

# A Framework for Policy-Making on Trade, Agricultural Biotechnology and Sustainable Development

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## ACRONYMS

AAPARI	Asia-Pacific Association of Agricultural Research Institutions
AAPRESID	Argentinean Association of No-Till Farming
ACRE	UK Advisory Committee on Releases to the Environment
BIO	Biotechnology Industry Organization
BSE	Bovine Spongiform Encephalopathy (Mad Cow Disease)
Bt	Bacillus thuringiensis
CBD	Convention on Biological Diversity
CGIAR	Consultative Group on International Agricultural Research
CNA	Brazilian Farm Bureau
CONABIA	Argentinean National Advisory Commission on Agricultural Biotechnology
CTNBio	Brazilian National Technical Commission of Biosafety
DNA	Deoxyribonucleic Acid
DNMA	Argentinean National Direction of Agricultural Food Markets
EIA	Environmental Impact Assessment
ELISA	Enzymes-Linked Immunosorbent Assay
EPA	U.S. Environmental Protection Agency
EPC	European Patent Convention
FAO	Food and Agriculture Organization of the United Nations
FDA	U.S. Food and Drug Administration
GAIN	Global Alliance for Improved Nutrition
GATT	General Agreement on Tariffs and Trade
GEAC	Indian Genetic Engineering Approval Committee
GEF	Global Environment Facility
GM	Genetically Modified
GMO	Genetically Modified Organism
GTZ	German Agency for Technical Cooperation
IBSC	Indian Institutional Biosafety Committees
ICTSD	International Center for Trade and Sustainable Development
IDEC	Brazilian Consumer Protection Institute
IFPRI	International Food Policy Research Institute
IP	Intellectual Property
ISNAR	International Service for National Agricultural Research
ITDG	Intermediate Technology Development Group
LMO	Living Modified Organism
NAFTA	North American Free Trade Agreement
NCST	Kenyan National Council for Science and Technology
NGO	Non-governmental Organization
NIAB	Korean National Institute of Agricultural Biotechnology
OECD	Organization for Economic Cooperation and Development
PBR	Plant Breeders' Rights
R&D	Research and Development
RCGM	Indian Review Committee on Genetic Manipulation
RIS	Research and Information System for Developing Countries
RDA	U.S. Rural Development Administration
SAGENE	South African Committee for Genetic Experimentation
SAGPYA	Office of Biotechnology of the Secretary of Agriculture, Food and Fisheries in Argentina
SENASA	Argentinean National Service of Agricultural and Food Health and Quality
SPS Agreement	Agreement on Sanitary and Phytosanitary Measures

TBT Agreement	Agreement on Technical Barriers to Trade
TRIPS Agreement	Agreement on Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
UNEP	United Nations Environment Program
UPOV	International Union for the Protection of New Varieties of Plants
USDA	United States Drug and Food Administration
WTO	World Trade Organization

## I. INTRODUCTION

Biotechnology is transforming the processes and the products of agricultural research, as well as the institutional and economic environment of agricultural technology development and innovation systems. Advances in the biological sciences are producing quantum leaps in our knowledge about the way plants and animals grow and synthesize useful products, as well as the scientists' ability to transform them. Scientific breakthroughs in the area of genetic engineering have greatly expanded the possibilities of handling and transforming micro-organisms, plants and animals. These advances are affecting agricultural practices through alternative plant breeding methods and pest control strategies, as well as the development of plants with enhanced agronomic traits and nutritional characteristics.

Agricultural biotechnology, and particularly as it involves genetic modification, promises a number of important benefits. These include improving agricultural yields by increasing the resistance of crops to pests and enabling them to flourish in harsh natural environments, improving the productivity of farmers, and reducing pesticide use. While these benefits have largely been confined to the agricultural sector, and the immediate physical environment surrounding it, future technological advances may yield additional benefits, including the development of foods that improve the health of consumers.

At the same time, concerns have been raised about the potential negative impacts of genetic modification. From an environmental perspective, critics note the possibility of cross-pollination and gene flows to traditional varieties and the inability of regulatory systems to adequately manage the trade in genetically modified (GM) seeds in a way that ensures their segregation from traditional varieties. With respect to development impacts, scepticism has been expressed about the ability of agricultural biotechnology to fulfill its promise, given the trends such as lack of focus on the development of crops and

traits that would meet the needs of resource poor farmers, difficulty of poorer groups in accessing technologies protected by patents, and the potential for biotechnology innovations to displace traditional agriculture.

Agricultural biotechnology thus poses particular challenges and opportunities for regulators and policy-makers. In itself, however, it is neither good nor bad: agricultural biotechnology is merely a tool that, in order to serve sustainable development, should be oriented towards economic, social, environmental and other public policy objectives. Countries must define their broad agricultural and development policy objectives and only then determine whether, how or to what extent the development and adoption of GM technologies and products can facilitate them. In this regard, there is a range of needs and priorities that regulators and policy-makers may have to take into account and balance in their choices. These needs and priorities include promoting food security, reducing agricultural poverty, increasing access to global markets, improving environmental quality and the welfare of agricultural workers, protecting biodiversity, improving public health through safer or healthier foods and encouraging the domestic development of research and development.

Establishing an adequate approach to agricultural biotechnology – addressing and balancing the different needs, priorities, and objectives in national, regional, and international instruments and policies – is a complex task. Developing countries have particularly struggled to develop policies and regulations that consider and respond to the specific challenges and opportunities posed by agricultural biotechnology. The need for such policies and regulations, however, is mounting. For the most part, developing countries do not produce GM crops, but the importation of such crops and derived products is increasingly widespread. Efforts are thus underway to evaluate the implications on their respective economies, environment, and societies, and to adopt the policies that will orient the use of agricultural

biotechnology towards national, regional, and international sustainable development goals.

The objective of this report is to identify the particular policy and regulatory considerations and options for developing countries in connection with the development and commercialization of GM technologies and products. In addition, this report aims to examine some of the policy-making processes that facilitate the review of these considerations and options. After this introduction, Section II explores the distinctive issues raised by agricultural biotechnology in developing countries, and describes the different options

and considerations for relevant regulations and policies. Section III provides case studies on the way a number of countries, both developed and developing, have addressed the various promotional and regulatory issues posed by GM technologies and products. Section IV then elaborates a series of frameworks that should enable policy-makers to think through the various policy issues and options raised by agricultural biotechnology. Section V focuses on public participation, an important component in the design, implementation and monitoring of an agricultural biotechnology framework. Section VI concludes the paper with some final analysis and remarks.



## II. AGRICULTURAL BIOTECHNOLOGY AND DEVELOPING COUNTRIES: ISSUES AND POLICY IMPLICATIONS

Biotechnology is any technology that uses biological systems or living organisms to make or modify products or processes for a specific use.<sup>1</sup> In its broadest sense, biotechnology has been in use for thousands of years, beginning with the domestication and selection of plants and animals. More recently, however, the term has become associated with a scientific process that involves the manipulation of deoxyribonucleic acid (DNA), of an organism – this is “modern” biotechnology. Such biotechnology includes a variety of different scientific techniques (see Box 1).

The focus of this report, nevertheless, is on genetic modification: the deliberate alteration of the genetic make-up of plants and animals by adding, altering or deleting one of its genes. GM crops were first commercialized in 1994. Since then, the global area of transgenic crops has increased from 2.8 million to over 90 million hectares. The development and widespread adoption of these GM technologies and products presents significant opportunities for developing countries. As will be described below, however, it also raises a number of environmental, health-related and socio-economic issues that must be taken into consideration in national, regional, and international policy-making.

### Box 1. Beyond Genetic Modification: Other Forms of Agricultural Biotechnology

It is important to emphasize that, although this report focuses on policies associated with GM agricultural biotechnology, there are many important dimensions of agricultural biotechnology that do not involve genetic modifications. For instance, *marker-assisted selection* uses genotypic information obtained through DNA testing (or “genetic fingerprinting”) to assist in the selection of suitable individuals to become parents in the next generation. Biotechnology critics have hailed this technology as a viable alternative to genetic modification by allowing breeders to speed up natural plant and animal breeding programmes without the need for genetic modification.

Other techniques include *tissue culture* and *micro-propagation*, which involves taking small sections of plant tissue, or entire structures such as buds, and growing them under sterile conditions on specially selected media containing substances essential for growth with the objective to regenerate complete plants. This technique is particularly useful for maintaining valuable plants, breeding otherwise difficult-to-breed species (such as many trees), accelerating plant breeding and providing abundant plant material for research. The most common application of tissue culture in developing countries involves producing virus-free plantlets by heat-treating the tissue plant to kill any viruses present and then culturing cells from the plant’s actively growing tissue.

The use of *diagnostic tests* to fight plant diseases is another type of non-GM biotechnology. Molecular assays such as enzymes-linked immunosorbent assay (ELISA) can precisely identify viruses, bacteria and other disease-causing agents. ELISA has become an established tool in disease management in many farming systems and is now the most widely used commercial diagnostic technique in all regions of the developing world. Also, products based on *micro-organisms* play an increasing role in pest control and soil enrichment including bio-pesticides (i.e. pesticides derived from natural materials which are more selective, less toxic to humans and the environment and more effective at lower rates of application than conventional chemical pesticides), bio-fertilizers and products that aid fermentation and food processing. Research in these products is in the early stages in Africa and Asia, but developing countries such as China, India and the Philippines are already using advanced techniques. Studies on bio-fertilizers are currently being carried out in many developing countries.

## 1. Characteristics of Biotechnology–Based Agricultural Technology Systems

The specific challenges and opportunities for policy-making arise given the particular nature of agricultural biotechnology. The planting of GM crops and uses of the products derived from them inherently distinguish it from conventional agriculture. Differences, as will be seen below,

include the kinds of science on which technology development is based, the institutions involved in the technology development, the investment requirements of GM technologies, and the logistical infrastructure and role that industry plays in the technology diffusion process.<sup>2</sup>

### Different scientific base for technology development

Conventional agricultural research institutions, such as national agricultural research institutes and specialized research centres like those in the Consultative Group on International Agricultural Research (CGIAR), are what could be called “dedicated” systems. These systems are characterized by a “vertical” or “sectoral” structure: the development of the basic knowledge and its applications to technology generation are closely interrelated and are usually undertaken within the same organization. The usual direction of research in the search for new technologies is from specific problems to scientific inquiry. Such research systems are typically more closely linked to the users of agricultural technology, i.e. farmers, than to the scientific community.

biology, genetics, biochemistry and physiology. Biotechnology innovations are also applicable across a broad range of areas such as health, environment, manufacturing industry and agriculture. Due to its generic and horizontal structure, biotechnology development often lacks operational links to existing agricultural technology delivery systems. However, once new genetic constructs are available, for them to be of any economic value they must be integrated into the broad germplasm basis of existing commercial crop varieties, and large scale field evaluations need to take place to adapt the new products to local ecological conditions and cultural practices. Farmers will not accept them unless they are packaged in a genetic platform with acceptable production and productivity performance. These characteristics have direct implications both in terms of the diversity of the institutional actors involved, as well as with the structure of interactions between basic and applied research organizations.<sup>3</sup>

By contrast, biotechnology development is much more of a “horizontal” structure. The discovery of DNA and the principles of genetic engineering evolved from a close interaction among a number of the basic scientific disciplines, including

### Increased role for private sector<sup>4</sup>

In marked contrast to the Green Revolution, which was based on new plant varieties developed by public sector research institutions and centres of the Consultative Group on International Agricultural Research (CGIAR), the development and commercialization of GM crops has been largely driven by the private sector. The pioneers of agricultural biotechnology were chemical firms working with pesticides and herbicides that were looking for technologies with lower health and environmental impacts. As a result, it was the private sector – with companies like Monsanto

– that invested from early on in agricultural biotechnology research, conducted both in-house and through university researchers.

The traditional agricultural research scheme – a public sector specializing in basic research and a private sector oriented toward applied research – thus fundamentally changed in the field of biotechnology. A sizable share of what was once considered basic science, such as genomic mapping, is being conducted in the private sphere, by both large life science firms and smaller biotechnology

companies. This increased role of the private sector, promoted by the strengthening of intellectual property protection for biological inventions, has weakened one of the historical justifications for public support of agricultural research - the inability of private entities to sufficiently profit from research. It also raises problems for many developing countries, in which the lack of strength of the private sector is a substantive limitation for the future development of agricultural biotechnology.

Nevertheless, there may be a unique and distinct role for public-sector research, even as the private sector maintains its leadership in the field. Unlike industry, for example, the public sector is able to prioritize and maximize knowledge spillovers, by facilitating broad dissemination of research findings. This is particularly important in the development of basic research tools, which if developed by the private sector, would be protected by patents and might stifle further research and innovation.

#### Distinctive industrial infrastructure

Exploiting the potential benefits offered by biotechnology requires the capacity to take the results of research and development (R&D) and scaling them up to industrial production and marketing. The existence of input markets, capable of bringing innovations up to the farm gate, constitutes a necessary condition for effective technology transfer. Most of the relevant products of the biotechnological approaches to R&D are technologies of the “embodied” type: they must be packaged either in seeds or in other physical inputs, such as diagnostic kits, vaccines or yeast, before they can deliver their potential benefits. In this context, the existence of a functioning (in terms of variety turnover) germplasm market and industry is probably the most critical industrial component as it is through the seed that most of the input efficiency and product innovations are incorporated into the food and fibre production systems. The strategic importance of the seed sector is substantiated

In addition, the public sector is more able to conduct research in areas that may offer limited incentives for private companies – focusing, for instance, on GM varieties that meet certain nutritional or environmental needs in developing countries. Crop biotechnology research networks, for instance, offer opportunities of using biotechnology as tools of empowerment for rural communities. The Cassava Biotechnology Network, one such example, brings together researchers and end-users seeking to apply biotechnology tools to cassava – one of the key staple crops in Africa – in order to address challenges facing small-scale agricultural producers.

Public-sector research, however, faces the challenges that more and more of the knowledge and tools needed for are covered by intellectual property rights. Further research in agricultural biotechnology thus needs to prioritize public-private partnerships. Such joint research will allow both the private and public sector to bring their comparative advantages into agricultural biotechnology development.

by developments in its structure over the past ten years and the emergence of the “life sciences” industry.

However, only a few countries have a seed market with a large enough turnover to support an active pipeline of biotechnology-based innovations.<sup>5</sup> On the other hand, the diffusion of modern varieties – an indicator of the effectiveness of local crop improvement programs and of the potential for sustained germplasm turnover – has been steadily improving in many countries, indicating the potential for attracting investment into the commercial seed sector (Evenson and Gollin, 2001). Nevertheless, public policies are needed to address actions and instruments in relation to the development of the input industry, including investment promotion and other facilities for creating knowledge-based start-ups.

## High investment requirements and important potential spill-over effects

Biotechnology development is an expensive business. Even though there is increasing evidence that the costs of doing biotechnology research have been steadily decreasing, when compared to conventional agricultural research, biotechnology remains a much more expensive undertaking.<sup>6</sup> Traxler (2001) estimates that the total cost of placing a new GM product in the market, considering both the R&D and the regulatory process, are in the USD 1.5 – USD 4.5 million range for a “simple” trait, and between USD 5 and USD 15 million for a “complicated” trait. These estimates are confirmed by available data about the magnitude of R&D investment levels by some of the leading firms in this sector. For example, by 2004, Monsanto was expending around USD 540 million in agricultural biotechnology R&D, while Syngenta, Bayer and BASF were estimated to be devoting about USD 150 million each.<sup>7</sup> For most developing countries – with the exception of perhaps China, India and Brazil – the magnitude of the investment required represents a major limitation for the exploitation of this technology, especially if one considers the relatively long maturity time of required investments *vis-à-vis* the short term perspective and instability of investment trends in emerging economies.

However, the nature of the innovation process and the separation between the generation of the innovations and their applications to the agricultural environment is also an important source of opportunity. Institutions – or countries for that matter – do not necessarily need to have the capacity to innovate in order to reap the benefits of the new technologies. In fact, the biotechnology and the plant breeding research steps for GM crops grown commercially today have only occasionally taken place in the same institution, and even less frequently in the same country. Nearly all GM crops grown commercially anywhere in the world are the result of research

produced in the US, primarily by and based on biotechnology science performed by multinational companies.<sup>8</sup> In the case of Argentina, the second largest producer of GM crops in the world, herbicide tolerant soybeans and Bt and herbicide tolerant maize are based on genes imported from the United States and introduced into the local commercial germplasm base.<sup>9</sup> In the case of Bt cotton, the process is even more straightforward. This technology was developed by Monsanto for the United States, and then introduced into Mexico, South Africa and Argentina.

These dynamics raise an important consideration: the potential for developing countries to benefit from spill-over effects from technologies generated abroad. The spill-over potential is most relevant in downstream products, such as specific GM crops and varieties, because the complexity and cost of the required research declines (Pingaly and Traxler, 2001). As a result, for the time being, this potential is confined to a relatively small number of temperate and subtropical crops, though this may change as the pipeline of available innovations grows more diverse.

Moreover, there is no specific empirical evidence of spill-over effects regarding biotechnology programs. However, the magnitude of the estimated economic impact of the adoption of HT soybeans, calculated to be in excess of USD 1.5 billion per year in countries such as Argentina (Brooks, 2005), points toward high potential benefits.<sup>10</sup> Finally, spill-over effects can only take place if biotechnology innovations are in fact widely adopted across multiple national markets. However, the small size of many domestic markets makes it financially impracticable for biotech crops to be developed for them and some type of international cooperation would be required to achieve economies of scale.

## 2. Selected Policy Implications

Addressing these particular challenges and opportunities posed by agricultural biotechnology systems requires distinctive

policy approaches. Section III will consider and evaluate some of the regulatory systems already in place to respond to the distinctive

economic, environmental, and health impacts of GM technologies, crops and foods. Section IV will then present a comprehensive overview of the options, considerations, and potential trade-offs in biotechnology-related policy-making. The following paragraphs, however, will provide an initial consideration of some of the

policy implications resulting from the distinct nature of agricultural biotechnology, namely the development and application of the notion of “biosafety,” the evolving intellectual property protection of agricultural biotechnology, and the synergies and tensions in the link between trade and other relevant regulations.

***Biotechnology-Based Agricultural Technology Systems: Characteristics and Policy Implications***

CONVENTIONAL AGRICULTURAL TECHNOLOGY SYSTEMS	BIOTECHNOLOGY BASED AGRICULTURAL TECHNOLOGY SYSTEMS
<ul style="list-style-type: none"> <li>• Strong participation and leadership from public institutions as drivers of new technological concepts</li> <li>• Agronomic and applied science</li> <li>• Sector specific R&amp;D systems</li> <li>• Relatively low investment requirements</li> <li>• Predominance of bulk marketing logistical infrastructure, low product differentiation except for quality standards</li> <li style="text-align: center;">•••••</li> <li>• R&amp;D policy aims to guide agricultural development, establish priorities, and direct investments in public research institutes</li> <li>• Less need for regulatory measures</li> <li>• “Weak” intellectual property systems</li> <li>• Trade and technology not closely related issues</li> </ul>	<ul style="list-style-type: none"> <li>• Strong participation and leadership from the private sector in technology development</li> <li>• Technological applications closely linked to basic research</li> <li>• Horizontal R&amp;D systems</li> <li>• High investment requirements</li> <li>• Increasing demand for infrastructure allowing segregation and traceability systems</li> <li style="text-align: center;">•••••</li> <li>• R&amp;D policy mechanisms aimed at promoting inter-institutional collaboration, including public-private joint ventures</li> <li>• More need for regulatory measures, addressing, for example, biosafety and consumer protection.</li> <li>• “Strong” intellectual property protection systems</li> <li>• Technology and trade increasingly related</li> </ul>

### Biosafety

Since its very early stages of development, there have been both concern and controversy over the potential environmental and human health risks of biotechnology.<sup>11</sup> Similar concerns and debates typically affect major technological changes and innovations. Nonetheless, it is hard to think of a recent agricultural technological innovation that has prompted as much public anxiety and opposition. Much of this is linked to its perceived novelty, which in turn has made many citizens wary of its impacts. These concerns reflect a widely shared perception that agricultural biotechnology poses distinctive social, health and ecological risks that must be carefully managed. In this regard, the concept of “biosafety” refers to the safety aspects of the application of biotechnologies and

the release into the environment of GM plants and other organisms that could negatively affect plant genetic resources, plant, animal or human health, or the environment.<sup>12</sup>

One set of risks is associated with the safety of foods derived from biotechnology. Few biotechnology-based food products have to date been associated with negative impacts on public health. Nevertheless, some studies have documented negative effects in relation to consumption of GM foods, including in relation to the impact of the use of genes from allergenic crops, such as nuts, and to the particular impact of biotechnology on vulnerable populations, such as children.<sup>13</sup> These studies remain

controversial. Many consumers, however, do not accept the claim that such foods are substantially equivalent to those produced from conventional agricultural technologies. Rather, concerns that consumption of such foods may pose serious risks to human health continue in the absence of research into their long-term affects.

In some cases, these concerns reflect a lack of confidence in the capacity and competence of regulatory authorities to identify potential threats to public health. Even in those countries in which public confidence in government regulation is relatively high, there is substantial public support for labelling foods with GM content. In many cases, however, these demands primarily reflect a growing interest among many consumers in being able to choose foods on the basis of how they are produced. From this perspective, demands for GM labelling are similar to demands for the labelling of organic food, for example. Yet establishing the threshold of GM content for such labelling, as well as segregating food through the production and processing cycle, is complex and expensive. In addition, labelling requirements are often linked with efforts to restrict market access to GM technologies.<sup>14</sup>

Another dimension of biosafety concerns the impact of GM varieties on biodiversity. Concerns range from the contamination of traditionally grown crops by GM seeds, the possible spread of “killer weeds” and the impact of GM crops on wildlife. These concerns pose a much more complex challenge to regulators, as the environmental impact of GM seeds and crops can vary depending on the particular characteristics of the eco-system in which they are introduced. Thus a crop may be introduced without impairing biodiversity in one country, but may pose ecological problems when introduced into the fields of another.

