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Public GM Innovations, Safety Regulation, and ….. Results?

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Abstract

Disputes continue to flare over genetically modified (GM) crops, and their potential to enhance livelihoods in agricultural communities in developing nations. Benefits have been documented for a few GM crops, especially insect-resistant cotton**.** However, official permission to plant GM seeds on a commercial scale has not been granted in most countries, including a wide range of crops engineered by public research institutes in developing countries. This paper will examine progress in GM crop research from poorer nations, its regulatory status and direction, and whether or not results from this work can reach farmers. It does so by examining public GM research among 16 developing countries as demonstrations of innovation, then looking at the remaining steps they face particularly with regard to biosafety regulation. Recommendations addressing the study's implications are presented in the conclusion.

1. Introduction

Worldwide, the area cultivated to genetically modified (GM) crops is planted mainly to four crops (soybean, maize, cotton and canola) in five countries (USA, Argentina, Canada, Brazil, China) (James, 2004), in technologies that have been developed mostly by the private sector in the developed world. Although there is an active public sector in the developing world engaged in crop biotechnology (see Atanassov *et al*., 2004), few publicly developed products have so far reached farmers in these countries. This is why when we discuss biotechnology in the developing world we can only speak of "potential." Many of the technologies under development could generate agronomic and environmental benefits, or enhanced nutrition of people in the developing world that could improve their income and overall well-being. Most of the benefit evaluation of GM crops in the developing world is solely based on *ex post* data for insect-resistant cotton, as approved for use in several countries.

Potentially, GM crops carry contributions towards quality-of-life improvements. Such improvements include:

- Reduction in pesticide use that could benefit farmers and their communities not only for the direct effect of decreasing expenditure in this input, but also could reduce the overall health and environmental risks associated with their use,
- Increase in yields that can boost local production of food that can benefit over community economies and can reduce the reliance on imports or food shipments,
- Technologies that minimize the effects of biotic or abiotic stresses on crop development, such as salt resistance and drought tolerance that are major constraints in less favored lands where many poor farmers are localized,
- Delivery of alternative compositions and forms of carbohydrates and fats,
- Improved provision of vitamins, with new avenues of reaching the poor.

The adoption of GM crops such as insect-resistant cotton resulted in significant farm-level benefits in developing countries. An expanding body of literature analyzes the emerging farm-level economic impacts of GM crops in developing countries. Huang *et al*. (2001), for example, estimate the impact of genetically modified, insect-resistant cotton in China. This study indicates that the novel cotton variety in general has significant benefits for farmers, compared to conventional cotton. Based on surveys conducted in 1999 and 2000, the authors reported that, on average, growers using GM cotton reduced pesticide use from 55 to 16 kg of formulated product per hectare. In addition, GM cotton adopters reduced the number of insecticide sprays per crop from 20 to 7. In addition to a 70% pesticide reduction, the authors also noted the almost complete elimination of highly toxic organochlorines and

organophoshates insecticides. Preliminary evidence in this study suggests that the use of GM cotton resulted in significant positive effects on the environment and farmers' health.

Traxler *et al*. (2001) arrived at similar conclusions in their study on farm-level impact of GM insect-resistant cotton in the Comarca Lagunera region in Mexico. The most notable changes observed were a reduction in pesticide use, an upward yield trend and a decrease in the cost of production. The result has been increased profitability — reaching a nearly US$ 600/ha net benefit during years of very high pest pressure, and equal profitability in low pest-pressure years — and an associated reduction in the risk associated with cotton production failures from insect infestations. Qaim *et al*. (2003) observe very similar effects for GM insect-resistant cotton in Argentina. They report that, on average, adopting farmers used 50% less insecticides compared to plots grown with conventional cotton. They also achieved yield increases of more than 30%.

In the developing world, insect-resistant GM maize varieties, resistant to the European corn borer have been approved for commercial planting in The Philippines and South Africa. Preliminary claims from The Philippines point to yield increases of 30 per cent and cost reductions of 20 per cent during the first year of introduction (Pew AgBiotech Buzz, 2003).

In parallel with the expanding production of, and trade in GM crops, a debate has evolved about the potential environmental and food safety risks posed by these new products. As with most innovations in food and agriculture, the real or potential effects on the environment and human health were not clear-cut in advance. Genetic modification in particular has been subject to intense public scrutiny, possibly as a result of society's lack of familiarity with GM products, and, most importantly, the potential scale and irreversible nature of any harmful effects following their large-scale release. Consequently, genetic modification and its products are commonly subject to government regulation and risk assessment.

