace sound judgement, experience and ingenuity or leave so little room for manoeuvre that freedom to explore new avenues is inhibited. A variety of models and approaches are available, some based on participatory bottom-up approaches.

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

Priority setting therefore requires a comprehensive approach for assessing the agricultural biotechnologies themselves and their transfer to end users and, in so doing, takes account of both their functional and institutional dimensions. The results will always be speculative, open to uncertainties and different interpretations and certainly cannot reliably be extrapolated from one country to another or even from one location to another within the same country. It is therefore important to review results against studies from other countries with similar and different socio-economic conditions.

Given the paucity of information about the long-term costs, benefits and risks associated with essentially all biotechnologies, especially in relation to the rural poor, new approaches are needed to assess and draw comparisons between conventional approaches and advanced biotechnologies in food and agriculture, and the positive and negative social and economic impacts they are likely to have both in the immediate and in the long term.

2. Enabling Policies for Agricultural Biotechnologies

(a) Creating and renewing awareness, knowledge, skills and infrastructure

Establishing or strengthening indigenous capacities for S&T, including infrastructure, is key to acquiring, absorbing and diffusing agricultural biotechnologies for development. The options and opportunities available are numerous, but the benefits may be undermined by a lack of policies for avoiding “brain drain”, which is surely a prime example of extreme ineffectiveness in policy-making, because it entails huge costs to societies that pay for investments but then do not enjoy the benefits. While domestic policies alone are insufficient to deal with this issue, improving employment opportunities, salaries and other conditions of employment, and ensuring the availability of the necessary equipment and supplies are part and parcel of an effective capacity-strengthening policy package.

Training in biotechnology has also become highly globalized, and opportunities abound for nationals from developing countries to study, train and participate in scientific exchanges through workshops, courses etc. under the great variety of programmes associated with intergovernmental and institutional agreements. For example, the Biosciences eastern and central Africa (BecA) hub which has been set up on the campus of the International Livestock Research Institute in Nairobi provides a common R&D platform, research services, training and capacity building opportunities with top-class facilities and personnel. Last year, BecA hosted more than 180 African students and scientists in workshops and bioinformatics courses.

In addition to building up PhD and postgraduate training opportunities, countries could consider supporting innovation by giving greater encouragement within their S&T systems to both public-private sector partnerships and to meeting the demands and requirements of private enterprise. Initiatives might include:

- “Re-engineering” existing university departments and curricula by focusing on areas and approaches that are presently inadequately covered, e.g. degrees in regulatory affairs, product development, bioinformatics, technology transfer and entrepreneurship/commercialization;

- Creating new institutions and rebranding existing institutions for R&D;

- Creating institutions such as “biotechnology incubators”, “technology parks” or “clusters” specifically for scaling up and commercializing research outputs.

Incentives could also be provided for qualified citizens working abroad to participate in national activities by introducing specific instruments for this purpose.

(b) Funding of national science and technology and BFA activities

Securing appropriate and consistent levels of funding for agricultural S&T has been highly problematic for most developing countries, whose investments usually fall far short of the global average of 1% of agricultural GDP. Awareness of the critical role of agricultural research for addressing food security, poverty reduction and sustainable use of natural resources must be improved to tackle the pervasive underinvestment in public agricultural research in developing countries. Political commitment to raise awareness and investments in R&D appropriate to meet the needs of smallholders is therefore a top priority. With its additional requirements for infrastructure and organizational, scientific, technical and legal skills, and the challenge of addressing the many other priorities that have surfaced in recent years, introducing agricultural biotechnologies makes that task all the more urgent.