There has been significant pressure for GM food and crops to be regulated by the same bodies and through the same statutes that have historically governed other foods and agricultural technologies. Public concerns about

both consumer safety and the environmental impact of agricultural production are long-standing. Virtually all governments thus already have food safety standards, as well as regulations governing the use of pesticides and new seed varieties. Animal husbandry practices are also regulated. For example, the United States adopted a product-based approach that does not distinguish biotechnology products *per se*. In practice, however, many governments have established distinctive institutions, rules and procedures for approving GM foods and crops. In the European Union (EU), for example, a process-based approach considers that additional regulatory steps are required to adequately assess the risk of GM crops. Policy approaches to biosafety thus vary broadly, ranging from highly precautionary regulatory systems, where every new biotechnology innovation is analyzed on a case by case basis, to “promotional” or open systems, where risk evaluations from other countries are fully accepted as part of the approval process.

The regulatory environment for GM foods is further complicated by two additional factors. One is a lack of scientific consensus as to their potential risks. It is still unclear what constitutes appropriate evidence of the health and environmental impacts of GM technologies, how any risks should be determined, assessed and measured, and who is responsible for such analysis. More broadly, to which extent and on what dimensions should GM foods and crops be assessed or regulated differently than those produced from conventional agriculture is still divisive. A second related factor has to do with the limited scientific capacity of many governments to undertake such assessments and determinations. In many cases, regulatory approvals have been stalemated by governments whose regulatory budgets and expertise are already strained, and thus do not have the capacity to assess – and thus approve or disapprove – GM technologies.

Because of these concerns and the controversy surrounding them, initiatives directed at minimizing possible environmental and health risks have evolved *pari pasu* with the development of

biotechnology tools and products as an integral part of the R&D and investment policies in the sector. Many countries – mostly OECD members, but also an increasing number of developing countries – have established biosafety regulations and risk evaluation mechanisms to accompany the product development process from the laboratory level, through the field and commercial scale trial levels, and, eventually, to monitor the performance of the new organisms in order to assure their safety for human and animal consumption.

But such biosafety regulations are, by nature, complex and lengthy, representing probably the single most time-consuming and costly step for the introduction of new plant varieties and the products derived from them. A substantial amount of information is required by many national regulatory bodies as part

#### Intellectual property protection

Intellectual property rights are one of the primary tools used to promote research and development in agricultural biotechnology.<sup>16</sup> Given the high investment required to develop new GM technologies and products, it has successfully been argued that stronger intellectual property protection is necessary to stimulate research and to allow recovery of investment. As international rules increasingly raise the level of intellectual property protection, however, there is rising concern about the potential negative impacts on the dissemination of knowledge and important products, further R&D, food security, and the conservation of biodiversity, among other fundamental areas of public policy. Determining the appropriate application of such rules for agricultural biotechnology is thus an important policy challenge.

Patents and plant variety certificates are the main types of intellectual property rights used in agricultural biotechnology. At the international level, the minimum standards of intellectual property protection are established by the Agreement on Trade-related Intellectual Property Rights (TRIPS Agreement). The TRIPS Agreement thus determines the cases in which patents must

of the risk evaluation process. In addition, in many regulatory systems governments retain a relatively high level of political discretion regarding final regulatory approval, increasing the uncertainty of the approval processes, and thus adding to the costs of product development.

These regulatory barriers are of particular importance for smaller countries as they impinge on their ability to attract external R&D and capture spill-in benefits. These regulations can also discriminate against national public research institutions and national firms by limiting their ability to become actively involved in product development. As such, public institutions and firms typically have fewer financial resources than the large multinational corporations, and it is more difficult for them to bear the additional costs involved.<sup>15</sup>

be granted, obliging countries to grant patents for all fields of technology, including biotechnology. However, the TRIPS Agreement provision also allows countries some flexibility, allowing them, for example, to establish exceptions to patentability, including on plants and animals other than micro-organisms.

The scope of patentability, therefore, impacts both the safeguarding of the investment and the access that others will have to the invention. Indeed, because many developing countries do use these exceptions and also have problems with enforcing existing patents, many foreign investors feel they lack assurance that their property rights in GM technologies will be adequately protected. On the other hand, high levels of patent protection may result in food security, biodiversity, and socio-economic problems. For example, there is considerable debate about the actual impact of patent protection on innovation and diffusion in agricultural biotechnology. The patenting of many GM crops innovations by private companies and universities – particularly when a particular innovation is covered by multiple patents – creates so-called “patent thickets” and veritable legal gridlocks for further

research (Yamin, 2003). In this regard, patent protection mechanisms are not a new issue with respect to agricultural research, but now proprietary claims are not only increasing but are rapidly enveloping research tools. As many developing countries focus their R&D on marginal innovations and minor improvements in existing technologies, their efforts may be blocked by strong patent protection.

In addition, more extensive patent protection is also considered problematic for achieving the objectives of other international agreements, particularly the 1992 Convention on Biodiversity (CBD). The CBD recognized the sovereign right of States over their natural resources, including genetic resources. Access to such resources thus can only take place on the basis of prior informed consent and mutually agreed terms. In addition, there are provisions on the need for prior consent and sharing of benefits for indigenous and other local communities that have historically safeguarded the resources. The negative impact of patents, as private rights, granted over genetic resources is thus a cause of alarm for many biodiversity-rich countries.

Similar concerns arise in relation to increased levels of plant variety protection. As mentioned, the TRIPS Agreement does not require countries to grant patents for plants and animals or for essentially biological processes for their production. However, it does oblige countries to provide for some type of intellectual property protection, either by patents or by an effective

*sui generis* system or by any combination thereof. The most widely used *sui generis* system for plant variety protection is the International Convention for the Protection of New Varieties of Plants (UPOV Convention). Even though plant variety protection developed separately from patent protection and is considered to be more appropriate for the particular nature and characteristics of agricultural innovation, higher levels of protection have raised similar concerns as those in the patent field. Revisions to the UPOV Convention, for example, have generally served to progressively strengthen plant breeders' rights.

Intellectual property issues go beyond the scope and levels of protection. Other relevant issues include enforcement capacities, which are critical to managing the regulation of and trade in GM crop varieties. In addition, the "privatization of science" brings a new management challenge for research institutions, particularly in developing countries, as many are not well equipped to deal with proprietary knowledge. The lack of negotiating skills and the administrative and bureaucratic limitations of research institutions impact their ability to acquire, negotiate, and protect intellectual property rights, and often represent tangible barriers for accessing certain strategic technologies. Moreover, intellectual property policies are also necessarily linked to broader economic policies, such as the creation of the appropriate environment for direct foreign investment and greater participation by foreign firm in domestic markets.

#### Multiple and evolving regulatory frameworks at the international level

There are a number of relevant, and not always coherent, international provisions governing trade and agricultural biotechnology. The two most important set of international rules include those established in the context of the World Trade Organization (WTO) and those established by the Cartagena Protocol on Biosafety (Biosafety Protocol). Although WTO rules do not explicitly address biotechnology, several WTO agreements are applicable to trade in the field: the General Agreement on Tariffs and Trade (GATT), which establishes the basic principles and rules for

trade in goods; the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), which deals with food safety and animal and plant health regulations; and the Agreement on Technical Barriers to Trade (TBT), which addresses technical regulations and standards, including packaging and labelling requirements.

Of these WTO agreements, it is the SPS Agreement that is considered to be the one with the most significance for trade in agricultural biotechnology.



The purpose of the SPS Agreement is to promote international trade by limiting the use of SPS measures as disguised barriers to trade. To do this, the SPS Agreement encourages the use of internationally recognized SPS standards, deeming any measures based on these standards to be in compliance with WTO provisions. However, countries retain the right to adopt different or more stringent standards, as long as their measures are based on “scientific principles” and scientifically justified.<sup>17</sup> The SPS Agreement does incorporate a limited version of the precautionary principle, allowing countries to take measures in cases of insufficient scientific evidence, as long as such measures are temporary and procedures are in place for a review. These provisions were at the core of the recent *EC-Biotech* case, in which the United States and other countries challenged the application of the EU regulations on approval of biotechnology products.

The impact of the SPS Agreement on biosafety regulations that may restrict trade can be problematic in a number of respects. Most obviously, there are no internationally agreed standards for the safety of GM foods and crops; hence no global benchmark that could provide a framework to guide national regulations as well as to measure a country’s deviation from them. More importantly, the SPS Agreement assumes a rough scientific consensus, or at least the possibility of arriving at such a consensus, as to what SPS measures are in fact necessary to protect consumer and animal health and domestic plants. But no such consensus currently exists in the case of many GM technologies.

For its part, the precautionary provision in the SPS Agreement raises as many questions. How long can a nation impose restrictions on imports of GM crops and seeds while it is gathering additional information? How much additional information is required before a nation must come to a decision regarding an appropriate standard? In fact, much of the dispute both within countries and among them regarding the safety of GM foods and crops is attributed precisely to disagreements regarding the adequacy of our current knowledge or understanding of the risks associated with them.

Complicating international trade in GM products and seeds still further is that they are also governed by an international agreement that specifically applies to them. This is the Biosafety Protocol, which became effective in September, 2003. The Protocol is a binding international agreement linked to the Convention on Biological Diversity (CBD). Its objective is to provide a set of globally acceptable rules to address the potential environmental risks associated with international trade in living modified organisms (LMOs). Formally, it regulates “the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.”<sup>18</sup>

To implement its objectives, the Biosafety Protocol establishes two primary procedures. The first procedure governs the intentional introduction of LMOs into the environment. Under these provisions, the exporters of a GM crop must provide the importing country with detailed information about its GM content or ingredients. The importing country can then undertake a risk assessment if it believes that there are potential risks regarding their importation. It is only required to permit importation after it has put into place adequate domestic laws and regulations. The second procedure governs foods or crops that will be consumed by humans or animals. In these cases, the safety standards of the exporting country must be communicated to the importing country. In addition, the Biosafety Protocol contains labelling requirements.

The nature of the relationship between the Biosafety Protocol and WTO agreements relevant to agricultural biotechnology is ambiguous. The preambular language to the protocol suggests that the Protocol is not subordinate to existing agreements, but also that it should be interpreted in a way that is consistent with existing obligations. In other words, the Biosafety Protocol is intended to supplement the WTO and the various agreements under it, not to supplant them.

At the same time, the Biosafety Protocol is clearly much more restrictive than the SPS Agreement. Under the Protocol, every signatory country is committed to undertake the needed actions to ensure the safe use of biotechnological innovations, especially when movement across international boundaries is involved. While the SPS Agreement explicitly limits the application of the precautionary approach – permitting its use only as a temporary measure – the Biosafety Protocol is more embracing of it. It specifically establishes the precautionary principle as a general guideline. The preamble to the Biosafety Protocol states that “when there is a threat of significant reduction or loss of biological biodiversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat.” In addition, importing Parties are permitted to impose restrictions on the basis of the *potential* harm of GMOs, rather than, as under the provisions of the SPS Agreement, evidence of *demonstrated* harm. Moreover, as noted above, the Protocol requires “advance informed agreement” from the recipient country when shipments involve living organisms intended for release into the environment and the provision of a “may contain” label for all commodities where GMOs may be involved. Both such provisions are lacking in the SPS Agreement, though in practice SPS provisions do permit labelling requirements under specific circumstances.

The differences between the SPS Agreement and the Biosafety Protocol clearly pose a challenge for international governance of transboundary movement of GM products, as well as national policies and regulations responding to these international obligations. At the same time, while the Biosafety Protocol has played an important role in strengthening the regulatory policies regarding GMOs, it leaves unanswered a number of critical questions. One of the concerns regards labelling provisions. Labelling is optional under the Biosafety Protocol, and the terms for its use are not specified. Accordingly, countries vary substantially in the specific threshold required before a labelling requirement is triggered, as well as the range of products for which a label is required. At the

same time, a number of different studies report that the market for foods subject to traceability systems is expected to grow – a trend that will also affect the policy environment for labelling and other biotechnology-related regulations.<sup>19</sup>

Another important yet unresolved issue is the level of safety that must be satisfied before an import containing GMOs is approved. Should countries be allowed to demand a higher scientific risk threshold for GM foods than for conventional ones? What consideration should a risk assessment place on the benefits of GM foods and crops? Finally, the Biosafety Protocol permits countries to take socioeconomic considerations into account in assessing the potential impact of LMOs on biodiversity, traditional crops, local cultures, community practices, food security, ethics religion, community benefits, and rural employment. In theory, these clearly give countries wide latitude to exclude GM imports, going far beyond the terms of the SPS Agreement, which confines the basis for legitimate restrictions on agricultural-related imports to demonstrated health and safety risks.

The diversity of regulatory requirements permitted by the Biosafety Protocol has had important commercial impacts. For example, US corn exports to the EU have been steadily falling since 1995, mostly due to differences in their regulatory approaches, as non-authorized crops cannot be introduced in the EU market. More importantly, EU restrictions have had an important chilling effect on adoption of GM crops by countries that export agricultural crops to the EU. One example occurred in Argentina, where the GMO approval process was designed to include a “market analysis” stage, so to avoid possible commercial conflicts with the EU, a major importer of Argentinean agricultural products. The result was a de facto moratorium for new GM varieties, between 2001 and 2004.<sup>20</sup> In practice, these kind of “cross effects” have had, in the case of Argentina, a significant impact of the competitiveness of the different crops, i.e. maize – a crop affected by the European moratorium, and with restricted access to EU markets of soybeans – approved for commercialization in Europe before the moratoria (Trigo, 2005).

The same kind of effects can be observed in other countries which have responded to EU restrictions by concentrating on R&D investments and crop adoptions towards crops with lesser potential trade conflicts, such as flowers, ornamentals, or cotton, rather than food crops. Significantly, the products produced by non-food crops need not be labelled, as they are generally not consumed by humans or animals, which – in turn – has

significantly reduced consumer opposition to their consumption. The selective approval of various GM varieties, along with labelling requirements, are introducing a new scenario for agricultural international markets, as they are making relevant for the first time, the technology used to produce particular agricultural products - an aspect that was formally considered much less important in defining market access.

### ***Key Points on the Characteristics of Agricultural Biotechnology and their Policy Implications***

- The potential of agricultural biotechnology should be assessed within the context of an overall agricultural research and technology development effort and not as a separate strategy.
- In terms of the required scientific research capacities, universities and nonagricultural advanced research centers are as important as the traditional agricultural research institutions.
- The large size of the needed investments for biotechnology development, emerging both from complexities of the science and the biosafety assurance processes involved, set the basis for significant economies of scale vis-à-vis the size of potential markets and the need for innovative strategies for accessing the new technologies, particularly in smaller countries.
- The private sector plays a central role in the development of biotechnology. Public-private interaction and the creation of new knowledge based enterprises are essential to any successful policy strategy.
- Plant breeding and the capacity to deliver seeds to farmers, which are essential components for success in conventional systems, require both substantial public sector investment support as well as private sector investment in seed development systems.
- Trade issues represent serious challenges to the international adoption of GM technologies. In particular, the capacity to segregate and differentiate products for different markets will be of increasing importance as the technology cycle evolves. These, in turn, will require important changes in the institutional and physical infrastructure supporting agricultural product and input markets.
- Biosafety and intellectual property are increasingly important elements of a countries' innovation and regulation system. The manner in which relevant provisions are established and implemented directly affect the environment for technology development and utilization.

### III. NATIONAL CASE STUDIES

This section explores the various policy dimensions of GM agricultural biotechnology in more detail, by presenting a series of national case-studies of how various governments have addressed the promotional and regulatory dimensions of GMOs. It examines both the wide range of public policies that have affected all aspects of GMOs – including the protection of intellectual property rights, research and development policies and capacities, biosafety regulations, and labelling requirements – as well as the political and economic factors that have shaped and informed these policy decisions. The latter include international treaties and agreements, the position of a nation's agricultural sector within the global economy, domestic political attitudes regarding the cultivation and consumption of GMOs, the participation and influence of non-

#### 1. Developed Countries

##### United States

In the United States, biotechnology products are not treated – for regulatory purposes – any differently than similar products that did not involve gene manipulation. The United States was the first country to approve and adopt GM agricultural biotechnology, and there has been relatively little public opposition of their introduction and consumption. In general, the introduction of agricultural biotechnology in the US has benefited from a sustained period in which health, safety and environmental “crises” have been largely absent, and in which political support for more extensive health, safety and environmental regulation has been relatively weak. Although public opinion surveys do report less than uniform public enthusiasm for agricultural genetic engineering, and some concerns – for example regarding negative ecological impacts – surface periodically, none of these considerations have ever been such to result in significant changes in regulatory policies.

Since biotechnology was framed as just another industrial process, lacking any special attributes or consequences, existing regulatory laws aimed

business constituencies in the policy process, policies regarding foreign investment and domestic institutional, technological, regulatory and enforcement capacities.

The country case-studies are divided into two categories:

- Developed countries, focusing on the United States, the EU, Japan, Korea, China Taipei, and Australia, and
- Developing countries. In turn, within developing countries, there are two subcategories - countries with well developed agricultural sectors, such as India, South Africa, China, Mexico, Argentina, and Mexico; and those with poorly developed agricultural sectors, namely Kenya.

at controlling specific classes of biotechnology products were considered sufficient to control any new risks associated with it.<sup>21</sup> American biotechnology policy thus remains rooted in the recommendations of the Office of Science and Technology, which issued a 1986 report entitled, “Coordinated Framework for the Regulation of Biotechnology.” This framework identified three agencies that already had legal jurisdiction over various aspects of this new technology, namely the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the U.S. Department of Agriculture (USDA). A Biotechnology Science Coordinating Committee was established to develop a common inter-agency approach on regulatory policies, and each agency established an institutional mechanism to implement those policies that fell within its jurisdiction. Thus the FDA was responsible for approving foods and animal drugs, the USDA for new crops and animals and EPA for environmental impacts.

This decision had important political implications. Because neither new laws, nor new regulations, nor a new agency was deemed necessary, the

opportunity for political or public participation in shaping biotech regulatory policies was reduced. In addition, because food products derived from biotechnology were not judged to affect the health of consumers any differently than products derived from conventional agricultural processes, the US government did not require such foods to be labelled. The lack of labelling, in turn, significantly reduced public awareness of the fact that a substantial and growing share of the processed food consumed by Americans contains biotechnology ingredients.<sup>22</sup>

There has been one notable regulatory policy failure – in 2000, a corn product approved for animal consumption found its way into the food supply. However, this problem was addressed by a modest policy change: uniform approval procedures were established for both product categories. In addition, the FDA subsequently strengthened its approval process for biotechnology foods. But the absence of any evidence of negative health effects from the consumption of such foods –including in the case of the policy failure noted above – has significantly diminished both public awareness of GM products as well as public pressures to regulate them more stringently.

Consequently, the United States grows and consumes more biotechnology derived agricultural products than any other country – and with much less domestic controversy. It also remains the only developed country with no labelling requirements. At the same time, policy developments outside the US have affected some American policies, most notably in narrowing the

#### European Union

Unlike the United States, the EU has created distinctive regulatory processes and procedures for GMOs. Initially, the EU viewed agricultural biotechnology as a promising new area of scientific R&D, and sponsored several major projects in agricultural biotechnology. However, mounting public opposition to agricultural biotechnology has been decisive in the development of relevant policies and regulations.<sup>24</sup> A number of factors altered public attitudes towards GMOs, including

definition of “substantial equivalence” in the FDA approval process of some bioengineered foods. While US public policies have not been affected by the Biosafety Protocol, which it has not signed, US private practices has been impacted by the adoption of more stringent regulatory policies in its trading partners. For example, Monsanto withdrew its application for genetically modified wheat due to resistance by export markets, American agricultural exports to the EU have been reduced, and many agricultural processors have been required to segregate GM and non-GM crops for export.

In terms of intellectual property, the United States provides high levels of protection for biotechnology. In 1980, in *Diamond v. Chakrabarty*, the U.S. Supreme Court ruled that a live, human-made micro-organism is patentable subject matter, thus extending patent protection to GM products. Patent protection extends to plant varieties. Such intellectual property protection is considered to have further promoted private investment in agricultural and other biotechnology. Research in agricultural biotechnology has thus primarily taken place through the private sector, since companies which invested in these new methods of agricultural production could be assured that they would be able to commercialize and thus reap the financial benefits of their research and development. By 2000, the US Patent Office had issued patents for more than 6,000 separate genes. The extremely strong protection of intellectual property for biotechnology is considered to have played a critical role in the lead that American firms have developed in this sector.<sup>23</sup>

an effective public campaign mounted by anti-GMOs non-governmental organizations such as Greenpeace, highly visible regulatory policy failures associated with mad-cow disease, and public uneasiness with the capacity of EU institutions to adequately protect public health and environmental quality. In addition, public opposition to the introduction of GM products were fuelled by widespread public uneasiness about technological innovation in agriculture

– and its threat to traditional agricultural practices and “natural” foods – and hostility to the American industrial influence over European food production that the introduction of GMOs came to symbolize.

Relevant regulations, first issued in 1990 and subsequently in 2001 and 2003, thus established specific procedures for approval of biotechnology products, taking into account both food safety and environmental release. These regulations are, moreover, considered highly restrictive.<sup>25</sup> The 2001 directive governing environmental release, for example, requires all new GM products – commercial crops as well as research plots – to undergo a detailed environmental impact assessment.<sup>26</sup>

The EU's labelling requirements are the strictest in the world. They are process-based, rather than based on whether the genetically modified DNA is present in the product itself. They combine a very low threshold – 0.9 percent and possibly as low as 0.1 percent in cases where the presence of GM content is known in advance – and require traceability from “the farm to the fork.” The impact of these labelling requirements, which were established as part of a comprehensive political agreement to facilitate the introduction of GM products into the food supply, have had to date precisely the opposite effect: they have generally encouraged retailers and food producers to avoid selling or incorporating GM ingredients in their products, lest they are required to be labelled.