Two of the type of risks broadly identified, relate to the possibility that crops or their relatives may invade new territory, displace existing plant communities, or reduce species biodiversity. They may have added importance in regions that are centers of origin or diversity for the crop.

- *Weediness* — the potential for a crop to become established and to persist and spread into new habitats as a result of newly introduced genes — is an issue when there is scientific evidence that acquisition of the new genes is sufficient to convert a domesticated species into a successful weed. For example, there are claims that "volunteer" (stray) herbicide-resistant canola (rapeseed) plants are persistent in Canada, and cannot be controlled by chemical means.
- *Gene flow* — in which new genes are spread by normal outcrossing to wild or weedy relatives of the engineered crop — becomes an issue if the new trait(s) confers a fitness advantage and becomes stably introgressed into the recipient relative, possibly with negative effects on biodiversity. This issue gained renewed importance following reports on the discovery of transgenic DNA in maize landraces in Mexico — a center of diversity for maize.
- *Pest and pathogen effects* include a range of possible consequences such as the emergence of target pest populations resistant to an engineered control mechanism, for example, through the expression of Bt (*Bacillus thuringiensis*) toxins that confer resistance to insect pests in plants. By introducing distinct resistance management schemes, the evolution of insect resistance can be slowed down.

- *Toxicity and allergenicity* is an issue associated with human health concerns and the safety of biotechnology foods and potential negative effects on non-target organisms, especially beneficial species (such as butterflies). With regard to human health, a particular area of concern relates to the use of antibiotic resistance markers as selectable markers in genetic modification of plants. In theory, this may lead to the development of pathogenic micro-organisms with resistance to antibiotics, although it has been concluded that the likelihood is extremely low (Kleter and Kuiper, 2003).

It should be noted that scientific evidence on *negative* environmental or health effects of GMOs has not been published to date — although, of course, their sheer spread is sometimes considered as a negative effect as such. A review of 81 EU-funded projects analyzing the environmental and health effects of different type of GMOs did not reveal any particular safety or environmental problem (Kessler and Economidis, 2001). Such findings were recently confirmed by the British Medical Association (BMA, 2004) who stated that the potential for GM foods to cause harmful health effects is very small and many of the concerns expressed apply with equal vigor to conventional foods. The BMA also identified several areas where more research is needed. However, these findings do not address the more fundamental issues raised against GM crops, particularly by civil society organizations, such as those related to ethical concerns or possible socio-economic impact.

Meeting safety standards for novel crops, as for all food and agricultural products, is now a widely accepted feature of agricultural research and development. However, GM crops have to meet new regulatory regimes or additional scrutiny beyond those of conventional crops. The need to identify/evaluate long-term health or environmental effects of GM crops arises in part because the transgenes are new to agricultural systems. Although they function the same as genes introduced through plant breeding, hybridization, introgression, and wide crosses, they are treated differently in terms of management, monitoring and evaluation. Safety considerations generally do not take into account potential benefits, such as those to be derived from the traits listed above.

As discussed in this paper, regulatory requirements in many cases present additional obstacles for public R&D institutes to move research results into farmers' fields. In addition, developing countries face a range of challenges in developing and implementing functional regulatory systems, which are discussed in section 5.

2. Purpose and Scope

The purpose of this paper is to review GM crops under development, their regulation, potential benefits, and query whether these crops will reach the farmer's field. The study of GM crops focuses on potential quality-of-life traits under research by the public-, rather than private-sector in developing countries. Regulatory necessities for GM crops are considered, comparisons with prior crop development are made, and the current state of regulation among developing countries is conveyed.

In order to ensure that research results reach farmers' fields, national research capacity should not be limited to undertaking research projects alone, but includes engagement with a broader innovation system, including specifying, accessing, interpreting and applying research. For agricultural biotechnology, research capacity also involves a spectrum of key elements and activities, including:

- Defining objectives and priorities for agricultural biotechnology;
- Developing and implementing a clear policy for (agricultural) biotechnology, and biosafety regulations;
- Developing R&D management capacity;
- Transfer of technologies, knowledge and skills to the private sector;
- Promoting international collaboration and technology transfer.