A number of options can be considered both to increase levels of funding and to move away from traditional instruments of funding. Most of these revolve around changing the division of labour in R&D between public and private entities and between national and regional or state entities, improving coordination between academia, public sector institutions and the private sector, and putting in place mechanisms or institutions that sit between the funders and beneficiaries of R&D to guide the research agenda and decide on who should carry it out. The options to be considered might also put a premium on collective responsibility for funding (e.g. through levies from producers, tax and other concessions for private firms and grants from foundations) and on the areas of early-stage capital funding and addressing the commercialization gap. They include:

- Redirecting part of the total public support package for agriculture (e.g. through subsidies and other policy instruments) to innovative technological packages directed to tackling priority constraints to sustainable production within disadvantaged regions with minimum economic potential;

- Introducing commodity levies and tax check-offs, and directing a proportion of the income to support "pro-poor" agricultural R&D;

- Encouraging commercialization of agricultural R&D. Although, experience indicates that commercial earnings may substitute for government funds rather than complement them and that this approach may therefore not increase overall levels of agriculture funding;

- Developing much closer partnerships with, and alignment between, policies, programmes, projects and funding mechanisms linked to R&D supported by other ministries and their donor communities (particularly with S&T and environment ministries);

- Moving progressively away from traditional arrangements such as "block grants" provided by the finance ministries and supplemented by donor contributions, and then allocated individually or collectively by agriculture ministries to centrally-based national agricultural research organizations. Instead, through progressive decentralization which provides an opportunity to adapt research to local contexts, to grant fiscal autonomy to state or regional governments and legal status to producer organizations and to encourage the establishment of national and regional research foundations with "arms length" boards or councils to expand and change the sources and flows of funding, including from donors;

- Changing the criteria for priority setting, the procedures for allocating funds, and the funding instruments used at national and state levels, basing these in all cases on competitive and often matching grants directed at a variety of entry points including more upstream and applied biotechnology research, technology development and scholarships;

- Linking research priorities more explicitly to wider social and economic needs, i.e. poverty reduction and rural development programmes and funding them accordingly. With the political spotlight now firmly on the Millennium Development Goals and the Paris Declaration on Aid Effectiveness, this approach could both increase national funding and encourage donors to step up and coordinate their support for research in rural areas;

- Creating formal structures and mechanisms for stakeholder participation in R&D policy, including its interrelated elements of priority setting, funding and review. Since the remit of most biotechnology advisory committees is wide, one option is to create a R&D subcommittee with expertise in S&T, innovation and socio-economic development, and including representatives from NGOs and civil society umbrella organizations, including those representing the agricultural/food sector;

- Giving increased priority to research that is jointly formulated and implemented through partnerships within the public sector (research institutes and universities), but more particularly through public-private partnerships (e.g. research institutes, universities and small and medium enterprises);

- Giving increased priority to research projects that arise from the analysis of constraints within local and regional product value chains and production systems;

- Establishing funding windows for S&T and innovation based on thematic "problem-based" priorities established by a government-level think-tank, a method that often requires multidisciplinary approaches and caters less to the scientific interests of researchers in specific disciplines;

- Establishing or strengthening intermediate funding structures between government and national S&T and innovation systems, such as research councils, foundations with administrative boards, peer-review panels etc.

These new approaches are still in their infancy. With the current global economic downturn and in light of the inevitable increases in transaction costs and the downstream movement of research agendas, it is unclear whether the new approaches will actually improve the efficiency and effectiveness of national R&D enterprises and the prospects for a more diverse and pro-poor relevant suite of biotechnologies coming on line in the years ahead.

(c) Regulation

Developing a regulatory framework for BFA (and especially for GMOs) is a complex, resource-intensive and potentially daunting process. Irrespective of the established regulatory structure, instituting new regulatory functions places enormous demands on national scientific, technical and administrative institutions that have not historically existed. Among others, the demands include: preparing dossiers for and responding to notifications; setting out guidelines for conducting risk assessments; issuing or refusing permits and specifying conditions; certifying and inspecting facilities and field sites; developing guidelines for post-release monitoring; methods for testing; and defining enforcement activities.

One of the main justifications for establishing new laws and regulations is to provide a unified or, at least, a well coordinated national system for dealing with BFA applications through a chain that stretches from R&D through GMO management to consumer information. Most countries have approached biotechnology regulation by establishing formal public institutions such as a national biosafety (or biotechnology/genetic engineering) authority (or board/committee/commission/council/executive council). These institutions act as a focal point for national BFA regulatory policy-setting and generally include representatives from all affected ministries, and have formal mechanisms to engage industry and the public in decision-making. It is important to note that such institutions are generally separate from the agencies that undertake standard-setting and risk assessments.