The EU experience suggests the important role of relatively stringent labelling requirements in preventing the introduction of GM varieties in the food supply, especially for a population that prefers not to consume them. In turn, stringent EU labelling requirements have contributed to the unwillingness of European farmers to plant the several GM varieties that have been approved, since they fear there will be no domestic market for them. Perhaps more importantly, the EU's labelling requirements, combined with the limited number of GM technologies it has approved for importation and domestic use, has had an important chilling effect on its trading partners, discouraging many of them from adopting GM technologies out of concern that the access of their exports to the EU will be restricted.

The EU now has a set of complex regulatory mechanisms in place to address public concerns. These regulatory mechanisms have had a positive impact in this regard – survey data report more public support for biotechnology applications in a number of countries. However, opposition remains strong – even recently increasing – in several others. In any event, the most important barrier to the adoption of GM crops and their introduction into the food supply is now not the policy process, which does enable several GM crops to be planted and several products derived from GM varieties to be sold – but consumer acceptance. Changes in the latter are likely to occur gradually, and may well require the introduction of GM varieties that provide health benefits to consumers, which has yet to occur.

#### Box 2. Applications of Biotechnology in the EU 1996-2002

	1996	1999	2002	CHANGE 1996-1999
Belgium	72	47	56	-25
Denmark	43	35	45	-8
Germany	56	49	48	-7
Greece	49	19	24	-30
Italy	61	49	40	-12
Spain	80	70	74	-10
France	54	35	30	-19
Ireland	73	56	70	-17
Luxembourg	56	30	35	-26
Netherlands	78	75	65	-3
Portugal	72	55	68	-17

	1996	1999	2002	CHANGE 1996-1999
UK	67	47	63	-20
Finland	77	69	70	-8
Sweden	42	41	58	-1
Austria	31	30	47	-1
EU 15 Average (Weighted with population)	62	49	51	-13

Source: Tiberghien, Yves and Sean Starrs (2003). *Focus on GM Food (only % of decided public, adding supporters and risk tolerant supporters)*.

The EU was a strong supporter of the Biosafety Protocol, playing a critical role in incorporating many of the precautionary language in the final documents. Its ratification of the Biosafety Protocol, however, has not affected its own regulatory policies, which are generally more stringent and many of which predate it. The Biosafety Protocol has, however, provided the EU with an important basis for the international legitimacy of its own policies and, as noted below, has contributed to more stringent standards in a number of signatories.

Intellectual property protection for biotechnological inventions has proved controversial in the EU. A ten-year debate led to the adoption on 6 July 1998 of EU Directive 98/44/EC on the legal protection of biotechnological inventions, known as the “Biotech Patent Directive”. Its purpose is to clarify the distinction between what is patentable and what is not. For instance, an invention relating to individual human, animal or plant genes and gene sequences, and their functions, can be patented as long as the other patentability criteria are fulfilled. However, the directive rules out the patenting of an entire

human body in the individual phases of its creation and development. The same applies to applications for procedures designed to allow human cloning, human germ line engineering or the use of embryos for industrial or commercial purposes.

The essence of Directive 98/44/EC was incorporated into the Implementing Regulations to the European Patent Convention (EPC). This part of European patent law now provides the ground rules for considering the patentability of biotechnology applications – alongside the principal criteria valid for all patents. Articles 52 and 53(b) EPC say what can and what cannot be patented. Biotechnical inventions are basically patentable, but with the following exceptions: methods for treatment of the human or animal body by surgery or therapy, and diagnostic methods practiced on the human or animal body; plant and animal varieties; and essentially biological processes for the production of plants and animals. Article 53(a) also prohibits the patenting of any invention whose commercial exploitation would be contrary to public order or morality.

## Japan

In Japan, the initial policy response to GM varieties was also highly supportive. As in the United States, Japan originally made no effort to regulate GM varieties any differently than any other agricultural process or product. However, as in Europe, the political environment changed dramatically toward the end of the 1990s. This change was spearheaded by NGOs, specifically consumer organizations with large local followings, who – unable to affect national

governmental policies at first – focused on local governments. Many of the latter acted to prevent both the testing and planting of GM crops. Surveys report that the majority of consumers still have concerns about consuming GM foods.

Faced with declining public confidence in its relatively permissive regulatory procedures – fuelled, as in Europe, by a domestic BSE crisis – the Japanese government responded by enacting

a series of more stringent regulations governing food safety as well as environmental approvals for biotechnology products. Under these laws, several GM crops have been authorized for sale. However, largely due to local opposition, none are grown in Japan.

Japanese legislation enacted in 2000 also requires the labelling of GMOs sold in Japan. This legislation, however, has significant loopholes. Only 31 varieties of food are covered, and some processed foods are excluded. The threshold for labelling is the use of at least 3 percent of GM crops, and GMOs have to be among the three largest components of a food product. Many important products do not require labelling — most notably GM soy used as cooking oil or for animal feed.

As in Europe, the establishment of labelling requirements has resulted in the absence of GM labelled products from supermarket shelves. Nevertheless, because its labelling requirements are relatively permissive, and 67 crops have already been approved for safe consumption, Japan continues to import substantial amounts of products produced from GM seeds. Significantly, more than four-fifths of Japanese soy imports are grown from genetically modified crops. Overall, Japan is by far the world's biggest importer of GM foods.

#### Korea

The pattern of consumer safety and environmental regulation of GMOs in Korea parallels that of Japan. The opposition of consumer groups and farmers concerned both about food safety and the environmental impact of agricultural biotechnology during the late 1990s led to a significant tightening of regulatory requirements in 2001. Korea now has specific approval requirements for all bio-engineered products, which include consumer safety standards and mandatory environmental impact assessments. Like Japan, Korea has not approved a single GM crop for cultivation and none are now being grown. However, a total of 36 GM products have completed safety assessments by the Korean Food and Drug Administration and can be imported.

Following its ratification of the Biosafety Protocol in 2003, Japan enacted a far reaching new domestic regulatory law which significantly tightened rules for GM testing and planting, requiring a more thorough environmental impact study. Under this legislation, the Ministry of the Environment not only reviews the overall impact of GMOs on the environment, but also the risk of contamination to individual wild plants in Japan.

Patent law is well-developed in Japan. As in the United States, patentable subject matter includes proteins, genes, cells, plants and plant varieties as well as animals and animal varieties. At the same time, Japan also has significant carve-outs which provide the government with the authority to withhold a patent for an invention that is deemed to breach public order, morality or human health. The Japanese government is actively involved in sponsoring research in biotechnology, including agriculture biotechnology. The total annual budget for biotechnology research is about USD 5 billion.<sup>27</sup> The bulk goes to financing university research and government-sponsored research centres. The global OECD database on patents shows that the share of global biotech patents held by Japan in 2000 was 11.3 percent (OECD, 2004). However, Japanese biotechnology is limited by a lack of integration between academic and private research, a lack of venture capital and bureaucratic rigidities.

As in the EU and Japan, public opinion surveys report widespread public anxiety about the safety of GMs and their impact on the eco-system, as well as strong support for mandatory labelling. In response to these concerns, Korea adopted relatively stringent labelling requirements in 2001. Due to trade friction with the United States, however, these requirements were eased a year later. As in the case of Japan, an important factor motivating Korea's move towards a relatively permissive labelling policy is its significant dependence on imported food. As a result of its lax policies on GM labelling, Korea continues to import large amounts of GM derived products, primarily soy and corn from the United States. It is estimated that about 10 percent of total food imports are GM.<sup>28</sup>



Korea was an early signatory of the Biosafety Protocol. However, it has not ratified the instrument, partly due to its inability to complete environmental impacts for all imported products. It has, however, supported policies related to the Biosafety Protocol – including labelling requirements – in international fora.

In terms of intellectual property protection, Korea has amended its patent law to cover microorganisms and microbiological processes, as required by the TRIPS Agreement. In Korea, patentable subject matter includes proteins, genes, and cells. Plant varieties are not patentable, though asexually reproduced plants can be. Animals and animal varieties are patentable. Like Japan, Korea has a large scope for patent carve-outs, encompassing public order, morality, and human health. The

#### Australia

In Australia, the regulatory and policy framework reflects a complex political picture. Although the country has a strong biotechnology agricultural lobby, there is also substantial opposition to the commercial application of GM technologies. This has been led by important segments of the agricultural community,<sup>31</sup> NGOs such as Greenpeace, and the Green Party, which is influential in a number of regional governments. Australia's federal structure has created political space for this opposition: all but one state have placed bans or moratoriums on GMOs, the effect of which has been to halt the planting of GM canola, notwithstanding federal approval.<sup>32</sup>

Nevertheless, polls show that the number of people reported willing to eat GM foods has steadily increased moving from 28 percent in 1999 to 48 percent in 2001.<sup>33</sup> At the same time, there is widespread public support for GM cotton on the grounds that it has produced substantial environmental benefits, as well as general public support for agricultural biotechnology, especially if it can produce consumer benefits, such as better nutrition.

Public policy closely reflects these somewhat paradoxical attitudes. Mandatory labelling

biotechnology industry has criticized what it perceives as a weak implementation and enforcement of intellectual property rules. Notwithstanding, the Korean government has been active in fostering research in agriculture biotechnology. In 2005, the Ministry of Agriculture and Forestry invested about USD 80 million in the development of new biotech crops.<sup>29</sup> The National Institute of Agricultural Biotechnology (NIAB) under the Rural Development Administration (RDA) is currently developing 44 GMO products among 15 crops (USDA, 2005a). These include herbicide resistant rice, virus resistant potatoes, insecticide resistant crops, anti-aging, anti-high blood pressure crops and Vitamin E enhanced plants.<sup>30</sup> However, the global OECD database on patents shows that the share of global biotech patents held by Korea in 2000 was only 0.9 percent (OECD, 2004).

of GM crops was established in 2000. These requirements are less demanding than those of the EU, but more stringent than those of Japan. Regulations require the labelling of all food and ingredients if they contain DNA or novel protein in the final food or if they have altered characteristics, with a demanding 1 percent threshold.<sup>34</sup> However, as in the case of Japan, a number of products are exempted from labelling, including restaurant food, oil sugars, processing aids, and additives.<sup>35</sup>

The growing acceptance of GM food in Australia reflects a relatively high degree of public confidence in the regulatory institutions governing GMOs, which are characterized by extensive public consultation. The 2000 Gene Technology Act requires safety approvals for all GM organisms or food derived from GMs. The regulatory body responsible for these approvals is in turn advised by three committees. One is a body of scientific experts who undertake risk assessments, the second consists of a group of ethicists who review ethical and moral issues and the third, larger committee is comprised of consumer representatives, environmentalists and concerned NGOs.

Australia, like the US and other major agricultural exporters, has not ratified the Cartagena Protocol, stating that it does not regard its requirements as necessary to protect domestic public health or biodiversity.

In terms of intellectual property protection, Australia has fully implemented the requirements of the TRIPS agreement and Australian patent law is far-reaching. As in the United States, patentable subject matter includes proteins, genes, and cells, to plants (and plant varieties and plant breeder rights), as well as to animals (Gold, 2001). The Australian government has also strongly supported the development of GM

technology and has committed significant funds to it. The multi-department Biotechnology Australia agency is well funded and active. It is responsible for the government's National Biotechnology Strategy. The objective of this strategy is to foster biotechnology for the benefit of Australian industry and farming, consistent with careful attention to human health and environmental protection (USDA, 2005d). The size of the Australian biotech industry, however, remains small and the percentage of world biotech patents owned by Australia stood at a mere 1.3 percent in 2003 (vs. 45 percent for the US and 11 percent for Japan) (OECD, 2004).

## 2. Developing Countries

### Mexico

Like Australia, Mexico is both a major agricultural producer and large food importer. Policies toward the introduction of GM crops are thus highly polarized, with the federal government seeking to promote agricultural commercialization, but with substantial public concern over the impact of biotechnology on traditional agriculture. Such concern was reflected, for example, in a recent and highly visible controversy surrounding transgenic maize, a crop which is at the heart of the national diet and which has significant cultural and social significance. In 2001, in spite of a ban on the cultivation of GM crops, a transgenic ingression from imported GM maize from the United States into indigenous maize varieties was reported.<sup>36</sup> As a result of the controversy, legislation has been drafted that establishes safeguards on the experimental planting of GMOs, and seeks to protect native maize varieties. Nevertheless, various environmental groups and farm organizations have called for the government to ban the importation of GM corn (maize).

The first Mexican law governing transgenic crops was a set of standards adopted in 1995. The regulation only established procedures for field testing, ignoring large-scale planting and cultivation. However, it was interpreted and applied more broadly. It was under this legislation that the large-scale planting and

commercialization of BT cotton was assessed, and later approved.

In 2003, Mexico approved a more comprehensive biosafety law that seeks to promote biotechnology while at the same time regulating its safe use. Its provisions permitted the limited release of GM crops, and required GM seeds to be declared risk-free before they are released for human consumption or planting. While criticized for emphasizing promotion at the expense of risk avoidance, the legislation did provide the Ministry of the Environment, which had adopted a more cautious approach toward biotechnology, an equal role alongside the Department of Agriculture in approving transgenic crops for deliberate release.<sup>37</sup> The 2003 legislation has already been criticized, however, for not requiring advance informed consent prior to the imports of certain GMOs, and for not adopting a precautionary approach to testing and large-scale releases, both of which are required by the Biosafety Protocol, which Mexico has ratified. The effective impact of this legislation on public confidence in the Mexican regulatory process as well as on the future rate of adoption of agricultural biotechnology remains unclear.

In this legislation, as well as the Mexican Health Act, requirements are also established for GM

products to be labelled for consumer information. These labels are intended to be clear, objective, truthful, understandable and useful for consumers. It is however unclear if these requirements are being effectively implemented. To date, the possible negative health impacts of consumption of biotech foods have not been politically salient in Mexico. Rather, public concern has largely focused on their environmental/cultural impacts on Mexican agriculture.

Despite the perceived shortcomings of the 2003 biosafety legislation, the Biosafety Protocol has had an impact on domestic policy. It prompted Mexico to join eleven other countries in participating in a Global Environmental Facility on national biotechnology frameworks, though again the related policy impact remains uncertain. The Biosafety Protocol further strengthened Mexican regulatory policies on biosafety by prompting the signing of an agreement with its NAFTA partners that implemented the Protocol's requirements that bulk commodity shipments state whether

they "may contain" transgenic varieties.<sup>38</sup> Thus, the Biosafety Protocol has been useful in providing additional justification and legitimacy to those segments of Mexican society, and policy-makers who favour a more cautionary approach to GMs.

Mexico's intellectual property system was designed in accordance with the TRIPS Agreement, the North American Free Trade Agreement (NAFTA), and the 1978 UPOV Convention. Its current patent law dates to 1991, with amendments made in 1994. The amendments allowed patenting of microorganisms, GM plants and animals, and other biological and genetic material, as long as other patentability criteria are met. Mexico's patent law does not grant protection to: essentially biological processes for the production, reproduction, and propagation of plants and animals; animal breeds; the human body and its living parts; and plant varieties. The latter are protected by the Plant Variety legislation of 1996, based on the UPOV Convention.

## China

Genetic engineering has been a critical component of Chinese agricultural policy since the mid-1980s.<sup>39</sup> Initial GMO regulations thus concentrated on a narrow range of scientifically demonstrated risks from genetic engineering. The Ministry of Science of Technology (MOST), which was then the lead agency in the field of biotechnology, established the first Chinese biosafety rules in 1993. The Ministry of Agriculture (MOA) then provided more detailed safety guidelines in 1996. The MOA has since become the lead agency in the regulatory process. Given its close links with the agricultural and biotech sectors, MOA is widely regarded as sympathetic to the commercialization of GM crops.

A shift towards greater caution occurred during the late 1990s, at a time when the international biosafety debate reached its climax. In 1999, China introduced a *de facto* moratorium on new GMO releases, effectively acknowledging shortcomings in the existing regulatory framework. New regulations were created that were more in line with the emerging international system of

biosafety governance. The revised regulations of 2001 and 2002 then provided greater attention to the potential risks and long-term threats to biodiversity and health derived from agricultural biotechnology.

With the adoption of a new national seed law in 2000, the final regulatory authority passed to the State Council, a central decision-making body at cabinet-level, while MOA continued to be in charge of risk assessment and management. This reorganization produced a more centralized system of GM regulation, thus acknowledging the greater political significance of biotech-related decisions.<sup>40</sup> The State Council issued a Regulation on Safety Administration of Agricultural GMOs in 2001, followed in 2002 by three implementing regulations issued by MOA, covering the areas of biosafety evaluation, import safety administration and GM food labelling.<sup>41</sup> These new acts provided a more comprehensive system of risk management, for the first time covering imported GMOs and providing consumers with some degree of choice through labelling. They also signified a

shift away from the previous product-based risk assessment of GMOs, as favoured by the United States, towards a more process-based approach, as practiced in the EU.

The move towards a more comprehensive and precautionary approach to biotechnology regulation has been heavily contested within China's policy elite — formed by government, scientific, and business representatives. On one hand, importer interests — mainly in the South — fear that the new emphasis on biosafety will slow down the future adoption of GM crops and impede agricultural trade liberalisation. On the other hand, agricultural exporters — mainly in the North — who sell to markets with GMO import restrictions consider stricter biosafety rules necessary to retain export markets. As in some other developing countries, the balance between exporter and importer interests has thus become a critical factor in the evolution of China's biotechnology policy. Given China's growing dependence on farm imports, it is possible that the pendulum will swing back in favour of regulations that do not restrict imports.

Another element affecting the internal policy debate on biotechnology is the growing role of civil society. Traditionally, there has been little debate on biotechnology and biosafety outside elite policy circles. Civil society groups, however, have made tentative steps towards greater involvement in these debates. Greenpeace, for example, is leading efforts both to raise awareness among Chinese citizens about the potential threats from GM food and to insert a social and environmental dimension to biotechnology decision-making.<sup>42</sup> There is some evidence of growing public awareness and concern about GM content in food, although this seems to be confined to the rising urban middle class (Zhong et al., 2002).

Increasingly, the link between biotechnology policy and trade has come to dominate policy debates. The development of stricter biotechnology-related regulations was partly due to a temporary EU trade ban on Chinese soy products after GM content was detected in 2000, calling into question the adequacy of China's

domestic regulations.<sup>43</sup> Nevertheless, the new rules also brought trade-related concerns. Since every shipment of GM crops had to now be issued a safety certificate based on a risk assessment, shipments of soybeans to the United States were held up temporarily, leading to a noticeable fall in these exports. The U.S. government accused China of "back-door" protectionism aimed at manipulating the burgeoning trade in soybeans and complained about the uncertain nature of the new biosafety rules, which in their view failed to give clear guidance. China eventually gave in to sustained diplomatic pressure from Washington and issued interim safety certificates to facilitate uninterrupted imports of soybeans before issuing formal three-year certificates in February 2004. The climb down by the Chinese authorities underlined the difficulties involved in implementing the provisions of the Biosafety Protocol, which, while not in force at that time, had served as a blueprint for the regulations. The significance of this episode to the biosafety efforts of less powerful trading partners was noted widely in the developing world.

China participated in the negotiations on the Biosafety Protocol as a key *demandeur* for stringent international biosafety rules. China signed the Protocol in August 2000, but did not ratify the agreement until June 2005, owing in part to intense domestic debates about the impact of the Biosafety Protocol on China's biotechnology policy. The regulations introduced in 2001 and 2002 helped to bring China's regulatory system more in line with the Cartagena Protocol and provided the basis for implementation of rules applying to the transboundary movement of GMOs.

Although Chinese representatives publicly claim to have put in place the required instruments for implementation, government experts concede in private that the country faces severe capacity gaps with regard to its ability to carry out risk assessment and particularly risk management, GM detection facilities at ports and other points of entry, and the regional and sub-regional biosafety offices that are required to implement national laws remain undeveloped. Recent reports on the growing problem of illegal planting of GM

crops suggest that China is still far from fully implementing the Protocol and national biosafety rules (Zi, 2005). The country is currently engaged in several capacity-building initiatives funded by UNEP, GEF and bilateral donor agencies (e.g. the German development agency GTZ), in an effort to build the necessary scientific, administrative and regulatory capacity to implement the Protocol.

The Cartagena Protocol has helped to shift domestic policy in the direction of greater caution, but domestic battles continue over the precise direction of China's biotechnology strategy. Trade policy concerns loom large in the domestic battles over the future of biotechnology and biosafety. The Cartagena Protocol has helped to upgrade biosafety concerns on the domestic agenda, but it was the spread of GMO import restrictions in key export markets for Chinese agricultural products that really moved the biosafety issue up the political agenda. Creating a biosafety framework that can be reconciled with China's long-term aspirations in the WTO context will thus be of primary importance.

In terms of intellectual property protection, China first adopted a Patent Law in 1984, and introduced amendments in 1992 and 2000. Article 25 of the Chinese Patent Law provides a list of subject matter excluded from patent protection similar to the one found in the European Patent Convention. Article 25(4) of the Chinese Patent Law excludes animal and plant varieties from patent protection. This exclusion is mainly directed toward organisms per se, so methods of breeding and products derived from these organisms remain patentable. However, for the methods of breeding to be patentable,

### South Africa

Biotechnology and its use in agriculture receive strong support from the highest echelons of the South African government. South Africa is a net agricultural exporter, although it participates in both exports and imports of certain commodity crops subject to genetic manipulation, notably maize and soybeans.<sup>44</sup> Significant efforts have thus been made to develop an overarching and coherent strategy for biotechnology promotion

they must not be "essentially biological" in nature; that is, human intervention should play a key role in the success of the process in order to meet Chinese requirements.

Currently, the Chinese Patent Office gives a broad interpretation to Article 25(4) to cover all plant and animal varieties including GM plants and animals. Thus, the only form of protection for plants in China is under the 1997 Regulations for the Protection of New Varieties of Plants, which follows the 1991 Convention of the International Union for the Protection of New Varieties of Plants (UPOV). BIO, a U.S. biotechnology industry group, does not consider this to provide its members, particularly those focused on GM plants and animals, adequate and effective protection (ASTA and BIO, 2007). In addition, patent and plant variety enforcement has generally been weak in China.