How such research capacity creates tangible outcomes requires a broader discussion of approaches and methods. The tendency now is for public research systems to develop capacity that is flexible, rigorous and actively involving a wider range of stakeholders. This includes approaches taking into account social and economic considerations, and other approaches allowing public research systems to address environmental and biodiversity concerns, resource degradation, public health issues such as HIV/AIDS, and other critical problems affecting agriculture.

3. Can Public GM Research Produce Crops with Quality-of-Life Benefits?

Currently, private industry is the most successful provider of GM crops in developed and developing countries alike. For this reason, such production is a significant concern in developing countries. Using only commercially derived GM crops may result in inability to save seed, no control over costs, and other unwanted effects of monopoly control. Arguments have been made for developing countries to consider biotechnology as part of their public-sector agricultural research agenda (Pinstrup-Andersen and Schioler, 2000). This research could provide the foundation for alternative sources of GM crops free from strong commercial control. However, until recently, no reliable data were available regarding such public research or its regulation.

A recent IFPRI study (Atanassov, 2004; Cohen, 2005) indicated that public research on GM crops has targeted species and traits of importance to developing countries; it identified forty-six successfully transformed crops being tested in developing countries (Table 1). The percentage of these transformation events — distributed by phenotype — is presented in Figure 1. Over half of the 209 events involved single genes that confer either viral or insect resistance. In nine events, multiple (stacked) genes are being tested for phenotypic combinations, such as insect resistance with herbicide tolerance.

Table 1. Number of transformations (Atanassov *et al*., 2004)

Region	Country	Number of trans. events	Sub-totals
Asia	China	30	109
	Indonesia	24	
	India	21	
	Philippines	17	
	Thailand	7	
	Malaysia	5	
	Pakistan	5	
Africa	South Africa	28	54
	Egypt	17	
	Zimbabwe	5	
	Kenya	4	
Latin America	Argentina	21	38
	Brazil	9	
	Costa Rica	5	
	Mexico	3	
East Europe	Bulgaria	8	8
All			209

Transformation events grouped by crop type are shown in Figure 2. Although cereals prevail, significant numbers of fruits, roots and tubers, and vegetables are represented, with each group containing diverse species. Progress transforming indigenous crops, is also significant. Although almost half of all transformation events are for rice, potato, maize, papaya, and tomatoes, the other half is spread over other 41 other crops, most of them indigenous, including pearl millet, papaya, mung bean, common bean, chickpea, cowpea, lupin, cacao, and coffee.

These combinations of crops and traits have great potential in areas not reached by the Green Revolution and in cases where such crops have been affected by new types of pests, water shortages, and/or where crops better suited to environmental constraints are needed. Benefits for poor farmers are directly related to the degree that such cultivars can substitute for chemical inputs. Furthermore, the products of public research carry the advantage of being free of restrictive proprietary controls set by commercial providers.

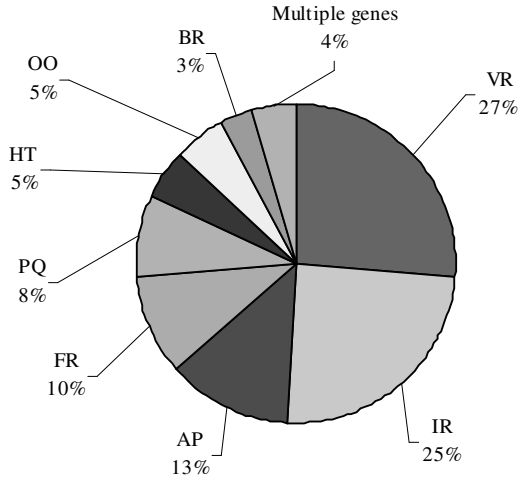


Figure 1. Phenotypic distribution and percent of total events (Atanassov *et al.*, 2004)

AP–Agronomic properties; BR–Bacterial resistance; FR–Fungal resistance; HT–Herbicide tolerance; IR–Insect resistance; OO–Other; PQ–Product quality; VR–Virus resistance.