In establishing regulatory policies for BFA, government authorities should consider:

- Using existing primary laws and the relevant legal authorities to promulgate regulations for BFA activities. This provides a basis for regulating GMOs within a short time;

- Introducing new primary laws and regulations. This is a longer-term undertaking, but one that might be justified where existing laws and regulations are very old; lack or provide questionable authority to regulate biotechnology or make such authority weak; and/or are confusing and lack transparency and coordination by being scattered among different ministries.

Either way, establishing clear criteria and standards for environmental and food safety including baselines, comparators, thresholds and indicators is critical. Moreover, agencies engaged in undertaking risk assessments should themselves have a clear funding base (often based on fees for services) and their staff should be appropriately skilled and conversant with international guidelines and principles for science-based risk assessment. In this regard, developing countries are becoming increasingly challenged to keep up with an ever-widening and constantly evolving battery of scientific skills and analytical tools used in GMO regulation. These efforts are assisted by information, guidelines and other decision-support materials available through, for example, FAO, the Codex Alimentarius Commission and the Biosafety Clearing-House (BCH), but their success 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.

Regulatory decision-making is both highly complex and has scientific, social and political dimensions. In some countries, socio-economic considerations may not be considered appropriate in regulatory regimes, leaving the market to respond to non-safety consumer demands. In others, it may not simply be the prerogative of scientists and government regulators – some societies increasingly want a say in how regulation is done and in the decisions that are made. It seems clear, therefore, that while product safety must be assured by the government, public confidence in biotechnology will increasingly require that socio-economic impacts are evaluated along with environmental and human health risks, and that people representing diverse views have the opportunity to participate in judgements about using new technologies. Fostering such approaches will need a significant revamping of the current approaches taken to providing assistance to developing countries for making rational technology choices.

The financial commitments made over the last 5–7 years to support the setting up of national biosafety systems has both skewed external investments and diverted significant internal investments, including human resources, into the specific, technically much more demanding and costly area of GMOs at the expense of possibly more easily developed, applied and profitable biotechnological approaches not requiring regulation, e.g. the use of molecular markers and possibly genomics for characterizing genetic resources and speeding up selection and breeding programmes. On the other hand, a few developing countries have reaped substantial rewards from their investments. This is a significant issue for reflection among national policy-makers and the international community

Many attempts have been made to “harmonize” biotechnology regulations regionally and internationally. Undoubtedly, the biggest success story is the work of the FAO/WHO Codex Alimentarius Commission, which has developed a series of principles and guidelines for food safety assessment of foods derived from modern biotechnology. Also, from the perspective of transboundary movements of GM plants, the international standard for phytosanitary measures (ISPM) No. 11, entitled “Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms” (2004), which was developed under the auspices of the International Plant Protection Convention (IPPC), is key for environmental risk assessment. Both the Codex Alimentarius Commission and the IPPC are relevant standard-setting organizations for the WTO Agreement on the Application of Sanitary and Phytosanitary Measures. Mention should also be made of the work of the Organisation for Economic Co-operation and Development (OECD) on risk/safety assessment of modern biotechnology covering food, feed and environmental safety, the main outputs being two series of “Consensus Documents”, one on the Harmonization of Regulatory Oversight in Biotechnology and the other on the Safety of Novel Foods and Feeds. The OECD has also developed the “unique identifier” for the global tracing of transformed events and which is currently being used by many GMO developers, as well as by the BCH and the FAO International Portal on Food Safety, Animal and Plant Health.

While there is clearly no shortage of information, nor lack of readiness on the part of numerous international and national agencies and private consultants to provide training and capacity-building services, considerable disagreement continues to exist within and across countries concerning the nature of the hazards, if any, and the appropriate approaches and methods for assessing the potential risks of employing GMOs in food and agriculture. There is also much disagreement about how to deal with socio-economic risks, about whether there is a need for labelling and about whether regulatory decision-making should directly involve people outside of regulatory agencies.