China has committed substantial government resources to research and development. By the mid 1960s, Chinese scientists were researching nearly 50 different kinds of transgenic plants, employing more than 100 different genes to transform them. By the end of this decade, more than 80 state-funded institutions were involved in agricultural genetic research. Scientists have been well funded and many have had excellent foreign training. One of China's major successes has involved Bt cotton, for which patents were obtained which is now as widely cultivated as Monsanto's Bt cotton variety. State resources for research in agricultural biotechnology are expected to increase substantially over the next decade.

and innovation in South Africa. A 2001 National Biotechnology Strategy outlines the government's vision for biotechnology's role in meeting broader food security, health and environmental objectives. A 2002 strategy document calls for suitable regulatory systems in order to participate as exporters and importers in the international trade in biotechnology products (NBS, 2001: v).

As a result, South African biosafety legislation has — in its broadest contours — been considered fairly permissive. This approach is politically feasible because there is currently little widespread public knowledge or concern about GM products. A recent survey carried out on behalf of AfricaBio, a pro-biotechnology NGO, claimed that a substantial majority of the population was unaware or unconcerned about GM foods, a finding that subsequent government-initiated surveys have confirmed (AfricaBio, undated). Unlike maize in Mexico, for example, no single crop subject to genetic engineering has the cultural resonance around which public debate can or has rallied. However, maize is also South Africa's most important crop, and commercialization of GM white maize may lead to future debates.<sup>45</sup>

In South Africa, the adoption of a biosafety law thus coincided with the first general release of GMOs, in 1997 (Morris et al., 2005). As in other cases, notably in Mexico, it was scientists engaged in biotechnological research that felt the need for, and led the way in, developing biosafety laws. Nevertheless, the GMO Act, which establishes procedures and an institutional structure for regulating GM products in South Africa, has some interesting provisions ensuring balanced policy discussions. Decisions on approvals of GM products are taken by consensus within an Executive Committee, consisting of representatives of agriculture, health, environment, science and technology and trade. This emphasis on consensus ensures that all represented government departments can, in theory, veto particular GM crop approvals.<sup>46</sup> Critics note, however, that the capacity for active public participation in the Executive Committee is limited.

Under the GMO Act, a number of GMOs — including three distinct varieties of cotton, three varieties of maize and one variety of soybean — have received general release approval, with an additional eight varieties of maize approved for commodity clearance, which allows for the importation of the maize varieties for use as food/feed (Morris et al., 2005). Several of these approvals have been challenged by different

civil society groups, including in a case that culminated in the first-ever official appeal of a general release permit, which the appeal board chose to modify, not revoke. Some commentators consider that these legal challenges have provided an important impetus towards the amendment of the 1997 GMO Act.

Another important element in South Africa's regulation of agricultural biotechnology is the recently passed labelling legislation. The legislation is considered a clear example of a permissive approach to GMOs, as it subscribes to the notion of their substantial equivalence with non-GM food. It only requires the labelling of a foodstuff obtained through genetic modification if it is significantly different in respect to composition, nutritional value, and mode of storage or preparation, allergenicity or human or animal origin.

South Africa ratified the Biosafety Protocol in 2003. With an overall political environment that supports rapid development of the biotechnology sector, it may seem puzzling that South Africa ratified the Cartagena Protocol — which is often portrayed by the technology's supporters as a potential hurdle to rapid domestic biotechnology development. The ratification can be explained however, as being politically unavoidable, given South Africa's emphasis on multilateralism and its desire to show solidarity with the concerns of other African countries, most of whom are strong supporters of the Protocol.

Ratification of the Biosafety Protocol has resulted in certain procedural adjustments to time frames in the current regulatory approval process. Discussions are also underway about how to meet the country's obligations to provide specific information about domestic GMO approvals to the Biosafety Clearing House. A recently passed Biodiversity Bill permits the Ministry of Environment to unilaterally require an environmental impact assessment (EIA) for particular GM crops prior to approval, if it is deemed necessary. Such an EIA is distinct from the risk assessment called for by the GMO Act, which is often based on a desk-top study. Although the impact of this requirement remains unclear,

its inclusion is seen by supporters as in keeping with the Biosafety Protocol and as a victory for those seeking more attention to environmental impacts of GMO releases.<sup>48</sup>

The direction that biotechnology policy takes in South Africa holds a significance that goes beyond its own borders. Policy developments in this country are often seen, whether legitimately or not, as the litmus test for how things might develop in the African continent as a whole. South Africa's potential to be a "gateway" to the rest of Africa for GM products, as well as for biosafety regulations, makes developments of particular interest to both proponents and opponents of agricultural biotechnology.

## India

In 1989, the Indian Ministry of Environment & Forests (MOEF) established rules for the manufacture, use, import, export and storage of hazardous micro-organisms and genetically engineered organisms or cells, which have later been updated. The overall responsibility for the application of these guidelines rests with the Department of Biotechnology (DBT) under the Ministry of Science and Technology. In addition, the rules set up various competent authorities to implement different aspects of these regulations. In particular, the three agencies involved in approval of new transgenic crops are the Institutional Biosafety Committees (IBSC) established for monitoring institute-level research in GMOs; the Review Committee on Genetic Manipulation (RCGM), functioning in the DBT to monitor ongoing research activities in GMOs and small-scale field trials; and the Genetic Engineering Approval Committee (GEAC), which functions in the MOEF to authorize large-scale trials and environmental release of GMOs. The GEAC, specifically, is considered India's powerful biosafety gatekeeper. It can authorize import, export, manufacture, processing and sale of any GM organism (Ghosh and Ramanaiah, 2000). In addition, the RCGM has approval responsibilities for the development of transgenic plants, their growth in soil for molecular and field evaluation, and the import and shipment of GM plants for research purposes.<sup>50</sup>

In South Africa, no patent protection is available for plants and animals, even if they are genetically modified. Plant variety protection is available on the basis of the UPOV Convention 1978. The public sector is heavily engaged in biotechnology research, dating back to 1978, when a South African Committee for Genetic Experimentation (SAGENE) was constituted to encourage research in molecular biology and biotechnology in various spheres (Sasson, 2000). In the 1980s, biotechnology research centers were established with public funding. Beginning in the 1990s, South Africa was one of the first countries to undertake field trials and environmental releases of transgenic crops. While the public sector is involved with transgenic research, its products have yet to reach the commercialization phase.<sup>49</sup>

The GMO guidelines are quite thorough and well structured, and have operated reasonably well. However, in the case of Bt cotton, there was a degree of confusion regarding the approval process, particularly regarding the specific responsibilities of each agency, and public confidence in the system was eroded. Specifically, civil society groups questioned an approval granted by the RCGM to Mahyco/Monsanto for Bt cotton. The controversy over the approval of Bt cotton has fuelled public concerns about the safety of biotechnology, and has contributed to the delays in approving other GM crop varieties.

In addition, the Indian government is under pressure from civil society groups to impose a non-GM trade policy both in imports and exports. However, the country's relatively small volume of agricultural exports makes this issue of limited importance.<sup>51</sup> India's anti-GMO trade policy was tested in 1998, when imports of soybeans were approved due to a shortage of internally grown mustard oil. Some of the imported soybeans were GM products. The government responded by requiring imported beans to be segregated, thus preventing them from being planted. Moreover, as a small soybean, sunflower and rapeseed meal producer, India has promoted exports of these products as "GM-free" to overseas markets such as Japan,

Indonesia, Thailand, the Philippines, the Gulf countries and the Middle East. (APBN, 2000b), though price premiums were difficult to secure since most of these exports were for animal feed. In the case of Thailand though, GM-free animal food is favoured because they export chicken to GM-conscious European market.

India does not have stringent food safety and labelling regulations. Consumer protection laws have been slow to emerge both in general and for GM foods in particular. Because India does not yet officially grow or import any GM foods, it has been able to continue operating within food safety policies that draw little or no distinction between GM and non-GM food ingredients.<sup>52</sup>

In addition, new guidelines allow for test results generated in certain other countries, such as the United States, to be used in India on the grounds that food safety testing does not have to be site-specific. Labelling has not been an issue in India to date, because most food products are not packaged in the first place. The lack of GM food in its domestic market enables all of its soy or castor oil seed cake destined for Europe or Japan to be labelled “GM free” without costly market segregation.

#### Argentina<sup>53</sup>

Biosafety regulations constitute the main explicit agricultural biotechnology policy in Argentina, and these regulations have often been identified as one of the key elements allowing early adoption of GM technologies. During the mid 1990s and on the basis of the biosafety regulations, Argentina was able to quickly evaluate and release for commercialization the first GM crops – herbicide tolerant soybeans. Another factor contributing to the adoption of GM varieties is the existence of a strong and dynamic agricultural inputs and services sector, particularly in the field of seeds, which provided the local germplasm platform for the new genes. There are also strong synergies between the new GM technologies and the no-till practices that were adopted at the time in response to a growing soil fertility problem in some of the main farming areas of the country.

India has historically relied upon its own public sector and government scientists to develop new agricultural technologies, although the role of the private sector is recognized and even promoted in more recent policies. As a result, traditionally there has not been much of a focus on developing intellectual property protection for biotechnology, although India has had patent legislation since 1970. Nevertheless, there have been significant developments in this regard as India brought its legislation in line with the TRIPS Agreement. According to BIO, however, “the Indian patent system still excludes from protection most biotechnology inventions”. The Patents Office has also determined that the Indian Patents Act excludes from eligibility living organisms, ranging from microorganisms, such as bacteria or yeast, to stable cells lines, to transgenic plants and animals” (BIO, 2007). Plant variety protection legislation has also proved controversial and remains in suspense. For its part, the Indian government has, for more than a decade, allocated resources to develop GM crop varieties, including local adoptions of varieties developed elsewhere. These efforts have met with little success due not only to limited financial resources devoted to them but also to a lack of effective coordination with private sector firms.

In terms of public attitudes, although it is true that the environmental lobby was never strong in Argentina, it is also the case that the farming sector – clearly the main beneficiary of the technologies – was also never very vocal in supporting agricultural biotechnology. The one exception is the Argentinean Association of No-Till Farming, AAPRESID, which has been the main supporter of GM crops on the basis not only of improved productivity but also their environmental benefits. It was mostly the weight that agriculture carries in the Argentinean economy, and the potential role of the new biotechnologies in helping the recuperation on the sector after a long period of stagnation, that created a favourable environment for the acceptance of the technology.



The biosafety framework in Argentina dates back to 1991, and was instituted by Ministerial Decree.<sup>54</sup> It establishes a product, rather than process, based evaluation, and takes place on a case-by-case basis only in instances of potential risk to the environment, the agricultural production or the health of humans or animals. The evaluation process includes two distinct processes. One is the technical evaluation, which is conducted by National Advisory Committee on Agricultural Biotechnology (CONABIA) and examines the impact in the agricultural ecosystem. In cases of food or feedstuff derived from GMOs, it is the National Service of Agricultural and Food Health and Quality (SENASA) that is in charge of the technical evaluation.

The second evaluation – probably one of the most distinct features of the system – focuses on the commercial impact on export markets. It mainly analyzes the status of the GM product at issue in the destination markets, looking at whether the product has been approved or not and, as a result, whether the addition of a GM crop to Argentina's exports might represent a potential barrier to the access to these markets. This is a later addition to the biosafety system and was most likely brought into the picture in response to the growing international debate regarding the acceptance of the new GM technologies. For a time, it functioned as a “mirror policy:” a policy of only approving events already approved in the main export markets, mainly the EU, to avoid market risks.<sup>55</sup> This analysis is conducted by the National Direction of Agricultural Food Markets (DNMA).

A report is then prepared for the Secretary of Agriculture, Livestock, Fisheries and Food, which is charged with the final approval.<sup>56</sup> Over the years, more than 500 requests have been evaluated, but only nine events have been approved for commercialization.<sup>57</sup> The sequence of approvals highlights the evolution of the political environment, the evolution of the biosafety regulation, and other developments such as the ratification of the Cartagena Protocol, the enactment of new labelling and co-existence regulations, and the growing role of technical and trade considerations in the policy making process.

Indeed, there has been a major policy change regarding approvals. Once the EU adopted its new labelling and traceability regulations and resumed application of its approval process, the “mirror policy” was *de facto* abandoned. Two crops not approved for commercialization in Europe at the time were approved: RR maize (HT) and TC 1507 maize (IR). This decision was probably a reflection of the lesser importance of the EU for Argentinean corn exports, and was also linked to the fact that most of the country's exports to EU are of flint maize, which is produced under special segregation systems, so export markets would not be affected. The influence of this policy change in the long term is difficult to assess as both crops have since been approved by the EU, so the situation remains – in practice – the same as with prior policies.<sup>58</sup>

The Cartagena Protocol was signed, but not ratified, by Argentina. Again, the environmental lobby, although supportive of ratification, did not push heavily on the issue. Instead, the government chose to actively develop a policy of bilateral agreement with its main trading partners aimed at avoiding trade disruption, and lobbied “friendly” Biosafety Protocol Parties to prevent the adoption of stringent measures in areas such as liability.

Intellectual property protection for biotechnology in Argentina is based on two pieces of legislation. First, the Patents Law 24,481 and its amendments, which do not grant protection to plants, but allow the grant of patents to microorganisms, hybridomas and mono-clonal antibodies, nucleotides, and proteins. Second, a 1973 statute on Seeds and Phyto-genetic Innovations covers breeder's rights over new plant varieties. The black market for seeds, however, exceeded 50 percent of the entire market, which has created controversy with multinational companies. At this time there is no clear consensus as to the best alternative to the present system: farmers' organizations are divided between those supporting the reinforcement of a system based on the collection of royalties through the price of the seed – thus reinforcing competition among innovation suppliers – and those opposed to any royalty collection at all.

There are no specific investment promotion instruments for agricultural biotechnology in Argentina, other than the general funding mechanisms for the promotion of scientific activities and the promotion of public-private joint ventures in R&D. Recently, however, the Office of Biotechnology of the Secretary of Agriculture, Food and Fisheries, SAGPYA, has developed a Biotechnology Strategic Plan outlining policies and an action plan for 2005-2015. In this context, biotechnology is viewed as playing a critical role as a main source of technological solutions for agricultural productivity growth in the country. The development of biotechnology is also recognized to require cutting-edge science, political, legal and economic variables,

#### Brazil<sup>59</sup>

The biotechnology framework in Brazil includes biosafety and labelling regulations. In 1995, Brazil enacted a Biosafety Law, establishing guidelines for the safe use of genetic engineering techniques and the environmental release of GMOs. The Biosafety Law, which applies to all GMOs whether used for release into the environment or for human or animal food processing, prohibits the entry of GMOs into Brazil without prior approval. The National Technical Commission of Biosafety (CTNBio), part of the Executive Secretariat of the Ministry of Science and Technology, was set up as the responsible agency for establishing standards and regulations for activities and projects involving GMOs, and for issuing a conclusive technical opinion on the release of any GMO into the environment. Later, the Biosafety Law was amended to also give CTNBio final power for approving the release and food use of GMOs. Several positive technical reports have been released by CTNBio, including on GM soybean, corn, and cotton. Labelling requirements entered into force in 2003, establishing a 1 percent threshold for food and food ingredients destined for human or animal consumption that contain or are produced with GMOs.<sup>60</sup>

Although the above institutional framework has been formally approved both at the legislative and executive levels, the debate behind the use of agricultural biotechnology is far from over

and external and internal negotiations. This plan proposes to diversify the application of biotechnology, both in terms of the number of tools employed, as well as in the sectors of application. It also focuses on the need to create a favourable environment – in political, legal and public acceptance terms – for the creation and development of biotechnology-based companies, and also for the consolidation of the existing companies. The plan was elaborated through a participatory mechanism, which involved stakeholders from the agricultural, livestock and forestry sectors, and is expected to constitute a guiding instrument for both public and private efforts in the field. To date, however, there is still no funding allocated for these purposes.

in Brazil. The Brazilian Consumer Protection Institute (IDEC) has led petitions to declare certain provisions of the existing legal framework as unconstitutional, including provisions on the authority of CTNBio and on the minimum threshold that triggers labelling requirements. IDEC has the support of the campaign “Brazil: Better Without GMOs,” sponsored by Greenpeace and integrated by environmental and consumer groups, including government officials within the Ministry of Environment, some political parties, the Catholic Church, and the Landless Movement. These campaigns are having an impact among meat processors and within the food processing industry, as well as with some Brazilian retailers, especially the large supermarkets under French ownership. However, the acceptance of biotech crops in Brazil remains strong among producers.

Brazil has developed a relatively strong intellectual property rights protection regime that covers agricultural biotechnology.<sup>61</sup> As a result, a number of foreign firms have made substantial investments in Brazil, purchasing local Brazilian plant breeding, seed multiplication and distribution firms. Brazil has allocated public funds for biotechnology research focusing on soybeans, cotton, maize, potatoes, papaya, common black beans, bananas, cassava and rice. While the sums allocated have been modest, these public

investments have led to the patenting of a system of crop transformation applicable to multiple crops species. In addition, the government has field tested their own transformed herbicide-resistant soybeans and virus-resistant potatoes,

## Kenya

The basis for agricultural biotechnology in Kenya was established by the Regulations and Guidelines for Biosafety and Biotechnology, published in 1998 by the National Council for Science and Technology (NCST).<sup>62</sup> These regulations establish specific requirements for the assessment of the ecological and health impacts of GMOs. A National Biosafety Committee (NBC) was created to implement the regulations, with tasks ranging from reviewing proposals for imports to conducting field trials or commercial release of GM crops. Since its establishment in 1996, however, the NBC has struggled to operate with limited facilities and budget resources. As a result, regulatory approvals have been paralyzed.<sup>63</sup> Nevertheless, two research stations have been established and field trials are underway (USDA, GAIN Report, 2005). Future developments will depend on the development of adequate regulatory capacities and procedures.<sup>64</sup>

Kenya's trade policies have been precautionary towards GMOs. Under the biosafety regulations, the NBC must give separate approvals to GM crop and plant materials imports. In addition, there is a wider policy of farm trade protectionism, aimed at protecting domestic farmers from international competition. For example, Cargill's seed company was not allowed to sell its hybrid maize seeds in Kenya, thus maintaining Kenya Seed Company's 90 percent monopoly. Nevertheless, import permit procedures and other restrictions have been quickly put aside in cases of emergency. In receiving food aid, for example in the context of the drought appeal made in 2004, GM maize was imported without any risk assessment.<sup>65</sup> Kenyan importers, retailers and consumers have not expressed serious concerns about importation, sale or use of transgenic products. The government has not shown concern regarding the potential risk of losing export markets due to its approval of GM crops. Domestic production of soybeans and oilseeds – GM versions of which

though the commercialization of these transgenic varieties is dependent on the successful outcome of negotiations for commercial license agreements with the international firms that hold the relevant transgenic patents.

are resisted by importers in some countries – is limited. The main products that Kenya exports – namely coffee, tea, and cut flowers – do not yet have GM varieties in Kenya or elsewhere.

Since production or import of GM crops in Kenya is negligible, the government has not yet felt any pressure to implement a policy of labelling GM crops. Additionally, public health officials have not targeted GM crops in light of other more pressing health concerns Kenya's food consumers routinely face. The biosafety regulations indeed do not address food safety issues, which are governed by the 1980 Food, Drugs and Chemical Substances Act, administered by Ministry of Health. This law predates development of GM crops and is designed to protect against more conventional concerns such as poisonous or adulterated food addressing substances, ingredients, and additives in the food. More general product labelling rules make no specific reference to GM products. In fact, GM labelling in Kenya is unlikely to be required for two reasons. First, the Ministry of Health has many other problems to worry about other than food safety. Second, most of the food sold and consumed in Kenya is not manufactured, processed or pre-packaged, making any labelling requirement impracticable.

Kenya was the first country to sign the Biosafety Protocol. Ratification followed in 2003, and a Biosafety Bill was drafted in 2005 to bring Kenya's law and practice in line with the Protocol. The draft Bill is considered "fairly uncontroversial," dealing with applications for the contained use, field trials, import and export, and placement of GMOs on the market (Kameri-Mbote, 2007). However, it fails to address some key issues, including labelling and public participation. It also does not cover food aid and has only vague provisions on liability and redress. The draft Bill has not yet been discussed in Parliament.

In Kenya, no patent protection is available for plants and animals. A plant variety protection law was enacted in 1991, which preserved the traditional practice of farmers to replicate, replant and exchange protected seed varieties for their own use, along the lines of the UPOV Convention 1978. Private investment in biotechnology has been minor, but the level of protection of intellectual property has not

been a factor, but rather broader economic and political constraints. Historically, Kenya has had a relatively strong record of public investment in agricultural research, though this has recently lagged due to funding reductions as well as a decline in support from international donors. Relatively little research has been devoted to agricultural biotechnology.

### 3. Observations and Preliminary Conclusions

A number of observations emerge from these case studies. An important point arising from the study of experiences with biotechnology policy, for example, is the significant diversity that exists among regulatory systems despite international attempts to encourage harmonized approaches (Newell, 2003). The aim of the SPS Agreement and, to a lesser extent, the Biosafety Protocol, as well as guidelines developed by UNEP and the OECD, is to encourage nations to harmonize and coordinate their regulatory requirements for agricultural-related processes and products in order to facilitate agriculture-related trade. Yet national regulations remain highly divergent. For example, in the critical case of product labelling, the US, India, South Africa, Argentina, and Kenya have no effective labelling requirements while the EU has very stringent labelling requirements. Japan, China, Brazil, Australia, Korea, China Taipei, and Mexico fall between. But even within these broad categories, specific national labelling requirements differ.

Public policies toward the approval of GM crops for commercial cultivation are similarly diverse. Four of the countries in our study, namely Korea, Japan, Kenya, and Chinese Taipei currently do not allow GM crops to be grown, while each of the other countries examined has granted some permits. Relatively little GM acreage or few GM crops are planted even in those political jurisdictions which have authorized some of them. Thus in the EU, for example, GM crops are only grown in three of the twelve Member States, and in modest quantities. China has authorized the planting of three GM crops, but of these only cotton is grown in large quantities. Australia permits the growing of four GM varieties

but again, only one, namely cotton, is grown in significant quantities. In Mexico and India, only GM cotton is permitted to be grown. The only countries in which substantial quantities and diverse kinds of GM crops are grown are the US, South Africa, Brazil and Argentina. Thus in the case of cultivation, *de facto* variations are even greater than *de jure* ones.

These variations reflect the absence of effective international governance of GM crops and foods. In particular, the Biosafety Protocol has permitted countries some latitude in shaping their domestic policies. Flexibility in the TRIPS Agreement regarding intellectual property protection of biotechnology products has also contributed to differing approaches. National policy discretion and variations have been encouraged by the substantial differences between the regulatory policies of the EU and the United States, the countries that historically have played a critical role in setting international trade and regulatory standards. In effect, countries are free to model their regulatory and IP policies after either the EU or the US. While some have followed the latter, more have been influenced by the policies of the former, in part due to the fact that the EU is a more important agricultural export market than in the US for many countries.

Another relevant observation is that nations generally have more permissive policies toward the importation of GM varieties than with respect to their cultivation. Thus the EU imports substantial amounts of GM soy, primarily for animal feed, while Korea, Japan, Kenya, and Chinese Taipei, which permit no domestic cultivation, also import substantial amounts

of GM products. In Australia, Mexico and China, which essentially only grow GM cotton, substantial imports of other GM food products are permitted.

In addition, a policy shift toward more stringent importation, labelling and cultivation requirements is clear. The only exceptions to this pattern are the United States, South Africa, Argentina, and Brazil, where regulatory policies have been both relatively stable and permissive. Kenya is also a partial exception, where there are signs that policies are becoming more permissive. With the (possible) exception of Australia, public opposition to GM food and food crops appears to have recently increased.

An additional important factor increasing the general tightening of requirements for importation, cultivation and labelling of GM foods and crops is the Biosafety Protocol, which has enabled many countries to strengthen their domestic regulatory capacities and requirements. Provisions in the Protocol have strengthened the hand of environmental ministries in many countries such as India and China. In India it is now Ministry of Health and ICMR which are pushing for a regulatory system with stronger biosafety components than their counter-parts in ministries of trade or agriculture might like to see (IFPRI/RIS, 2007).

The enhanced profile of biosafety issues in government approval processes has not necessarily translated into improved capacity to enforce biosafety provisions, particularly in larger developing countries, where the scale of the illegal trade in GM seeds is thought to be large but state capacity to regulate it, weak. At the level of international trade, seed and grain traders in many developing countries point to the fact that they are rarely, if ever, asked for the documentation required by the Cartagena Protocol when exporting their products. There appears to be an implementation gap, therefore, between the provisions for biosafety in international and national regulations and capacity deficits and lack of awareness among government officials and those overseeing the transboundary trade in GMOs respectively.

The general pattern of national policies toward GMOs reflects prevailing economic conditions and political contexts. Most obviously, nations that are dependent on agricultural imports for various commodities, such as the EU, Japan, China, Chinese Taipei, Korea, Australia, Kenya and Mexico, have developed relatively permissive policies toward the import of GM varieties, though many still require crop segregation. In the case of policies toward domestic cultivation, these appear to be importantly shaped by both domestic and international considerations. For advocates of biotechnology, opposition to the planting of GM varieties merely reflects the influence of protectionist agricultural interests, which see no benefit in cultivating them, allied with NGOs who are opposed to them in principle. It is also the case, that opposition to the technology reflects different social priorities, cultural views of food and technology, as well as the organization of interested political groups. For example, the opposition to GM foods in the UK has to be understood in relation to previous scares around food, most obviously the BSE mad cow disease and the lack of trust expressed in food regulation authorities to manage risks appropriately despite their claims to competence. When U.S exporters to the UK refused to segregate foods containing GM from non-GM foods, a consumer backlash ensued against the technology as a whole. In India, sensitivity about the patent claims of multinational companies regarding basic food stuffs has to be seen in light of the controversy and legal disputes that followed over attempts to patent basmati rice by a U.S. company, a crop and a variety that is closely tied to national identity.

This is not to downplay the importance of agricultural interests, but merely to highlight the importance of a range of other social, political and cultural determinants of technology choice. In the United States, Brazil, Argentina, South Africa and China, agricultural interests have generally been supporting GM cultivation – in the first three countries because they are major food exporters and in the latter two because their governments have adopted and maintained promotional policies toward GMOs from the outset. What all five countries have in common is the relative weakness of NGO opposition to

GM crop cultivation. Australia is a mixed case: as a major agricultural exporter, there are strong commercial interests in favour of GM cultivation, but there is also substantial domestic NGO opposition, most notably with respect to food production. In the case of India, agricultural interests strongly support GM cultivation in the one crop, namely cotton, in which it is a major exporter, while alliances of farmers opposed to unconditional liberalization and NGOs have restricted the cultivation of other crops. Indeed a recent ruling of India's Supreme Court has put a halt to all GM crop trials until controls are strengthened in light of the illegal growing observed in the state of Gujarat. Chinese Taipei has very little domestic agricultural production, so farmers are not an important political constituency.

Among the most striking patterns is the significant difference in policies toward the cultivation and importation of GM products depending on whether they are intended or not for food. The closer a GM product or crop is related to supplying foods for human consumption,

the more likely it is that both planting and consumption are restricted. Thus, governments that have permitted GM cultivation have done so, in general, for non-food crops, most notably cotton. This reflects the substantial concerns about the cross-pollination of GM and non-GM crops in many countries. Moreover, it reflects the influence of labelling requirements, which do not apply to non-food-related GM products, and also do not generally apply to agricultural products intended for animal consumption. Clearly, labelling requirements are a critical factor shaping many national restrictions on GM food cultivation. Countries that are agricultural exporters, even modest ones, such as India and Kenya, are generally reluctant to grow GM crops intended for human consumption because of concerns that the food products in which they are introduced will be required to be labelled, and therefore food processors will not use them, supermarkets will not sell them, and consumers will not buy them. This is especially true for those countries that export to the EU, whose food labelling requirements represent a *de facto* barrier to their importation.

## IV. POLICY CONSIDERATIONS, OPTIONS, AND TRADE-OFFS IN AGRICULTURAL BIOTECHNOLOGY

As observed in the national case studies, there are a variety of approaches to agricultural biotechnology regulations and policy-making. Indeed, it would be impossible to develop an effective “one-size-fits-all” framework in this field, given the different economic, social, and environmental needs in each country, as well as the varying capacities of the public, private, and civil society sectors. Nevertheless, from the experience of both developed and developing countries, it is possible to identify certain common dilemmas and challenges in regards to agricultural biotechnology, as well as the importance of addressing these dilemmas and challenges in the context of broader policy goals.

The present section sets out, on the basis of the above-mentioned case studies, a potential frame of reference for policy-making in trade, agricultural biotechnology, and sustainable development. This frame of reference begins by focusing on the reason that policy-makers are considering agricultural biotechnology – that is, on the economic, social, and environmental

needs that it is hoped that appropriate policies in this field will address. In this context, the potential role of agricultural biotechnology in addressing these needs is determined.

Then, relevant policy options are determined to guide agricultural biotechnology development towards the identified needs. In this regard, the frame of reference notes that strategic choices will need to be made; insofar there will be policy objectives that compete and conflict. In managing these trade-offs, countries will need to consider various factors. For instance, the context in which policies and regulations will be developed is essential, including the government’s regulatory and enforcement capacities, public and private scientific and research structures, economic and trade priorities, private sector characteristics and aims, and public concerns. In addition, the policy space available for different approaches, taking into consideration the international legal framework for each country, as well as political pressures, is also fundamental in any regulatory determination.

### 1. The Role of Agricultural Biotechnology in Addressing Economic, Social and Environmental Needs

The development of regulatory frameworks that consider the potential offered by agricultural biotechnology, but also address potential drawbacks and public concerns, requires policy-makers to carefully consider and balance the risks and benefits in relation

to their broader policy goals and necessities. Some of the particular policy areas that may need to be considered in developing regulations for agricultural biotechnology include economic development, sustainability, food security, and food safety.

#### Economic development

What has attracted many companies and governments to research and investment in agricultural biotechnology is the prospect of large economic returns. Indeed, considered as a key part of the “knowledge economy,” biotechnology is central to the growth strategies of leading industrialized and newly industrializing economies. According to BIO, the total value of publicly traded biotechnology companies

in the United States was USD 410 billion as of Dec. 31, 2005, and bioscience activities – which include but are broader than biotechnology – employed 1.2 million people in that country in 2004 (BIO, 2007b). It should be noted, however, that focusing on economic growth and increasing revenue as the primary policy objective is likely to concentrate attention on crops and varieties that are most relevant to wealthy consumers.

Soya — used widely in feed and processing for cattle — and cotton — of course a key material in the garments industry — have attracted much more attention than research and investment into sorghum or millet, for example.

Nevertheless, a strategy that prioritizes the economic growth potential of biotechnology may also have important knock-on benefits for poorer farmers, who have been traditionally excluded from new market opportunities. Indeed, considering economic benefits within a broader framework of sustainability is more likely to be economically sustainable too, since short-term economic growth, if environmentally

unsustainable and socially de-stabilising, is not growth that can be maintained in the long-term. Even for countries at a relatively low stage of development, a strategy aimed at improving income through export earnings associated with biotechnology production, might provide much needed revenue for other developmental purposes. For example, Argentina has faced heightened problems of food shortages and food insecurity in the wake of the financial crisis in 2001. The vast investment in biotechnology in the country, while not aimed at remedying these problems, has resulted in export revenues, particularly from soya, that are used, in principle, to tackle poverty within the country.

### Sustainability

One of the UN Millennium Goals is ensuring environmental sustainability, integrating the principles of sustainable development into all country policies. Reversing the loss of environmental resources is thus an important policy goal in many countries. The role of biotechnology in advancing environmental sustainability, however, is highly contentious. Advocates of great use of agricultural biotechnology claim that GM agriculture is 'doubly green' (Conway, 1999). According to its proponents, agricultural biotechnology has tremendous potential to reduce the environmental impact of farming, limiting

chemical usage on farms, promoting practices such as no-tillage farming (which is considered to reduce soil erosion and prevent water loss), and increasing efficiency by producing more food and fibres on less land. Critics of biotechnology argue that the direct and indirect impacts of GM crops will have negative environmental impacts on both the non-GM varieties and non-target plant and animal species. More broadly, there are fears that adoption of GM plant varieties could encourage a tendency towards mono-cropping, intensive farming, and mechanisation of agriculture with adverse impacts on biodiversity.

### Box 3. Technology Needs Assessments

To determine relevant policy goals and the potential role of agricultural biotechnology in their advancement, a technology needs assessment can be a useful tool.

Technology needs assessments can be defined as a set of country-driven activities which involve relevant stakeholders in a consultative process to identify and determine the needs of countries in response to national priorities and policies, the available technology alternatives, and the potential benefits, costs and risks of such technologies.

In general, the process of technology needs assessments includes the following steps:

1. Establishing criteria for evaluation of technology by integrating core economic, social, and economic goals.
2. Identifying different technology options.
3. Evaluating technologies on the basis of established criteria.
4. Discussing results with all relevant stakeholders.
5. Prioritizing technologies.
6. Reporting results to policy-makers.
7. Conducting follow-up.



As the potential risks and benefits to the environment will differ in various contexts, more information would be necessary on the genes, species, and ecosystems that could be impacted – both negatively and positively – with the use of agricultural

biotechnology. Policy-makers would thus be able to identify how agricultural biotechnology would promote or detract from its sustainability goals, and attempt to find zones of congruence between economic, social and environmental needs.

### Food security

Food security is defined as a situation in which all people at all times have physical and economic access to sufficient, safe, and nutritious food to meet their dietary needs and food preferences for an active and healthy life (World Food Summit, 1996). It is a serious policy concern for many developing countries. Proponents of agricultural biotechnology consider that it can play an important role in enhancing access to food in the developing world, increasing the production of food staples, improving production efficiency, and providing needed nutrition. “Golden rice” is given as an example – a type of rice enriched with beta carotene to help combat vitamin-A deficiency, a major cause of blindness in the developing world – as well as new varieties of corn, sorghum and wheat with more lysine, plants that resist viral pests, and foods with extended shelf lives that are being developed. Nevertheless, harnessing agricultural biotechnology for food security will depend on the broader enabling environment for the technology, as well as on addressing the systemic problems of agriculture.

in which biotechnology may and may not contribute to agriculturally sustainable development.

In times of emergency, however, the scope for careful reflection about the potential of biotechnology to help address problems of chronic food insecurity is reduced. Countries such as Zambia and Ethiopia have already become embroiled in controversies about the receipt of GM food aid in a context of widespread hunger in those countries. The dilemma government officials faced was whether to accept the food aid, in the absence of a full risk assessment, in order to feed a starving population, or to insist on GM-free food donations, supplies of which were available in neighbouring countries and reduce risks of potential environmental and human health impacts. Making important decisions about the desirability of GM crops under such circumstances, bypassing the role for a national strategy and debate about implications for sustainable development, is highly undesirable, but in some cases unavoidable when emergencies such as this arise.

There is also the risk that the introduction of a new technology has the effect of displacing or undermining existing rural livelihoods. For this reason, governments such as Malaysia and Ethiopia pushed for the inclusion of socio-economic criteria in the Biosafety Protocol. Other governments such as India have included impacts on rural livelihoods as an explicit stage in the process of assessing a GM crop. It is quite likely then that for many developing countries, especially those heavily reliant on agriculture, that food security would be an appropriate starting point for assessing the ways

For governments wanting to prioritize food security, it might be possible to require applicants wanting to cultivate a new variety or trait to demonstrate the potential benefits of the technology directly for rural development. Specifically, technology promoters could be required to show the benefits for poorer farmers in the areas and with the soils and materials currently at their disposal. Complementary policies such as tax benefits (breaks), subsidies, or public-private arrangements for technologies that directly benefit resource rural development might also be an option.

### Food safety

Food safety is a central policy objective around the world – from industrialized countries focused on a high level of protection of human health and

consumers’ interests in relation to food to less developed countries struggling with food-borne diseases as a leading cause of illness and death.

In developing countries, for example, the use of fewer pesticides might be a consideration for the promotion of agricultural biotechnology as an element of a food safety strategy. However, food safety in the field of agricultural biotechnology has more commonly come up as a concern in developed countries.<sup>66</sup> In particular, consumers

in EU countries have expressed concern about the negative health impacts of GMOs, including the introduction of allergens, higher levels of toxicity, uptake of transgenic DNA by humans, and increased resistance of bacteria. In these countries, food safety may be a key driver for policy decisions on agricultural biotechnology.

### *Harnessing Agricultural Biotechnology to Advance Policy Objectives*

- If biotech is seen as a key trade and competition strategy, relevant partners and competitors must be identified. In Argentina's case, a 'mirror policy' was explicitly aimed at securing access to key European markets. In China, consumer resistance around GM food, on top of a rejection of some of its exports to Europe, was enough to encourage a cooling towards the technology.
- If sustainability is the driving objective, the national capacity to develop and implement adequate environmental and biosafety measures must be assessed. Similarly, with food safety, changes in other forms of agricultural production might be required to accommodate the new technology in a way that satisfies policy goals. Capacity-building may also be necessary to allow the gauging of food safety – especially if the aim is to export to markets with higher food safety standards.
- If food security is the primary objective, questions of capacity in terms of direct delivery to farmers may be relevant. In many countries, extension services between government and farmers have been cut back as a result of structural adjustment packages. Selecting the type of biotechnology that will serve a given policy need is only the first step. Mapping the steps by which it would be accessible and deliverable to poorer farmers is critical. From there, implications in terms of infrastructural support and related issues can be read off this mapping of a technology pathway. Only by laying bare key assumptions about delivery in practice is it possible to see whether the technology is likely to serve the identified policy goal.

## **2. Identifying Policy Options to in Relation to of Agricultural Biotechnology**

Several policy areas might need to be reformed in order to construct a coherent framework aimed at minimizing the potential risks and maximizing the potential gains associated with agricultural biotechnology, including:

- Biosafety
- Intellectual property
- Food safety
- Trade and competition
- Research and Development

A number of policy interventions are possible within these areas. In part, the type of instruments to be applied will depend on how proactive is the government's overall position on biotechnology. Existing experiences from different countries indicate that some have been much more aggressive than others in their selection of specific policy instruments (Paarlberg, 2001). Some countries have adopted what could be identified as a "promotional" or "permissive" policy approach designed to attract investments and facilitate technology transfer and utilization, while others have been

more “precautionary” or “restrictive”, selecting policies and instruments that may slow down the pace of development and adoption of the new technologies. Instruments associated

with investment, biosafety and IPR regulatory systems and labelling are the policy categories where the “attitudes” gradient is more relevant (see Box 7).

#### Box 4. RApproach to Agricultural Biotechnology

	PROMOTIONAL POLICY	PERMISSIVE POLICY	PRECAUTIONARY POLICY	PREVENTIVE POLICY
BIOSAFETY	Rare screening or approval based on approvals in other countries	Case-by-case screening for demonstrated risk, based on intended use of produce	Case-by-case screening for scientific uncertainties as well as demonstrated risks, owing to the novelty of the GM process	No case-by-case screening; biosafety risk assumed because of GM process
FOOD SAFETY AND CONSUMER CHOICE	No regulatory distinction between GM and non-GM foods for testing or labelling	Separate but comparable safety standard when screening GM foods; Labels for some GM products, but based only on detectable GM content	Separate and higher standard when screening GM foods, and comprehensive labelling of all GM foods, enforced through fully segregated market channels	Ban on sales of GM foods or requirement of warning labels that identify GM foods as unsafe for consumers
INTELLECTUAL PROPERTY	Patent protection for all biotechnology products, plus plant breeders' rights under UPOV 1991	PBR under UPOV 1991	PBR under UPOV 1978, which preserves farmer's privilege	No patent protection for plants or animals, or lack of enforcement
PUBLIC RESEARCH INVESTMENT	Public investment on and donor support of crop transformation capacity	Public investment to breed into local varieties the desirable traits of GM crops already transformed elsewhere	No significant public investment on local breeding or transformation of GM crops; allow donor funding of GM trait transfers through conventional breeding	Neither public investment nor donor funds on the development of any GM crop technology

Source: Paarlberg (2001)

Policy options will also depend on the prioritization of the policy goals. If food security is the overriding policy aim, a policy initiative led by the Ministry of Agriculture which develops a strategy for food security and biotechnology might be appropriate. The initiative might call for larger investment in research by the public sector, aimed at developing crops and varieties, GM and non-GM, that address key development needs already identified. In donor-recipient countries,

support could be called upon from foreign donors to support such initiatives. The governments of the Netherlands, Denmark, U.K and US have given such assistance to countries such as Kenya in the past aimed at enabling priority-setting processes or providing direct support to research.

If sustainability is the key driver, a strengthening of biosafety provisions may be appropriate. This might require closer cooperation with Ministries

of Agriculture and Trade to ensure that imports and exports meet strict biosafety requirements and quarantine restrictions, as these are now often ignored in routine trading transactions involving modified crops. New mechanisms of coordination between these departments may be necessary to ensure that biosafety and broader environmental concerns are mainstreamed into all steps in the decision-making process. This may also require a strengthening of capacity at lower levels where state and sub-state agencies are responsible in countries such as India, for example, for overseeing biosafety at the laboratory level.

If the adoption of a particular biotechnology application is seen as a vehicle for increasing growth through exports, a key role for the Ministry of trade and international affairs (or their equivalents) would be envisaged. Biotechnology might be identified as a priority within a new trade and competition paper and resources required to serve this new objective. It would be the responsibility of this ministry to promote biotechnology in overseas markets while ensuring that national trade rules meet all the countries' obligations under the Biosafety Protocol and WTO agreements (the relevance of international commitments will be further analyzed below). If

a link has been made to addressing food security through growth opportunities for farmers who can sell products on the domestic market, then a more important role for the Ministry of Agriculture may also be envisaged to provide the right support to make sure this policy objective is realized.

If attracting foreign investment in biotech is seen as the key way to either generate growth and/or help to tackle food security issues, then a revision of patent laws and regulations concerning plant breeders' rights may be appropriate. If the goal of promoting growth has been strongly related to the pursuit of food security, such revision would have to take into account points of conflict with existing or necessary protection of farmers' rights and provisions on access and benefit-sharing identified in article 8(j) of the Convention on Biodiversity, as well as existing exceptions and rights owed to plant breeders.

Another way of considering policy options is presented in Box 8. National policies are identified with a distinction between those concerned with access to the technology and those concerned with utilization. Each of these two broad policy categories contains specific policy objectives and corresponding instruments.

Box 5. Policy Instruments in Alternatives Biotechnology

		POLICY GOALS	INDICATIVE INSTRUMENTS	
ACCESS	Creating an enabling environment for the development of biotechnology	Making explicit government support for biotech.	National Strategy Documents, biotech. action plans,	
		The promotion of direct foreign investments	Regulations for capital markets and foreign participation in input markets	
		Facilitate trade in the agricultural inputs sector	Tariffs and quarantine legislation	
		Establishment of biosafety regulatory framework that is transparent in its requirements of importers and those seeking approval for particular crops.	National biosafety committees, training programs, international – regional harmonization of regulations and procedures, funding for research on biosafety related issues	
		Implementing intellectual property regulatory mechanisms	Plant breeders rights (UPOV78, UPOV91), patent laws covering biological materials and processes, trade secret protection and trademark legislation	
	Development of local R&D capacities	Consolidating / improving existing agricultural research capacities, particularly in relation to crop improvement	Increased investments in existing research institutions Regional /international networking mechanisms	
		Increasing public investments for R&D and human resources development in areas related to biotech	National biotechnology program/strategy	
		Improving research org. and management mechanisms to facilitate inter-institutional work (public-public as well as public-private)	Networking and project funding, human resources and personnel policies that allow scientists to move between institutions, joint venture mechanisms.	
		Promoting private sector participation & investments in R&D activities	R&D grants and subsidies, tax credits	
		Facilitate participation of domestic institutions in international R&D efforts	Funds for project preparation activities.	
		USE	Development of industrial and marketing system capabilities	Consolidating / improving the organization and functioning of input markets; in particular seed production and distribution systems
	Facilitate the creation of industrial capacities to exploit biotech. products and tools			Risk & venture capital mechanisms, incubators, technology parks
Improving logistical capacities in the agricultural marketing systems	Public investments in logistical systems, credit lines for infrastructure development at the farm and local levels			
Developing quality identification / certification systems for agricultural inputs and products	Establishment of labeling standards, identity reservations systems, regulations for private certification services.			