This global regulatory divide suggests that while considerable scope exists for improving understanding and reducing regulatory costs among developing countries through the pursuit of informal collaboration and the mutual recognition of voluntary guidelines, the prospects for comprehensive harmonization of biotechnology regulatory oversight within developing country regions do not look promising because: (a) decision-making is essentially about dealing with uncertainty and societal value judgements concerning levels of acceptable risks; (b) within all developing country regions, national policies on GMOs currently range from moratoriums to approval of field trials through to commercial field releases; and, (c) science can only inform, but never replace, the decisions of policy-makers and societies regarding what they consider to be legitimate and justifiable reasons for particular courses of action.

This certainly does not mean that the harmonizing of science and data requirements cannot be improved. Examples of voluntary guidelines might include: approaches for conducting risk assessments, for dealing with confidential information, on criteria and procedures for authorizing and overseeing confined field trials, on methods for obtaining and reporting molecular characterization data, methods of analysis and sampling for GMOs in different matrices, conducting post-release environmental monitoring and producing consensus documents on the biology of plants used by smallholders in developing countries. Hence, while there is general consensus that harmonization of regulatory approaches across countries is important, more important at this juncture is coordination and harmonization of GMO regulation between the different relevant government ministries within a country.

This may be sufficient justification for developing countries to consider adopting a “Biosecurity” approach, defined by FAO as “a strategic and integrated approach to analyzing and managing relevant risks to human, animal and plant life and health and associated risks to the environment”. Many developing countries simply cannot afford sector- or GMO-specific approaches and could benefit greatly from a more integrated approach without necessarily creating new or unified structures. This would also provide an opportunity for greater harmonization of terminology and methodology for risk analysis, while respecting the need for individual sectors to tailor risk analysis procedures to the characteristics of the risks involved.

3. Ensuring Access to the Benefits of Agricultural Biotechnologies

a) Intellectual property rights

Clear and transparent policies for accessing and using both the research tools and tangible end products are an essential component of the enabling environment for fostering biotechnology innovation and diffusion. Increasingly, these materials and associated information have become the subject matter of grants of IP protection. Consequently, another critical requirement of a national biotechnology policy/strategy is that it should address the question of how a country intends to deal with the associated IP issues. Policies for accessing genetic resources for food and agriculture and sharing the benefits from using biotechnologies to develop useful products have likewise become increasingly important.

National policies on IPR and genetic resources should optimize the balance between, on the one hand, the interests of the creators (e.g. scientists, breeders) and investors, and, on the other, the interests of the wider society (farmers and consumers) who wish to use, directly and indirectly, innovations that are protected by IP. Striking a balance has proven increasingly difficult since the arrival on the scene of BFA, particularly advanced biotechnologies. Relatively recent policies within some national and regional jurisdictions have extended patent grants from innovative selection and breeding processes for genetic improvement to “life forms” (e.g. plant transformation tools, gene markers, DNA sequences and improved germplasm and varieties).

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. In designing and managing national IPR systems, countries should therefore be aware of:

- The core assumptions of the WTO’s agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement) and indeed of the UPOV (International Union for the Protection of New Varieties of Plants) Acts – namely, that IPR will stimulate international transfer of technology and therefore (bio)technology-related R&D in developing countries, as well as the wider exchange of improved breeding lines and varieties;

- The interrelationships between IPR (specifically the UPOV Acts and TRIPs Agreement) and (a) the core aims of the Convention on Biological Diversity (CBD) and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) – namely, access to and fair and equitable sharing of benefits from using genetic resources, the conservation and the sustainable use of genetic resources for food and agriculture, the preservation of and respect for the knowledge, innovations and practices of indigenous and local communities/farmers’ rights, and (b) national food security;

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

- The costs and benefits of implementing national IP legislation for BFA innovations consistent with international rules. These will be country-specific and depend on, among other things, the status of current legislation, technical and administrative capacities, and subject matter eligibility criteria, e.g. the number of plant species protected. The costs of implementing patent administrative systems will certainly be higher than for *sui generis* plant variety protection systems, while the potential benefits (with many underlying caveats) include contributions to greater productivity, trade, incomes and food security.

Developing countries intending to build strong breeding capacity involving biotechnology should nevertheless be aware that granting patents for gene constructs and GMOs will increase the price of seeds, propagating materials and other products because of the IP-related "technology fees" charged by patent owners. They should also be aware that 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. 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.