### Managing policy trade-offs

Although equally valid in themselves, policy objectives and options relevant to agricultural biotechnology may compete and be in conflict, pulling governments in different directions at the same time. The development of policies to promote a domestic biotechnology industry or a decision to invest in modern biotechnology research assumes a set of national priorities in which biotechnology has a key role to play. This may undermine the policy options that see a smaller or even non-existent role for biotechnology, which Paalberg characterizes as *ëpreventive*.<sup>1</sup> Likewise, a national moratorium on the importation of GM crops – as countries such as Bolivia, Croatia and Egypt have established in the past – leaves little scope for more promotional policies such as tax breaks for the purchase of essential equipment to develop GM crops, which India has endorsed, for example.

In addition, even where policies might be complementary, there tends to be a lack of coherence in most policy-making on biotechnology. Policies on biosafety, for

example, often relate poorly to policies on technology promotion. Difficulties in reconciling patent protection and farmers' rights provisions are common. Such conflicts may be inevitable, deriving, for instance, from unresolved conflicts between international treaties. The important issue at the national level is to find a process for establishing and acting on priorities when conflicts do occur. It is a matter of prioritizing policy goals and options, and realizing existing synergies.

Having noted above some of the policy goals and options that governments have at their disposal, Box 9 below identifies some of the key *cross-cutting* trade-offs between competing policies that developing countries, in particular, face. These trade-offs exemplify potential tensions, without necessarily constituting “either/or choices.” For example, it is possible to have public and private capacity-building at the same time; or, in the design of a national biosafety system, to incorporate elements of regulatory systems which are product-based.

#### Box 6. Potential Policy Trade-Offs in Agricultural Biotechnology

<i>Innovation and intellectual property protection</i>	Promoting and protecting innovation in the public and private sectors, while allowing smaller producers and farmers access to public germplasm and technologies useful to their needs.
<i>Trade and economic policy</i>	Seeking improved access to key export markets and reductions in subsidies for producers in those markets, while maintaining support for rural livelihoods and food security.
<i>Research and development</i>	Promoting private leadership on agricultural biotechnology in R&D, investing in a public agricultural research system driven by priorities of access, affordability and food security, or seeking public-private partnerships.
<i>Biosafety risk assessment and management</i>	System based on substantial equivalence, a fast-track, one-stop approval process that encourages investors, yet may undermine confidence in the process and public trust; or a specific regulatory system tailored to unique political, cultural, economic as well as agro-ecological needs, which is better able to capture multiple risks and unique country needs but likely to face resistance from commercial developers.

<b><i>Public participation</i></b>	Involving the public and all relevant stakeholders, providing all relevant information, which will ensure an inclusive and balanced discussion, but may be slower, more costly, and frustrating for the private sector; or involving only regulators, applicants, and selected stakeholders on the basis of commercial confidentiality.
<b><i>Enforcement</i></b>	Establishing state monitoring on rules on identification, traceability, and liability, which is essential but may need to consider limits of government capacity, particularly in settings in which there may be an important complementary role for firm-level enforcement; or private enforcement through intellectual property rights, or technological mechanisms.

### Policy space for determining a regulatory framework for agricultural biotechnology

An important consideration in identifying and selecting policy options in various areas is the effective policy space available. Limits to this policy space may be both legal and political. From a legal perspective, international instruments addressing agricultural biotechnology determine certain commitments that national policies must respond to. There are a number of relevant agreements, which include several WTO rules – including those on agriculture, technical barriers to trade, sanitary and phytosanitary measures, and intellectual property – and the Biosafety Protocol. This situation is compounded by the lack of coherence between these agreements in some areas.

An example of a critical tension that is coming to the fore in the regulation of GMOs arises in the case of public participation. The increasing emphasis on public participation in the design of regulations, not least within the Biosafety Protocol itself, sits uneasily with moves by bodies such as the WTO. This becomes clear from reading the details of the full evaluation of how governments are interpreting and implementing their commitment to fulfil Article 23 of the Cartagena Protocol regarding the public involvement in the design of their National Biosafety Frameworks (Glover, 2003). Engaged publics sought to raise issues about why their society needed biotechnology, as well as broader social, ethical, moral and religious

issues regarding the technology's development and application which were subsequently found to be 'off-limits' in terms of those issues that were presented to them as legitimate to discuss and which governments were in a position to act upon. Policies and measures for which there may be popular demand, such as labelling, comprehensive and precautionary forms of risk assessment, forms of trade protection for the poor, restrictions on investment in domestic seed markets or even moratoriums on the trade in GMOs, are increasingly difficult to enforce on the basis that they are incompatible with global trade accords.

In addition, political pressure may arise both in an international and national context. Sometimes, there is a link between the legal and political limits to policy space. International agreements may provide a buffer from political pressure, allowing a government, for example, to take stricter biosafety measures on the basis of multilateral consensus. In addition, ambiguities and tensions among these agreements may provide a political opportunity for countries to adopt a variety of national political strategies regarding the regulation of biotechnology products, and in so doing, preserve decision-making autonomy. Millstone and van Zwanenberg (2003) argue that there is sufficient ambiguity in the respective accords dealing with these issues that developing countries can carve out for themselves a broad

domestic priority-driven agenda without fear of direct conflict with WTO rules.

Regardless of the international legal framework, there is clear political pressure to adopt standard approaches to risk assessment and regulations that are minimally disruptive to trade. This pressure is reinforced by the actions of GM exporting countries lobbying weaker governments on a bilateral basis, and using the leverage provided by aid and the looming threat of trade sanctions against non-compliant countries. Pressure to fashion a narrow system of biosafety regulation that prioritises market access also comes from the biotechnology industry itself, seeking minimal disruption to the international trade in GMOs.

Only more powerful developing country governments such as China and India may be in a position to accept commitments on their own terms and to resist pressures which they feel go against their national interests. Most developing countries, on the other hand, find themselves torn between WTO pressures to open their markets to agricultural imports and resistance from farmers' groups whose livelihoods may suffer from sudden exposure to global markets; they find that their ability to act upon concerns regarding the socio-economic impacts of GMOs on incomes, livelihoods and food security are constrained by international instruments which only deal with the environmental implications of the technology, and they find that global rules on intellectual property rights sit uneasily with indigenous traditions of innovation and ethical concerns regarding the patenting of living organisms, for example. As Zambia, Bolivia and India, amongst others have also discovered, when a leading GM exporter is also cast in the role of aid donor, the temptation to link the two policy goals is overwhelming, thereby bypassing altogether processes of national deliberation regarding the technology's acceptability to a society.

Many of the case studies explored in this study demonstrate complex patterns of manoeuvring on the part of governments to buy themselves time and space to define for themselves a biotechnology strategy that reflects their priorities, or to advance the commercial prospects of domestic rivals to global biotechnology firms. Biotechnology

companies frequently complain about the role of scientists from national agricultural research centres, with their own commercial interests in biotechnology development, in vetoing competitors' applications for approval on government committees. Likewise, in the face of pressures from investors about alleged delays in certifications for imported GM products, the government of China was able to defend its actions with reference to the time frame of 270 days allowed under the Cartagena Protocol on Biosafety.

Given what is at stake in the global debate about biotechnology, it is unsurprising that so many powerful forces have been brought to bear upon governments that are expected to balance the risks and opportunities associated with the technology in their decision-making about its role in their national development. From multinational companies to vocal civil society activists and well organised scientific communities, competing interests are aligned to press governments to adopt their positions. The extent to which countries are able to resist such pressures, to preserve their own decision-making autonomy, depends very much on the state in question. 'Bounded autonomy'<sup>67</sup> describes the policy space that governments are able to preserve in the face of these pressures in which they can formulate and implement national development strategies. Regarding biotechnology, the issue is the ability of governments to exercise political and social control over the technology in ways which serve broader developmental ends.

The nature of state-society relations is central in this context. In cases in which the state is insulated from civil society, such as in China, the early and aggressive development of GM crops was attributed, at least in part, to the absence of activist pressure (Paarlberg, 2001; Newell, 2003). Likewise, Paarlberg (2001) relates the role of NGOs, particularly western-based activists, in the more precautionary approaches to biotechnology adopted by governments such as India and Brazil in decision-making about biotechnology. It is important, however, not to overlook the many other sources of domestic resistance to technology development, even



within government, as well as genuine public concern regarding the scope and pace of the technology's development.

The degree of scope that governments have to make free choices about biotechnology development and regulation is a function of a number of factors. One is a government's own perceived interest in the issue and the extent to which biotechnology is prioritized as an area of strategic economic importance. For a country like Argentina, seeking to become a global leader in GM products, the assistance of industries in designing regulations to support this goal is, of course, welcomed. Other countries are more ambivalent about their relationship with biotechnology firms because they are unsure of where to position themselves in the global marketplace for agricultural products. China and Brazil, for the reasons given above, might fit into this category.

Where a country is located within the supply chain also has a bearing on their ability to resist pressures to alter regulations according to the

preferences of buyers. Developing country firms seeking to export to Europe or North America may be forced to meet the regulatory requirements of those countries. To gain a share of global markets, countries such as China and India have to apply measures in consistent and non-discriminatory ways in order to be consistent with global trade rules.

Regulations are not only exported through bilateral governmental pressure, or through efforts at harmonisation orchestrated by international organisations, but also through the vehicle of the supply chain and inter and intra-firm trade. A range of informal, bilateral, trade, aid and market-based pressures have been used to constrain those countries adopting regulatory models threatening to the interests of biotechnology exporters. Such pressure seems to sometimes be more of an immediate catalyst to action than well-intended but abstract commitments contained in the texts of global legal instruments, as well as a determination of the national policy objectives and relevant options.

## V. PUBLIC PARTICIPATION

The prior section discussed the importance of identifying key overarching policy goals which will help to assess the potential contribution of agricultural biotechnology; determining the way in which the technology is to make this contribution through, for example, the production of needs assessments; and establishing the policy and regulatory options available to support policy goals. During these steps, as well as in the final determination and implementation of the national policies on agricultural biotechnology, engaging all relevant stakeholders and the public in general is important to enable an inclusive and balanced debate.

It is true that activities covered in Section IV are usually undertaken within governments, and it is only once priorities have been pre-determined and means identified that the public is invited to participate in discussions about policy implications of proposed changes. However, there is significant scope to involve a range of interested and affected parties in all steps of decision-making. There is a critical relationship between *policy objectives* and the *policy-making process*. Policy-making processes that involve key stakeholders are better able to set priorities and identify the means of delivering them. Conflicts and trade-offs between (different policy) goals and priorities can be identified, discussed, evaluated and acted upon through open and honest processes of engagement.

In addition, given the potential risks and benefits associated with agricultural biotechnology,

### 1. Purposes and Choices of Objectives

Public participation can serve different purposes. At one end of the spectrum, public consultations can be used in a 'market-research' function to ensure that biotechnologies become accepted by a sceptical and worried public. At the other end of the spectrum, participation can be used to deepen a democratic process in which citizens are entitled to know about the impact of technologies on their economy, society, and environment and to make their views known. In

perhaps especially for developing countries, it is important to put decisions within a broader context of public policy debate about the future of food and agriculture. As consumers, employees, parents, producers and citizens, people have a right to be involved in decisions which have the potential to affect profoundly the way they live. All governments have the obligation to encourage public consultation and participation in the design of biosafety policies under the Cartagena Protocol, but unfortunately only a few have used the opportunity to launch a wider public debate about agricultural futures in their countries in which biotech may, or may not, have a key role to play.

The present section suggests ways in which governments can facilitate and enable public participation in the process of priority-setting, regulation, and implementation. Using a variety of methods of public participation, tailored to national needs and resource constraints, governments can seek to weigh the *pros* and *cons* of different agricultural strategies, moving from questions about whether to adopt biotechnology to critical questions about what economic, social or environmental needs biotechnology can and cannot address. Though particularly focused on the ways in which publics can be brought into biosafety decision-making, these tools, strategies and lessons can, for the most part, apply to decision-making around related trade, intellectual property, and broader agricultural issues.

any public participation process, it is important to determine and communicate the purpose and expected follow up — how decisions will be taken forward or acted upon. Clarity and honesty are necessary to avoid a situation in which people are being asked to lend credence to decisions that, in reality, have already been made.

In terms of the structure of public participation, the purpose shapes what approaches are likely

to be most useful. For example, opinion polls about the adequacy of biosafety regulations give a snapshot picture of whether there is public trust in a regulatory system, but they

#### Who participates?

An important aspect of all participatory processes is the identification of stakeholders and analysis of their interest. This is more complex than commonly imagined. There is no simple, proven method for stakeholder analysis in the formulation and implementation of policy, but it is vital that actors convening participatory processes consider certain issues

#### Who creates the space for participation?

In the development of national policy and regulatory frameworks, the expectation is that the government provides the information, leads the consultations, or calls for participation. Some countries have a law of public participation, such as in Bolivia. Laws on the right to information, as in Norway or the Aarhus Convention, make it easier for the public to be meaningfully involved in decision-making about biotechnology.

Spaces or opportunities for public participation, however, can also be created by other actors. Who creates the space has implications for what can happen within it: a government might be expected to take up and utilize more readily the outcomes from participatory deliberation in a space that it has created itself than from a discussion promoted by an NGO. On the other

#### Levels of participation

There are different degrees of participation. Information-sharing is the lowest level. It does not in itself constitute a significant degree of participation, but it is a precondition for all other types of participation. Consultation means soliciting views without necessarily committing to act on those views. Joint decision-making and citizen-led initiatives are, in this scheme, the highest levels of participation. Most activity in the area of biotechnology is confined to the first two levels at the moment, but there are also examples

do not involve the public in how decisions are made. The following sub-sections examine some of the considerations and options for the design of participation.

carefully. These issues include how stakeholders are identified and by whom; the heterogeneity of interests and knowledge that they bring to the process; the fact that different stakeholders will want or need to be involved at different stages in the process; and that it is probably neither desirable nor feasible for all stakeholders to be involved at all stages.

hand, by opening a space for participation, the government is in a position to unilaterally set the agenda, dictate what constitutes acceptable outcomes, and define what is within limits and what is off-bounds.

Different kinds of space are not necessarily antagonistic. In Brazil, India and parts of the EU, there are a mixture of spaces created by governments and spaces created by NGOs eager to influence the course of decision-making. Citizen juries and other NGO-led processes can be very effective at identifying the concerns of groups that are often overlooked in government led consultations, such as poorer farmer groups. Government-led consultations may be aimed at drawing on the expertise of environmental NGOs in the design of their biosafety framework.

of citizen-led initiatives. There is no reason to assume that one level automatically leads to the next, or that a process must encompass the full set of steps to be valid. But it is useful for all interested parties to clarify, through prior reflection and continuous reappraisal, the levels of participation that they are seeking and those that are feasible within given constraints.

There is no one way of designing a participatory approach for the development of a biotechnology

framework, but a review of recent experiences demonstrates a number of innovative practices which have been positively received in the countries in which they have been used:

- *Consultations:* In the Netherlands, when a draft decision on the deliberate release of GMOs is deposited for inspection, anyone may submit written reservations to the administrative authority. In the UK, all proposed releases are advertised and placed on a public register for the public to comment. Governments can facilitate internet dialogues with the public, as in China, or as in Canada, encourage people to submit comments via the web that are then compiled in a report and distributed during a multi-stakeholder consultation.
- *Multi-level consultations:* Many countries have organised these at the state and federal levels, including parliamentary hearings. Public hearings can be organised by independent councils or local authorities for all approvals, as in Denmark, with reports of the consultation being published afterwards. In Denmark, consultations have also been organised at the neighbourhood and workplace levels even for GMOs for contained use only. In the UK farm-scale evaluations of GMOs have been conducted on sites decided on the basis of local consultations.
- *Evaluation:* Stakeholder Forums, such as the African Biotechnology Stakeholders Forum, can be set up to review biosafety procedures on an ongoing basis. Key to their success is honesty about areas of uncertainty and lack of scientific understanding and the need for new procedures to cope with this.
- *Independent Advisory Committees:* Examples include the ACRE group or the Independent Scientific Steering Committee in the UK. NGO-led and business-led consultations also have an important role to play as business initiatives in India and the use of citizen juries in Brazil and India suggests. These help to draw into the process the views of stakeholders often missed by government-led consultations. NGOs with a long and credible reputation for working with local communities can play an important part in using participatory methods to consult such groups. ITDG (now Practical Action) have done this to positive effect in Zimbabwe.
- *(Royal) Commissions:* These can be independent bodies that produce recommendations, such as in New Zealand. In this case, the Commission looked at the risks and benefits of the technology, as well as broader public interest issues including human health and the adequacy of regulatory processes. It was also able to target the particular needs of indigenous groups such as the Maori through workshops and fora for young people about the safety of GMOs.

#### Information-sharing vs. information-gathering

Information sharing is indeed an essential and basic building block of participatory processes; but for all stages of participatory processes – including information-sharing – to be designed, facilitated, and sustained effectively, information-gathering is also needed. To know what sort of information needs to be provided, in which format, and to whom, a government needs first to know who the interested public is, what its concerns and interests are, and what access it has to different kinds of information or media. There is a range of participatory techniques and approaches for gathering information, which can help to orient

information-provision and other aspects of engaging the public in policy processes.

There are many tools that countries have used to disseminate key information about biotechnology and biosafety to their publics and to promote public understanding and awareness of these issues. Not all are equally accessible to all interested parties or participants. Access to information-technology (IT)-based communication, for example, is very limited for most people in large parts of Africa, Asia and Latin America. For many countries, lack of factual information about biosafety remains

a key problem. For other countries, there is a plurality of information sources, but their neutrality and independence is often questioned. A key role remains for governments to take a proactive role in widely distributing strategic information to the public, both about their rights as citizens and consumers and how to exercise them, as well as basic background information on biotechnology.

Tools for information and education include:

- *Surveys of communication needs:* In New Zealand a benchmark survey of a representative cross-section of the population was undertaken to assist the government in the development of a public information campaign.
- *Information Dissemination:* Through instruments such as leaflets that explain the regulatory process and how people can be used in decisions, translated into local languages, and distributed widely and free of charge. Creating Councils, bureaus and networks to communicate with the public on biosafety issues, as has been done in Brazil, Poland and Canada can make a difference, but to be credible they have to be independent from biotech companies that currently sponsor many of them. Kenya's Interlink Rural Information Service plays an important role in disseminating information on biotechnology to rural areas. The Biotechnology Trust of Zimbabwe also seems to have been effective at facilitating debate and raising awareness about biotechnology development in Zimbabwe.
- *Using the media:* Publishing details of new approvals in local and national newspapers provides another way of informing the public. To make the best use of the media, some training for journalists in biotechnology issues may be necessary, as has taken place in Kenya and elsewhere. Improving the quality and accessibility of information released to the media and being cooperative rather than secretive and defensive with the media improves the chances of getting balanced and accurate coverage.
- *Awareness-raising about participation:* Advertising events and meetings in local media is essential. Making the public aware of forthcoming government meetings is also important to encourage people to submit comments. In Brazil, for example, although meetings of CTNBIO take place behind closed doors, agendas for the meetings are posted on the web site before the meetings.

### Representation and intermediation

Invariably, attempts to share information, consult or foster the participation of the public will engage more readily certain sections of the public than others. Since resources for information-sharing, consultation and participation are always finite and are often scarce, governments tend to reach out only to those who claim to be intermediaries or representatives of these majorities (such as NGOs or trades unions). This raises serious questions about who represents

whom, how, and by what means they were selected or identified. Again, resource constraints usually preclude governments investigating too closely the validity of 'representatives'; but the general point remains that unless targeted efforts are made to extend information, consultation and participation to specific stakeholder groups, coverage will likely be patchy, reproducing information inequalities and a limited circle of participation.

### Accountability

The credibility of public participation initiatives appears to be highly contingent on the degree of accountability and responsiveness that the public senses on the part of the convening institutions. Governments would do well to address in advance questions of accountability to participating

members of the public. How strong a commitment can be made at the outset to incorporate inputs made by the public in consultations? Will feedback be given? Where inputs are not incorporated, will explanations be provided as to the criteria for rejecting them?

### Points of procedure

Clear procedures for constructing spaces for public participation are essential. There are many recognised and recurring problems for practitioners to be aware of, as is described in Box 10.

### *Challenges of Public Participation Procedures?*

#### EXPECTATIONS:

- Insufficient transparency on part of convening institution(s) as to their expectations and parameters of process;
- Insufficient attention to investigating interested parties' expectations and reconciling these with expectations of convening institution(s);
- Lack of clarity over who is accountable for the process and its outputs.
- Timing:
- Insufficient notice given to interested parties of forthcoming events or processes;
- Insufficient time allowed for genuine consultation or participatory process to occur.

#### INFORMATION:

- Not disseminated widely enough or in appropriate languages, styles or formats;
- Not disseminated in good time for interested parties to prepare their inputs in timely fashion, including consulting with constituencies if they are present as representatives;
- Not enough access to alternative, impartial analysis, produced by actors other than the principal institution(s) involved;
- Inadequate attention by convening institutions to provision of feedback to those consulted/participating on what happened to their inputs – on what basis these were/were not included.

#### REPRESENTATION:

- Consultation and participation by invitation only, using criteria that are not transparent nor devised on the basis of close knowledge of the full range of interested parties;
- Those parts of the population which are hardest to reach – the poorest, furthest from capital city etc – not sufficiently represented.

#### FOLLOW-UP:

- Insufficient provision made for conducting follow-up with all parties involved;
- Failure to take into account likelihood of changes in government etc which could threaten sustainability of process.

## 2. Public Participation in the Different Stages of a Biotechnology Strategy

Though the focus of this document is on the design stage of a coherent biotechnology strategy, the policy process for a biotechnology framework can be seen as moving through several stages: development, implementation and monitoring. Each of these stages presents different challenges, and potential spaces for varying degrees of stakeholder participation and deliberation about policy options. Box 11 describes some of the

choices and potential processes and tools for the various stages of an agricultural biotechnology framework. In some ways these approaches can be considered part of a cycle of feedback loops, through which questions about the scope and nature of biotechnology regulation are continually revisited in the light of practice and subsequent evaluations of their effectiveness and popular support.

### Box 7. Choices and Tools for Public Participation in Different Stages of Agricultural Biotechnology Policy-Making

STAGES	CHOICES	PROCESSES	TOOLS
<i>Development</i>	<ul style="list-style-type: none"> <li>Who should participate in the design process?</li> <li>Are people able to effectively participate?</li> <li>Which institution is responsible?</li> <li>Which issues need to be considered, which do not?</li> </ul>	<ul style="list-style-type: none"> <li>Identifying key stakeholders, going beyond groups that identify themselves as stakeholders</li> <li>Ensuring adequate legal frameworks (rights to information, access to decision-making) are in place.</li> <li>Ensuring people are sufficiently informed about the issues to engage meaningfully with the process</li> </ul>	<ul style="list-style-type: none"> <li>Local and regional consultations to discuss issues and solicit views.</li> <li>Laws enabling public participation and access to information.</li> <li>Decision trails showing how views will be carried forward, follow-up explanations about how and why inputs have or have not been used</li> </ul>
<i>Implementation</i>	<ul style="list-style-type: none"> <li>How far to include people in decisions about:</li> <li>The roles, duties and powers of responsible agencies</li> <li>Mechanisms of reporting, public scrutiny and accountability.</li> <li>The location and design of field trials.</li> </ul>	<ul style="list-style-type: none"> <li>Openness about applications for commercialization and for patent protection.</li> <li>Openness about the purpose, location and design of trials.</li> <li>Opportunities for public comment</li> </ul>	<ul style="list-style-type: none"> <li>Using risk analogies with which people are more familiar.</li> <li>Public registers of applications under review (for crop approval, patent protection) with opportunities for public comment and obligations to respond to public comments.</li> </ul>
<i>Monitoring</i>	<ul style="list-style-type: none"> <li>How to involve people in reflection and evaluation of the adequacy of the existing frameworks of biotechnology regulation?</li> </ul>	<ul style="list-style-type: none"> <li>Sharing and explaining findings of trials, creating feedback mechanisms and procedures for acting upon these</li> <li>Feedback on trade negotiations with respect to agriculture and biotechnology</li> </ul>	<ul style="list-style-type: none"> <li>Non-specialist involvement in advisory and review committees on trade, intellectual property and biosafety</li> <li>Local level evaluations with opportunities for public comment.</li> <li>Constructing mechanisms for ongoing participatory (re)evaluation of the system for regulating biotechnology</li> </ul>

### 3. Linking Policy Objectives, Tools, and Public Participation

There are clearly numerous examples and experiences that show that the public and other stakeholders can participate in the design, implementation and monitoring of biotechnology policy frameworks. Various tools, techniques and mechanisms, both formal and informal, can consolidate and further this. However, these diverse practices also need to be thought about

in terms of the challenges associated with particular country contexts.

Box 12 draws on the previous sections to show how the policy goal which biotechnology is to be employed requires particular processes and tools to enable decision-making that is transparent, inclusive, and effective.

**Box 8. Linking Policy Objectives, Tools, and Public Participation**

POLICY OBJECTIVE	PROCESS/KEY DECISIONS	TOOLS
<i>Economic Growth</i>	Which domestic producers could benefit and how? Which export markets could be accessed? What are the pros and cons of different technology pathways? (economic gain, environmental and social costs)	National independent commission on biotechnology and the national economy. Public hearings from experts, stakeholders and those with relevant experience from other countries that have adopted related strategies Media campaigns to advertise public meetings and to encourage debate about the pros and cons of different growth-oriented strategies.
<i>Sustainability</i>	Which types of sustainability are to be enhanced? What contributions might biotechnology make? What are the trade-offs across the economic, social and environmental pillars of sustainability?	National Commission on Biotechnology and Sustainability with a mandate to solicit views from stakeholders Citizen's panel with rotating representation to provide inputs at key moments in the process Focus groups to deepen understanding and discussion of key policy trade-offs. Results compiled in a report for public discussion
<i>Food Security</i>	What sort of agricultural base does the country want/ need in 10-20 years time? What should be the balance of public-private and foreign-national investment? How to incentivise pro-poor applications of biotech? Does the infrastructure exist to deliver the technology to smallholder farmers	Demand-driven public information campaign on different technologies for combating food insecurity Independent panel on agricultural futures Complementary citizen panels on pros and cons of different agro-technology paths Consultation on appropriate policy tools to encourage R and D in biotechnology Participatory evaluations of rural infrastructure and outreach to farmers
<i>Food Safety</i>	Whose food safety standards should be adopted? Is there adequate capacity to ensure this safety? What are the costs and benefits of increasing food safety? (for producers, consumers)	Government led review of international food safety standards Public information campaign about the ability of biotech applications to increase food safety Public hearings involving experts and lay stakeholders Multi-criteria mapping to weigh importance of pros and cons of technology choices

No source



#### 4. Contexts Matter: Different Settings, Different Challenges

As we have emphasized, the framework provided in this document does not provide a one-size fits all approach to managing the complexity of decision-making around agricultural biotechnology and sustainable development. Depending on key choices and decisions made early in the process, countries will take different policy and regulatory courses. The same is true of the process they choose to arrive at these key decisions.

What works in some places is not going to work in others. A range of different factors affect the choices a country can make about processes and tools of public participation for the design, implementation and monitoring of biotechnology policy. Countries may need to consider the following issues in thinking about the sort of process useful in achieving the overall goals they have identified and that reflect the political and resource constraints they may face.

- The policy objectives for public consultation
- Available resources and capacity
- The level of civil society and other stakeholder involvement with biotechnology issues
- How to effectively target groups that are not mobilised or represented
- The history and level of understanding of participation in the country
- The adequacy of existing channels of representation into decision-making
- The balance between legal and constitutional provisions on participation and informal political mechanisms

##### Consultation and participation

The level of demand for participation and consultation is important. In some OECD countries, there are high levels of demand for participation in biosafety policy discussions, based on a marked lack of trust in scientific and regulatory institutions. However, in other cases, there may simply be no demand for participation, which will mean that efforts in this direction are largely supply driven. While this does not

- Which strategies to use at which points in the policy process and for which decisions;

In Denmark, for instance, there is a strong tradition of extensive participation at all levels of society, and critically there are resources and capacity to match this. This is reflected in the in-depth consultative activities carried out by the Danish Board of Technology. In other settings, such as the UK for example, there has been a lack of trust in official science, and so it has been important to make plenty of information available. In Kenya and Zimbabwe, while there have been concerted attempts to engage civil society in the development of biosafety frameworks, reflecting traditions of participation in these countries, resource and capacity constraints are serious issues. In China, attempts to widen reflection on biosafety issues have occurred more within the bureaucracy than with civil society.

Forms of public participation must reflect the different situations, capabilities, and stages of development of each country. Imposing unrealistic demands for participation and consultation, or advocating particular techniques, in settings where such approaches are unlikely to work is problematic. An understanding of how contexts differ is important for the development of a biotechnology policy that engages different stakeholders. This sub-section explores some of these issues, both in relation to consultation and participation, and information exchange and awareness-raising.

undermine the case for participation, *per se*, it is important to guard against assuming that all countries have the same needs and capacities. Governments may want to limit the efforts and resources committed in this direction where there is less evident demand. Political cultures are also important in this respect. Civil society takes different forms in different places, and the way it articulates itself in the policy process

varies. It should not be expected that there will be a variety of NGOs engaging in biotechnology policy networks in all places. In some it will be politically unwelcome, in others civil society will simply not have the capacity to engage.

Clear legal rights for citizens and specific obligations for states can encourage government to be more open and responsive to different actors with an interest in biosafety policy

#### Different places, different stakeholders

The range of stakeholders is another contextual factor that varies between countries. In some settings, stakeholders may be clearly identified, and well articulated. However, in other places this is not necessarily the case. Consumer and farmers groups in some of the case study countries are not well organised or resourced, and so have been harder to engage.

In addition to the degree to which stakeholders are well-defined and vocal, the precise range of stakeholders has implications for the potential polarisation of debates, and effective management of a biotechnology process. Some countries have a diverse and intense range of

#### Information and awareness-raising

The ways in which information can be exchanged is also context specific. Information is, of course, not neutral. In some instances, it can be more useful to some stakeholders than others. For example, information detailing the regulatory systems of different countries, collated and standardised, may be more useful for companies looking for investment opportunities than for rural populations. This is not necessarily a problem, and may be positive, but it should be considered in order to encourage equal engagement of all stakeholders.

It is sometimes implicit that making as much information available as possible is always a good thing. However, there are occasions

processes. However, while these can be critical, an emphasis on legal systems as a way of handling policy problems is also culturally specific. In some political systems there may be other ways to encourage inclusion and facilitate participation of different parties without specific reliance on legal mechanisms. Further, placing the emphasis on law can raise issues of efficient use of scarce resources and access in some developing country settings.

interest groups concerned with biotechnology issues. In some places there may be groups that will lose and others that will clearly gain from the introduction of GMOs (organic farmers, particular exporters or food processors, for instance). Other countries may have a biotechnology industry, or substantial research capacity that will take a strong line on biotechnology issues. The point is that the configuration changes in each country: In some places the fault lines are clear and wide, in others they are less apparent. This inevitably affects the path a country takes in decision-making. Consensus is easier to build in some places and conflict or attempts to undermine processes are more likely in others.

when it may be important to understand why a government might not want to publish all the details of GM applications and trials, and assessment criteria. In some settings, governments may feel that they are the target of campaigns by multinational corporations to dominate their seed markets. In situations in which there is ambivalence over potential GM strategies, governments necessarily have to be careful about how they manage multinationals. Multinationals may have experience and resources to use information in a way which governments cannot match. By making too much information public too early, or inviting too much engagement, governments may narrow the range of options available to them.

## Capacity issues

Finally, capacity to develop and implement biotechnology frameworks varies between different countries. There are several aspects to this. In many Southern contexts the demands on a limited number of people with expertise in biosafety can be quite heavy. There may be a lack of trained staff able to implement and monitor a framework, or facilitate others to do so.

It is also the case that stakeholder engagement with a process may also depend on how realistic

the process looks in the first place. Stakeholders may be unlikely to want to engage with a process that sets up elaborate systems, perhaps based on international models, which may be difficult to implement. Controlling GMOs is more difficult in some states than in others. A country with several international borders and surrounded by countries using GMOs, such as Brazil, may find it hard to control transboundary movements.

## VI. CONCLUSION

In a 2004 note summarizing capacity-building needs, the Executive Secretary of the Biosafety Protocol noted that over 56 percent of Parties and other governments required support in developing their biosafety laws. This is not surprising, given that the development of a biosafety law is a complex process, demanding the consideration of national needs and priorities, the consultation of all relevant stakeholders, and the establishment of an efficient yet practical legal framework. Indeed, over 120 countries around the world joined the UNEP-GEF National Biosafety Framework projects in order to develop their biosafety legislation.

Developing the broader legal and policy framework for agricultural biotechnology implicates even more considerations, options, and stakeholders. The development and commercialization of agricultural biotechnology products needs to be oriented towards economic, social, environmental, and other public policy objectives. Policies and regulations across a variety of areas are required to respond to the specific challenges and opportunities of agricultural biotechnology and ensure it serves as an instrument of sustainable development. Given the characteristics of biotechnology-based agricultural systems, for example, there are important considerations not only for biosafety but also for intellectual property and trade policy.

On the basis of the experience in agricultural biotechnology of various countries, this paper aimed to identify the considerations, options, and trade-offs policy-makers must take into account in developing a regulatory framework. A “one-size-fits-all” framework is not feasible, given the different needs, priorities, and capacities in each national context. It is possible and necessary, however, to develop and adopt an adequate approach for policy-making in trade, agricultural biotechnology, and sustainable development. Such an approach must place agricultural biotechnology in the context of broader policy goals, recognize and resolve potential conflicts

between needs and priorities, and result from an inclusive and balanced public debate.

As noted in Section IV, an initial step is determining the reason that agricultural biotechnology is being considered — that is, on the economic, social, and environmental needs that it is hoped that appropriate policies in this field will address. The potential role of agricultural biotechnology in addressing these needs must then be established. For example, agricultural biotechnology may be an important tool to achieve food security, a central concern for many developing countries. Its potential to increase the production of food staples, improve production efficiency, and provide needed nutrition is often noted. Nevertheless, the introduction of a new technology may also displace or undermine existing rural livelihoods.

To guide agricultural biotechnology to effectively address the identified needs, moreover, adequate policies will need to be developed. Following the food security example, harnessing the benefits of agricultural biotechnology will depend on the broader enabling environment for the technology, as well as on addressing the systemic problems of agriculture. Governments may also establish specific requirements in the relevant regulations — obliging applications for new GM crops to demonstrate the potential benefits to rural development. Complementary policies such as subsidies or public-private partnerships aimed at enhancing rural development may also be an option.

In this regard, this paper emphasized that there will be competing policy objectives — strategic choices will need to be made. In managing these trade-offs, several factors are relevant. The policy space available for particular approaches will differ in each national context, depending on the country's commitments under various treaties. The government's regulatory and enforcement capacities, public and private scientific and research structures, economic and trade priorities, private sector characteristics and aims, and public concerns will also impact

policy and regulatory determinations. In terms of risk assessment, for example, some countries may choose a system based on substantial equivalence – a faster, simpler approval process that encourages investors, yet may undermine confidence in the process. Others will choose an approval system specifically designed for biotechnology products, perhaps also incorporating consideration of national political, economic, and agro-ecological needs, which may better capture risks posed by the introduction of GM crops, but is likely to face resistance from commercial developers.

Section V, which addressed public participation, notes the critical relationship between the policy-making process and effectively achieving policy objectives. Beyond public consultation and participation requirements linked to biosafety, policy-making processes that involve key stakeholders are better able to set priorities and identify the means of delivering them. Few countries, however, have launched a public debate about food, agriculture,

and the potential role of biotechnology. In part, this is due to lack of knowledge as to how to embark on what is often a complex process. This section suggested ways in which governments can facilitate and enable public participation in the process of priority-setting, regulation, and implementation of agricultural biotechnology policies.

Through distilling past experiences with agricultural biotechnology policy-making, this paper aimed at contributing to the complex process of designing and implementing a regulatory framework that will respond to national needs and priorities. Given the hugely differing context among countries around the world, this paper can only provide a general frame of reference for thinking and discussion. Nevertheless, the suggested approaches should facilitate a more comprehensive and coherent process, which will assist countries in advancing towards international, regional, and national sustainable development goals.

## ENDNOTES

- 1 *The description of biotechnology and genetic modification is taken from Baumüller et al, “Biotechnology: Addressing Key Trade and Sustainability Issues,” published by ICTSD in 2007.*
- 2 Modern biotechnology does not represent, however, an alternative to conventional agricultural research technologies, but can be seen as complementary to them. Most biotechnological applications represent either tools to improve the effectiveness and efficiency of conventional approaches, or - in the case of transgenic crops - are highly dependent on the existence of established conventional breeding programs. The most likely scenario in the short and medium term will thus not be one of radical change, but rather one of technological “hybridization,” whereby new technologies will play a role in improving research and development (R&D) methodologies and diagnostics both in plant and animal production. Advances in conventional technologies will remain the primary source of growth in production and productivity. Biotechnology, however, is likely to become an increasingly important component of agricultural innovation. This in turn is likely to require important changes in the institutional set up within which innovation processes evolve.
- 3 According to CABI, towards the end of the 1990s about 65 percent of all scientific publications related to intermediate biotechnologies and close to 70 percent of those involving modern or advanced technologies come from university researchers (Trigo 2000). This picture is supported by the sparse data available as to where agricultural biotechnology capacity is located. A FAO survey of the LAC countries, undertaken in the early 1990s (Villalobos, 1997) identified more than 1000 researchers working in biotechnology related areas; the majority of them in universities, while traditional agricultural research institutions accounted for about 35 percent, and private firms, for the remainder. More recent data, also for LAC, from an ISNAR survey, also show the universities as the most active player in the field, with the public agricultural research institutions appearing only in the case of the larger countries. (ISNAR 2000). Other sources show the same situation to be true for other areas of the world (Komen and Persley, 1993, Tzotzos and Skryabin, 2000, Asian Development Bank, 2001, and FAO-AAPARI 2002).
- 4 Elements of this sub-section are taken from Baumüller et al, “Biotechnology: Addressing Key Trade and Sustainability Issues,” published by ICTSD in 2007.
- 5 According to the Internacional Seed Federation, only seven countries in the region -Brasil, Argentina, Mexico, Chile, Uruguay, Colombia and Peru- have formal seed markets in excess of USD 10 million a year (<http://www.worldseed.org/statistics.htm#TABLE%201>).
- 6 The costs of gene sequencing needed for the use of molecular markers technologies is reported to be less than 10 percent of what it was during the mid 1990s (Maredia et.al., 1999). A similar trend is true for transformation technologies, which are becoming more routine and effective as there is an increasing amount of available information coming out of on-going genomic and bioinformatics research efforts.
- 7 David J. Spielman et al, “Will Agbiotech Applications Reach Marginalized Farmers? Evidence from Developing Countries,” *AgBioForum*, 9(1): 23-30.
- 8 The exceptions are virus resistant papaya developed by Cornell University (James, 2000) and Bt cotton developed by the China Academy of Agricultural Sciences (Pray, et al).

- 9 Argentina had over 15 million ha of transgenic crops in the year 2004. Introduction into local germplasm took place through existing conventional variety improvement and hybrid development programs. This characteristic is further highlighted if one considers that all HT soybean production in Brazil -the third largest GM producer in the world, with more than 5 million Ha- and Paraguay -the fourth largest producer with almost 2 million Ha- were originally illegally introduced using Argentinean varieties.
- 10 Similar developments can be noted with respect to Bt cotton in China and Mexico (Monsanto / Delta & Pineland originated varieties), where the largest fraction of overall benefits (85 percent) has been identified as being received by farmers (Pingaly and Traxler, 2001).
- 11 When talking about environmental, food safety and consumer acceptance issues, we are essentially referring to genetic engineering techniques and GMOs, as the other main techniques (tissue culture, diagnostics and genetic markers) raise few serious questions dealing with biodiversity, consumer or ethical concerns.
- 12 UNEP, Division of Environmental Law and Conventions, "List of Acronyms and Glossary Terms," available at <http://www.unep.org/dec/onlinemanual/Resources/Glossary/tabid/69/Default.aspx?letter=B>.
- 13 For example, see: "Evaluation of Allergenicity of Genetically Modified Foods," Report of a Joint FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology, Jan. 22-25, 2001, available at [www.fao.org/es/ESN/food/pdf/allergygm.pdf](http://www.fao.org/es/ESN/food/pdf/allergygm.pdf).
- 14 There is often a strong relationship between the stringency and comprehensiveness of a country's labelling requirements and the extent to which its citizens consume food products produced by GM technologies.
- 15 Even though, as indicated, there are no good estimates of the actual costs of putting a new product through the regulatory process, a simple calculation can provide an idea of how stringent these cost may become for smaller companies and organizations. If one takes as a basis the usual 10-12 percent discount rate used for project evaluation, if the approval for commercialization takes more than 5/6 years, regulatory costs -considering only the cost of having capital immobilized and not the direct costs that may be originated in the regulatory process itself- become the largest component of the total cost, no matter what may have been the actual research costs of developing the innovation.
- 16 The overview of biotechnology and intellectual property is taken from Baumüller et al, "Biotechnology: Addressing Key Trade and Sustainability Issues," published by ICTSD in 2007.
- 17 The same applies if no international standards exist. Moreover, the standards they adopt cannot discriminate or create disguised barriers by requiring different levels of SPS protection in comparable situations.
- 18 Cartagena Protocol on Biosafety, Article 1.
- 19 Estimates indicate about a 25 percent share of the traded corn and soybeans in 2005 and in the US in ten years maybe up to 25-30 percent of all agricultural markets) (Commission of the European Communities, 2001).

- 20 The Argentinean GMO approval process includes besides the environmental and human health safety tests, a commercial impact analysis designed to evaluate the potential impact that the new event may have on market access conditions for Argentinean agricultural products (for a detailed discussion of the Argentinean systems see (Burachick and Trainor, 2001 and Trigo et.al., 2002).
- 21 The assessment that commercial biotechnology posed no special health or environmental risks was subsequently affirmed by a high-level policy report produced by the National Research Council in 1989.
- 22 Although there is strong public support for labelling, the general high level of public confidence in the adequacy of existing regulatory laws and institutions has made these public preferences less politically salient.
- 23 As an example of the high level of protection, take the 1995 modification to patent law protecting biotechnology processes from findings of obviousness if they lead to the production of new and nonobvious product. (35 USC 103 (b)).
- 24 In addition, divisions among the European Commission (a split rapidly developed between the Environment Directorate and the Directorate Responsible for Research and Development with the former favouring more restrictive regulations focusing on the process of biotechnology) resulted in the decentralization of controls over the introduction of GM innovations to the Member States.
- 25 In turn, these regulations were intended to end a de facto moratorium on the approval of biotechnology products, in effect between 1999 and 2004. The United States, Argentina, and Canada challenged this de facto moratorium before the WTO, and it was found to be - in so far it was still in place - inconsistent with international trade rules. In 2004 and 2005, several biotechnology products were approved.
- 26 Currently, limited amounts of GM corn are grown in three European countries.
- 27 "Japanese Biotech Booming and Linked with Midwest," Wisconsin Tech Network, 28 March 2005.
- 28 Threats by Korean wheat millers to boycott American wheat if Monsanto's application for GM-wheat were approved by the government, however, led Monsanto to withdraw its application.
- 29 Sang Ki Rhee, "Korean Initiatives on Biotechnology: Challenges and Opportunities," presentation to Expert Group Meeting, BINASIA, 29-30 April, 2004, Bangkok, Thailand, available at [http://www.binasia.net/binasiadownload/downloadFile.asp?file=EGM\\_CP\\_Korea\\_presentation.ppt](http://www.binasia.net/binasiadownload/downloadFile.asp?file=EGM_CP_Korea_presentation.ppt).
- 30 National Institute of Agricultural Biotechnology (NIAB). Available at: <http://www.niab.go.kr/bio/english/safety/safety03.jsp>.
- 31 There are substantial divisions with the farming community, with some sectors attracted to the efficiency gains from planting GM crops, while the majority are more hesitant due to fears of consumer resistance.
- 32 To date, the federal government has approved four plants for commercial release: two kinds of carnations, BT cotton and transgenic canola.