Another aspect 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, or for that matter for protecting farmer-bred varieties (i.e. coverage of "traditional" and more informal communal systems of innovation by farmers and indigenous communities). These are concepts covered under multilateral biodiversity agreements (the CBD and the ITPGRFA), and which countries also have to address in ways that are both consistent with international trade agreements and between different pieces of legislation.

Inevitably, no single IP system will suit the needs and goals of all countries or serve all agricultural systems within an individual country. Consequently, in the process of designing IP legislation and related policies, countries wishing to use IP as an "enabler" of BFA should (a) make realistic projections about the future role of biotechnologies in helping to meet their national agricultural and wider food security and poverty reduction goals, and (b) make maximum use of the flexibility inherent in internationally agreed rules.

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 and trade secrets.

(i) Laws and institutions

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 issues it poses. 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 interconnected tasks, the outcomes of which may be significantly influenced by national and international development, research funding and commercial organizations.

Consultative mechanisms therefore need to be established to reach agreement and strike compromises between groups both within and outside the food and agriculture sector which invariably will have widely different perspectives on a number of fundamental questions (particularly with respect to patents) concerning legislation, its implementation and enforcement. These include: To what extent and in what forms should IP protection be available? Who can or should own the agreed IPR? What institutions will be put in place to identify and manage technologies to be accessed and protected, and how will they be resourced (staffed, equipped)? How will legislation be enforced?

(ii) Management options for research institutes

The strategic IP management choices open to public organizations to access biotechnology tools and technologies for research, development and diffusion will depend on R&D capacity, objectives, cost, conditions, public acceptance etc. The choices available include: using gaps in patent and protected variety jurisdictions; using research\experimental use exemptions incorporated within national legislation; material transfer agreements; licensing agreements; purchasing outright; public-private sector partnerships; and negotiating royalty-free access to proprietary genes, genetic constructs, and germplasm either directly or by using the services of third-party brokers. Other options include public sector partnerships, patent pools and open-source licensing.

Potentially useful as all these modalities may be, it must be emphasized that it is not simply patent information or access to an IP-protected tool or product that is important for successful technology transfer. Also essential is the associated knowledge, which many owners of IP continue to guard carefully, and which can only be accessed through appropriate material transfer or licensing agreements.

(iii) Legal or institutional structures and IP/knowledge-transfer policies

Virtually all research institutes and universities in industrialized countries dealing with BFA have established Technology Transfer Offices (TTOs) staffed by people trained in advising on and processing IP applications, and equipped with the negotiation and business skills for securing agreements with third parties that are either seeking access to IP-protected products or hold IPR on products of research-related or commercial interest to the institution that runs the TTO. The TTOs also deal with non-proprietary assets such as textbooks, training manuals, software and audio-visual material. In some cases, public institutions have allowed or even encouraged their staff to set up spin-off companies.

Policy-makers in developing countries should be aware of the following potential issues regarding the commercializing of IP assets in the public sector:

- There is the risk that the focus of BFA research will shift away from a predominantly public-goods mission towards private interests (i.e. from upstream to near-market research and from concentrating on species and traits important to small and resource-poor farmers to species and traits of interest to export- and commercially-oriented operations). It is important therefore that the principles for seeking protection and managing biotechnology IP further the mission of the institute i.e. foster both access and diffusion of both their proprietary and non-proprietary assets to the poor and food insecure;

- The ability to obtain royalties from licensing protected varieties and other biotechnology materials to third parties or from the outright selling of other intellectual assets, contracts, consultancy fees, etc. can raise revenue for the institute and/or scientists involved. In normal circumstances, however, licensing protected assets will not be sufficient to cover the costs of seeking, maintaining and licensing patents relating to BFA;

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

Before embarking on the complex and expensive business of applying for IP protection in the first place and establishing TTOs for managing it 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 making and maintaining an inventory of the assets in the public and private sectors, irrespective of whether they are 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 develop partnerships for R&D and commercialization, even if the national legislation excludes the IP protection of life forms.