- 33 Survey Finds Australians Perceptions of Risk Changing,” Media Backgrounder, 2004, available at [www.biotechnology.gov.au](http://www.biotechnology.gov.au).
- 34 GEO-PIE Project, “Case Study: GMO Labeling in Australia and New Zealand,” available at <http://www.geo-pie.cornell.edu/issues/ANZlabels.html>.
- 35 According to consumer groups, although approximately 60 percent of processed food in Australian supermarkets contains GMOs, labelling is only effectively required on 5 percent. As a result, the overall impact of labelling requirements has been limited, though they have prompted food processors to examine the ingredients of many products, and whenever possible, replace GM ingredients with conventionally produced ones in order to avoid labelling and thus possible consumer resistance. Currently, GM soybeans, canola, corn cotton, potatoes and sugar beet are imported.
- 36 Secretariat of the Commission for Environmental Cooperation (CEC), “Maize and Biodiversity: The Effects of Transgenic Maize in Mexico: Key Findings and Recommendations,” 2004. The cultivation ban was lifted in 2004. Permits have since been granted for 151 releases, including for tomatoes, cotton, soybeans, and squash. However, cotton is the only GM crop grown commercially, and planting is confined to the industrialized north, relatively distant from the cultivation of non-GM cotton.
- 37 It also established an inter-agency committee for biotechnology, charged with developing and coordinating Mexican policies.
- 38 This provision is triggered only in cases where the transgenic material is above a minimum threshold of 5 percent - a level widely criticized by environmental groups as too lax. This regional agreement has, however, enabled Mexican authorities to demand more specific information from exporters about GM varieties.
- 39 To date, 77 GM crops have been approved for field trials, three of which have also been approved for commercial planting. Of the three authorized crops, only insect-resistant Bt cotton has been grown on a large-scale. China accounted for 58 percent of total production of this crop in 2003. China also imports large amounts of GM products, most notably soybeans, from the United States.
- 40 Some observers also interpret it as an attempt to take regulatory authority away from regional governments that had been able in the past to approve field trials by foreign biotechnology firms, as it happened in Hebei in 1994 with the controversial decision to introduce Monsanto’s GM cotton variety (Paarlberg, 2001: 132).
- 41 It is the State Environmental Protection Agency that is chiefly responsible for biosafety issues, attending the biosafety negotiations, participating and hosting the UNEP-GEF project (Newell, 2003; Keeley, 2006).
- 42 Working within the constraints of the country’s political system, Greenpeace mainly focuses on disseminating biosafety research (international or domestic), conducting public opinion surveys and getting food producers and retailers to exclude GM content in processed foods.
- 43 Trade concerns linked to the EU also appear to have played a critical role in the slowdown in the authorization process for GM soybean and other GM crops in that has occurred since the late 1990s (O’Neill, 2001).

- 44 The United States and Argentina are the two main exporters of transgenic maize and soybean to South Africa, and transgenic varieties of these two crops that were approved in these two countries have also largely been approved in South Africa, though based on risk assessments generated elsewhere. Although Europe is South Africa's most important agricultural trading partner, this is not the case for crops subject to genetic modification. Of the transgenic crops approved for general release in South Africa which may enter international trade, only cotton is exported to Europe (Wolson, 2005).
- 45 In particular, most South African maize is exported to other African countries, many of which restrict the importation of GM varieties. There also appears to be growing concerns about the trade implications of the approval of GMOs. A study on this was originally undertaken by the Department of Trade and Industry and now appears to have been followed up with work by the University of the Free State aimed at assisting in understanding the impact of different scenarios regarding trade implications on GMOs on South Africa.
- 46 This is distinct from some other countries where the Ministry of Environment, for example, often has less final authority over approvals than does the Ministry of Agriculture.
- 47 The permit had been awarded to Syngenta's transgenic Bt 11 maize variety, but was challenged by an NGO called Biowatch. The appeal board found that both the government and Syngenta had not appropriately followed information disclosure and other procedures as laid down in the GMO Act (Lazarus, 2004). However, rather than revoking Syngenta's permit, the appeal board chose only to modify it.
- 48 International influences have also been important in the debate in both South Africa and its neighbouring countries over food aid containing GM varieties, particularly from the United States. In the food aid crisis in 2002, it was South Africa's offer to mill maize into food aid (to prevent its planting as seed) at its ports of entry before it was sent onto other countries, which diffused the crisis to some extent (Zerbe, 2004).
- 49 The focus of public sector research has been on, inter alia, transgenic potato, sugarcane, maize, and strawberries, all of which are in various stages of development or field testing.
- 50 In 1994, with a revision in 1998, the RCGM approved the Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts, which cover areas of recombinant DNA research on plants, including the development of transgenic plants and their growth in soil for molecular and field evaluation. The guidelines also deal with import and shipment of GM plants for research purposes. India's policy on GM germplasm for research purposes is considered permissive. There are some extra bureaucratic steps required when importing GM materials, but imports have not been restricted. This is problematic because there is no clear dividing line between the approval responsibilities of the RCGM and the GEAC. For any quantity exceeding 10kg of imported GM material, there is potential for conflict.
- 51 India produces roughly about 10 percent of total world agricultural production, yet accounts for less than 1 percent of agricultural trade, in part due to agricultural protectionism (Sharma et al, 2003). Exports are also very modest despite the country's occasional large wheat stocks.
- 52 One adjustment resulting from the RCGM guidelines was higher food safety standards for GM crops. However, these standards were developed with conventional industrial toxicologists and hardly go beyond testing that would be required for pesticide residues.
- 53 Sources: Table 4 and its sources in Trigo Eduardo J. (2005b); USDA (2005b) and Trigo et al. (2002).

- 54 The initial decision to set up CONABIA in 1991 had little to do with interest on transgenic crops. It was a political response to the situation created by the unsupervised realization of a field trial of a bovine rabies vaccine by an international research institute. Once the trials became public and there was evidence that containment or appropriate information procedures had not been followed, a regulatory process was established. This occurred during the early years of biotechnology when international debate had yet to emerge, and this public policy was universally welcomed. A Ministerial Decree was regarded as an efficient way of solving a potentially important public opinion problem.
- 55 The policy was prior to the EU de fact moratorium on GM crops, which affected Roundup Ready soybeans, the main GM product at the time in Argentina.
- 56 The reports are not binding on the decision of the Secretary, nor is there a specific time period for the decision to be made.
- 57 All of these requests were made by multinational companies.
- 58 The decision could thus be interpreted as a “calculated risk” by Argentinean policy makers, aware that the EU’s de facto moratorium was coming to an end.
- 59 Source: USDA (2005c), and table 4 and its sources in Trigo (2005b).
- 60 Argentina has lodged a complaint with Mercosur officials, alleging that the new labelling rules constitute non-tariff barriers to Argentina’s products sold in Brazil.
- 61 Law 9,456 of April 25, 1997, establishes the legal framework for plant variety protection for both biotech and non-biotech varieties, but the law does not favour one over the other.
- 62 The initial effort to define a national biotechnology policy in Kenya was driven by interest in a specific crop, namely a virus resistant potato, which Monsanto had offered to make available for farmers in the developing world.
- 63 While the committee has 15 members from various ministries and universities, its full-time personnel consists of just one individual without personal research facilities. Because of these constraints, Kenya’s NBC is afraid of being accused of not following its own biosafety guidelines strictly enough.
- 64 The World Bank has supported regulatory capacity building under its National Agricultural Research Project, providing funding of USD 75 millions.
- 65 U.S. agricultural and food exports over the last five calendar years average USD 32.2 million with over 80 percent being food aid and monetized shipments under Food for Progress - the most important being corn and vegetable oils which had transgenic content.
- 66 The case of Zambia, however, should be noted. There, concerns were expressed regarding the safety of food aid even in a condition of food scarcity. Similarly, the recent controversy in India regarding levels of pesticides in drinks suggests that considering only wealthier countries to be concerned with food safety issues is a false perception.
- 67 For a fuller development of this argument and analysis see Newell (2006).

## REFERENCES

- AfricaBIO undated. Consumer Knowledge on Genetically Modified Foods. [South Africa] Available at <http://www.africabio.com/policies/survey.htm>
- AgBio Taiwan. Available at: <http://agbio.coa.gov.tw/english/english.asp>
- AgBios database. Available at <http://agbios.com>
- Agricultural Biosafety Clearing House (ABCH), GMO Status in Korea, obtained at: <http://kabic.niab.go.kr/bio/english/safety/safety03.jsp>
- American Seed Trade Association (ASTA) and Biotechnology Industry Organization (BIO) (2007). Letter to Mr. Michael Yost, Administrator, Foreign Agricultural Service, U.S. Department of Agriculture, June 29, 2007. Available at <http://www.bio.org/foodag/action/20070629.pdf>
- Asiabiotech Report (2005), obtained at: <http://www.asiabiotech.com/readmore/vol09/0918/tw.html>
- Asian Development Bank (2001). Agricultural Biotechnology and Asia's poor, ASIAR.
- Baumüller, Heike, et al. (2007). Biotechnology: Addressing Key Trade and Sustainability Issues. ICTSD.
- Biotechnology Industry Organization (BIO) (2007). Letter to Sybia Harrison, Special Assistant to the Section 3301 Committee Office of the United States Trade Representative, January 9, 2007. Available at <http://bio.org/ip/international/200702.pdf>.
- BIO (2007b). Biotechnology Industry Facts. Available at [www.bio.org/speeches/pubs/er/statistics.asp](http://www.bio.org/speeches/pubs/er/statistics.asp).
- Brookes, Graham and Peter Barfoot (2005). *GM Crops: The Global Socio-economic and Environmental Impact – The First Ten Years 1995-2004*, Dorchester, UK.
- BuaNews (allAfrica.com) (2004). Mangena Launches Biotechnology Policy. September 9.
- Burachik, M. and Traynor P.L. (2001). Commercializing Agricultural Biotechnology Products in Argentina: Analysis of Biosafety Procedures, International Service for National Agricultural Research, ISNAR, The Hague, The Netherlands.
- Byerlee, Derek and Greg Traxler (2001). "The Role of Technology Spillovers and Economies of Size in the Efficient Design of Agricultural Research Systems", In *Agricultural Science Policy: Changing Global Agenda*, Alston Julian M., Pardey Philip G., and Taylor Michael J. (eds.), International Food Policy Research Institute (IFPRI), Washington D.C., USA.
- Commission of the European Communities (2001). Economic Impacts of Genetically Modified Crops on the Agri-Food Sector: A First Review, Directorate-General for Agriculture, Commission of the European Communities, Working Document Rev. 2.
- Conway, Gordon (1999). "The Doubly Green Revolution: Food for All in the 21<sup>st</sup> Century." Cornell University Press (March 1999).

- Dhlamini, Z. (2006). The Role of Non-GM Biotechnology in Developing World Agriculture, Policy Brief, SciDevNet.
- Evenson, R.E. and Gollin Douglas (2001). The Green Revolution: An end of Century Perspective, obtained at: <http://www.williams.edu/Economics/wp/Gollin%20The%20Green%20Revolution.pdf>
- FAO/APAARI (2002). Expert Consultation on Biotechnology in Agriculture in Asia-Pacific, GM Crops in Asia-Pacific Region - Need for Enabling Regulations and Harmonization, 21-23 March 2002, Bangkok, Thailand.
- Glover, D. (2003). "Public participation in national biotechnology policy and biosafety regulation." (Working Paper, 198). Brighton: IDS.
- Ghosh, P. and Ramanaiah, T. (2000). "Indian rules, regulations and procedures for handling transgenic plants." *Journal of Scientific and Industrial Research*, 59:114-120.
- Gold, Richard (2001). Patenting Life Forms: an International Comparison, Prepared for The Canadian Biotechnology Advisory Committee Project Steering Committee on Intellectual Property and the Patenting of Higher Life Forms. Obtained at: <http://cbac-cccb.ic.gc.ca/epic/internet/incbac-cccb.nsf/en/ah00399e.html>
- International Food Policy Research Institute (IFPRI) and Research and Information Service for Developing Countries (RIS) (2007), "Economic Considerations of Biosafety and Biotechnology Regulations in India." Proceedings of a Conference in New Delhi, India, 24–25 August 2006. Available at [http://www.ifpri.org/pubs/books/IndiaProc/IndiaProc\\_toc.pdf](http://www.ifpri.org/pubs/books/IndiaProc/IndiaProc_toc.pdf).
- International Seed Federation, the World Seed Industry Federation, World Seed Trade Statistics, obtained at: <http://www.worldseed.org/statistics.htm#TABLE%201>
- International Service for the Acquisition of Agri-Biotech Applications, The Global Knowledge Center on Crop Biotechnology (KC), Global Status of Commercialized Biotech/GM. Available at: <http://www.isaaa.org/kc/>
- ISAAA (2004). Preview: Global Review of Commercialized Transgenic Crops 2004, International Service for the Acquisition of Agri-biotech Applications, Brief No.32. Available at: [www.isaaa.org](http://www.isaaa.org)
- ISNAR (2000). Recent Development in Agricultural Development in Latin America and the Caribbean, Background Report prepared for the Sustainable Development Department, Inter-American Development Bank, The Hague, The Netherlands.
- Kameri-Mbote, Patricia (2007). "Will Kenya's Biosafety Bill of 2005 ever become Law?" Available at <http://www.scidev.net/dossiers/index.cfm?fuseaction=dossierReadItem&type=3&itemid=623&language=1&dossier=6>
- Keeley, J. (2006). "Balancing technological innovation and environmental regulation: an analysis of Chinese agricultural biotechnology governance." *Environmental Politics* 15(2)293-309.
- Komen, John and Persley Gabrielle (1993). Agricultural Biotechnology in Developing Countries, A Cross-Country Review, ISNAR, Research Report No. 2, The Hague, The Netherlands.

- Krattiger Anatole F., and von Braun Joachim, Kluwer Academic Publishers, Dordrecht, The Netherlands.
- Lazarus, Peter (2004). Decision of the Appeal Board constituted in terms of §19 of the Genetically Modified Organisms Act 15 of 1997, Report by the Chairman of the Appeal Board.
- Maredia, Mywish, Byerlee Derek and Maredia Karim (1999). Investment Strategies for Biotechnology in Emerging Research Systems, International Consortium on Agricultural Biotechnology Research (ICABR), University of Rome, Italy.
- Millstone, Erik and van Zwanenberg, Patrick, “Food and Agricultural Biotechnology Policy: How Much Autonomy Can Developing Countries Exercise?” (January 22, 2008). Available at SSRN: <http://ssrn.com/abstract=513437>.
- Morris Jane, van Rensburg J.B.J, Hoffmann John H. and Lazarus Peter (2005). Good Regulatory Practices for Developing Countries – Lessons Learned in South Africa from an Appeal under the GMO Act, Paper presented at the 9th ICABR International Conference on Agricultural Biotechnology: Ten Years Later, Ravello, Italy, July 6-10.
- NBS (National Biotechnology Strategy, South Africa) (2001). Department of Science and Technology, Republic of South Africa, obtained at: <http://www.dst.gov.za/>
- Newell, Peter (2003). ‘Domesticating Global Policy on GMOs: Comparing India and China’ *IDS Working Paper* 206, September 2003. Brighton: IDS.
- Newell, Peter (2006). “Corporate power and bounded autonomy in the global politics of biotechnology” in Falkner, R. (eds.) *The International Politics of Genetically Modified Food*. Basingstoke: Palgrave.
- Organisation for Economic Co-operation and Development (2004), OECD Patent Database.
- O’Neill, Mark (2001). “Modified Crops Advocate Fears Lost Chances Through Cultivation Ban”, *South China Morning Post*, 18 April.
- Ornamental Fish International, website: <http://www.ornamental-fish-int.org/data-area.asp?aid=9820&gid=4839>
- Paarlberg, Robert L. (2001). The Politics of Precaution. Genetically Modified Crops in Developing Countries, International Food Policy Research Institute, IFPRI, Food Policy Statement, No. 35, Washington D.C., USA. Obtained at: <http://www.ifpri.org/pubs/fps/fps35.pdf>
- Pingali, Prabhu L. and Traxler Greg (2001). “Changing Locus of Agricultural Research: Will the Poor Benefit from Biotechnology and Privatization Trends?,” *Food Policy*, Elsevier, Volume 27, Number 3, June, pp. 223-238(16).
- Pray, Carl. E. and Fuglie K. (2001). Private Investment in Agricultural Research and International Technology Transfer in Asia, AER-805, USDA, November.
- Rifkin, J. (2006). “Beyond Genetically Modified Crops”, *Washington Post*, 4 July.
- Sasson, Albert (2000). *Biotechnologies in Developing Countries: Present and Future, Volume 3: Regional and Sub-regional Cooperation and Joint Ventures*, UNESCO, Paris, Barcelona.

Secretaria de Agricultural, Ganaderia, Pesca y Alimentos, Argentina, website at: <http://www.sagpya.mecon.gov.ar/>

Sharma, Manju et al (2003). "Agricultural biotechnology research in India: Status and policies." *Current Science*, Vol. 84, No. 3, February 2003.

Tai E International Patent Office, website at: <http://www.taie.com.tw/>

Tiberghien, Yves and Starrs Sean (2003). *The EU as Global Trouble-Maker in Chief: a Political Analysis of EU Regulations and EU Global Leadership in the Field of Genetically Modified Organisms*, Council of European Studies Annual Convention, Chicago.

Traxler, Greg (2001). *Biotechnology in a Complete System of a Genetic Improvement: A Perspective on Developed and Developing Countries*, International Food Policy Research Institute, Washington D.C., USA.

Trigo, Eduardo J. (2000). "The Situation of Agricultural Biotechnology Capacities and Exploitation in Latin America and the Caribbean", In *Agricultural Biotechnology in Developing Countries: Towards Optimizing the Benefits for the Poor*, Qaim Matin, Krattiger Anatole F. and von Braun Joachim (eds.), Kluwer Academic Publishers Group.

Trigo, E. J., Chudnovsky D., Cap E. and López A. (2002). *Los Transgénicos en la Agricultura Argentina: Una historia con final abierto*, IICA, Libros del Zorzal, Buenos Aires, Argentina.

Trigo, Eduardo J. (2005a). *La Transformación de la Agricultura Argentina*, *Ciencia Hoy*, Volumen 15 No. 87, Buenos Aires, Argentina, Junio/Julio.

Trigo, Eduardo J. (2005b). *The Status of Biotechnology Policy Making in Latin-American and the Caribbean Countries*, Buenos Aires, Argentina.

Tzozos, G.T. and Skryabin, K.G. (2000). *Biotechnology in the Developing World and Countries in Economic Transition*, Chapter Four, *Country Profiles*, 41-187, (China, Brazil, Cuba, India, South Africa, Egypt, Mexico, Russian Federation, Bulgaria, Chile, Colombia, Philippines, Indonesia, Zimbabwe, Kenya, Korea, Morocco, Nigeria).

UNIDO BINAS. Obtained at: [http://binas.unido.org/wiki/index.php/Main\\_Page](http://binas.unido.org/wiki/index.php/Main_Page)

USDA (2005a), Republic of Korea Biotechnology, *Biotechnology Annual Report*, GAIN Report KS5035, USDA Foreign Agricultural Service, 15 July. Obtained at: <http://www.fas.usda.gov/gainfiles/200507/146130304.pdf>

USDA (2005b), *Argentina Biotechnology Annual*. GAIN Report AR5033, USDA Foreign Agricultural Service, 21 October. Obtained at: <http://www.fas.usda.gov/gainfiles/200510/146131302.doc>

USDA (2005c). *Brazil Biotechnology Annual Agricultural Biotechnology Report*, GAIN Report BR5618, USDA Foreign Agricultural Service, 12 July 2005. Obtained at: <http://www.fas.usda.gov/gainfiles/200507/146130270.pdf>

- USDA (2005d). Australia Biotechnology Agricultural Biotechnology Annual Report, GAIN Report AS5024, USDA Foreign Agricultural Service, 14 July. Obtained at: <http://www.fas.usda.gov/gainfiles/200507/146130258.pdf>
- Villalobos, V.M. (1997). Current Status and Future Prospects of Modern Biotechnologies in Latin America and the Caribbean. Food and Agriculture Organization of the United Nations (FAO), Rome, Italy.
- Wolson, Rosemary (2005). Country Study: South Africa, NYU Project on International GMO Regulatory Conflicts, Draft version of June, on file with author.
- World Food Summit (2006). Plan of Action.
- Yamin, Farhana (2002). "IPRs, Biotechnology and Food Security." Foundation for International Environmental Law.
- Zerbe, Noah (2004). "Feeding the Famine? American food aid and the GMO debate in Southern Africa", *Food Policy*, No. 29, pp. 593-608.
- Zhong, F, Marchant M.A., Ding Y., and Lu K. (2002). "GM Foods: A Nanjing Case Study of Chinese Consumers' Awareness and Potential Attitudes", *AgBioForum*, Volume 5, No.4.
- Zi, Xun (2005). "GM Rice Forges Ahead in China Amid Concerns Over Illegal Planting", *Nature Biotechnology*, Volume 23, No. 637.