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

National and international S&T funding agencies and donors are essential catalysts of agricultural R&D and development, and with the advent of the genomics and proteomics era in BFA, the policies adopted by these agencies, including the question of disposition of rights to IP arising from the R&D supported by them, play a critical role in determining the policies, practices and behaviour of the research institutes and individual scientists that rely on funding from these sources.

The following principles and practices are 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;

- 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" agreed for the human genome project to include the sequencing of genomes of organisms that are both essential for, and act as major impediments to, agricultural production in developing countries. This means releasing all DNA sequences longer than, say, 1 000 base pairs to a public database within 24 hours and issuing a directive against patenting newly discovered DNA;

- Foster responsible patenting and licensing strategies, e.g. non-exclusive licensing should be considered when technologies owned or funded by public sector institutions are transferred to the commercial sector;

- 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 applications rather than granting blanket exclusive rights for uses that cannot be anticipated at the moment;

- In view of the complexity in determining freedom to operate 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 protection;

- Introduce explicit reservations of rights in commercial technology licenses to protect their own institutional objectives and support humanitarian applications.

To conclude, 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 technology transfer, development and diffusion is a huge challenge and still very much a 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 agricultural biotechnologies are to deliver on a pro-poor agenda.

b) Public awareness and participation

As biotechnology is a very broad topic with intersecting thematic areas including biosafety, food and feed safety, consumer protection, IP, seed certification, bio-ethics, as well as access to genetic resources and benefit-sharing, requirements for national capacity aimed at fostering public awareness information sharing are extensive. However, more than half of the developing countries surveyed for this document were either silent about public education/awareness and participation, or made only short generic statements about these issues.

Participation in BFA policy is practised in differing ways in different countries depending on local contexts, perspectives and public concerns. These practices 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.

International agreements and guidelines concerning biotechnology do not provide guidance on how the public should be informed, educated or engaged in decision-making processes, or how any decisions about GMOs might be communicated to the public. However, for providing information, obvious channels of communication include the internet, publications, radio, television, newspapers, workshops, public hearings, official bulletins, and even the labelling of products. As regards public participation, its scope would depend on whether participation is passive (e.g. through government gazettes or official public registers that ask for feedback by a certain deadline) or active (e.g. involving the sharing and communicating of information and views through public consultations and hearings, the results of which would be fed into decision-making and regulatory processes). Most rural communities, however, do not have access to the internet or understand the main international languages used on the internet and in much print media. Governments and their agencies, NGOs, civil society organizations and others will therefore need to rise to the challenge of creating spaces for activities to foster public participation by these communities.

In doing so they should ensure 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 FAO's independent Panel of Eminent Experts concluded in 2001: "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."

c) Agricultural extension

An important and often neglected biotechnology policy issue is agricultural extension. The lack of information and skills is one of the main reasons for the gap between the potential and the actual productivity/profitability of smallholder farmer systems. This lack limits the adoption of available technologies and practices and reduces their efficiency if eventually adopted.

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, which has contributed to a rapidly developing global food system, and the perceived lack of success of public agricultural extension systems in many countries.

The changes to extension systems and the new opportunities of BFA require the closer integration of researchers, extensionists, and smallholder producers and their organizations. The changes also require extension staff to upgrade their skills to become more capable both of understanding the implications of agricultural biotechnologies and of facilitating interactions between farmers and other stakeholders involved in the agriculture knowledge information system.

Acronyms and Abbreviations

BCH = Biosafety Clearing House

BecA = Biosciences eastern and central Africa

BFA = Biotechnologies in food and agriculture

CBD = Convention on Biological Diversity

FAO = Food and Agriculture Organization of the United Nations

GM = Genetically modified

GMO = Genetically modified organism

IP = Intellectual property

IPPC= International Plant Protection Convention

IPR = Intellectual property rights

ITPGRFA = International Treaty on Plant Genetic Resources for Food and Agriculture

NBS = National biotechnology policy/strategy

NGO = Non-governmental organization

OECD = Organisation for Economic Co-operation and Development

R&D = Research and development

S&T = Science and technology

TRIPs Agreement = WTO’s agreement on Trade-Related Aspects of Intellectual Property Rights

TTO = Technology Transfer Office

UPOV = International Union for the Protection of New Varieties of Plants

WTO = World Trade Organization