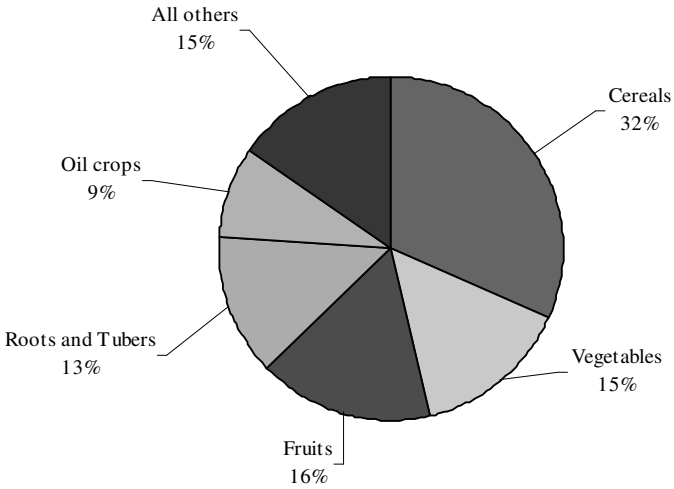


Figure 2. Percent transformation events by crop group (Atanassov *et al.*, 2004)

Data on types and numbers of research partnerships was also collected. Over 60% of these institutions are working without any partnerships. Another 23% are working public to public and only 10% were working with some kind of collaboration with the private sector. These numbers are derived as follows:

Table 2. Type and magnitude of partnerships among institutes in the 16 countries studied

Public sector partner	Number of trans. events	%
No partner	129	*61.7*
Public	47	*22.5*
Private	15	*7.2*
Foundation/Public	8	*3.8*
Private/other	6	*2.9*
All other (no private)	4	*1.9*
All	209	*100*

While partnerships (public and private) are often argued for, we see that there is virtually no experience with it now in the developing world. Institutions working alone are at a great disadvantage because they do not get access to the global expertise and knowledge that could help with their research.

4. Evolving Regional Capacities

By continent, researchers in four African countries (including North and Sub-Saharan Africa) completed 54 events, scientists in seven Asian countries produced 109, those in four countries in Latin America accomplished 38, and Bulgarian researchers produced eight (table 3). At the present time, the greatest number of events has been generated in Asia, though only the Philippines have approved a GM crop for feed, and has allowed commercial production in the field. Our work among transition economies has just started; hence, we only have data from Bulgaria for East Europe. We group by continent to review similarities and differences among neighboring countries.

These survey results by region capture several interesting points. First, while Asia is the most developed region in terms of having products across all stages of the research pipeline, the region's success is directly tied to the degree of investments in research, (for example, see report on China, Huang et al, 2001) and, the success that China (and to a lesser degree Indonesia and India) have had in insect resistant GM cotton approvals. Africa stands in sharp contrast to Asia as once all events from South Africa are excluded, there is little GM crop research elsewhere. Latin America advancement in GM crop research lies in between Asia and Africa. Again, however, once Argentina, as the region's biotechnology research leader, is separated from the other Latin American countries studied the amount of GM crop research in the region declines significantly.

Recent reviews of agricultural biotechnology research capacity in different geographic regions show a mixed picture, very much reflecting the overall state of agricultural R&D investments. Reviews on Asia (ADB, 2001) and Latin America (Trigo et al., 2002) confirm a

steady development of agricultural biotechnology R&D particularly in relatively large developing countries with well established infrastructure for research: Argentina, Brazil, Mexico and Chile in Latin America; and, China, India, Indonesia, Malaysia, The Philippines and Thailand in Asia. In these countries, human and financial resources allocated to biotechnology R&D are relatively high, experience with GMO testing and commercialization is growing, and government support programs and policies actively encourage R&D. It is no surprise that research institutes in the countries mentioned above are also actively involved in bilateral and international collaborative research programs in agricultural biotechnology.

The situation in sub-Sahara Africa stands in sharp contrast with that found in Asia and Latin America. Surveys by Komen *et al.* (2000) and Alhassan (2003) indicate that although biotechnology applications are increasingly incorporated in agricultural research programs, they primarily involve applications of cell biology (micropropagation) and disease diagnostics, while more advanced applications are found only in a handful of institutes, most notably in South Africa. Furthermore, research efforts are scattered over a wide range of products and institutes without critical mass, and most often heavily dependent on donor funding. Advancements in agricultural biotechnology are severely constrained by a lack of funds, skilled human resources, and equipment. Government priorities and policies to support agricultural research in general, and agricultural biotechnology in particular, are lacking or not being implemented.

As shown in Table 3 below, Asia conducts research on the largest variety of crops and events, followed by Africa, particularly South Africa. Bacterial resistance is the most limited trait to be researched, while the single most important group is the expression of insect resistance in Asia. As will be discussed later, such commonalities could lead to new forms of collaboration among neighboring countries, including new opportunities for exchanging transgenes and germplasm.

Table 3. Regional distribution of phenotypic traits by continent

	Crops under research	Virus resistance (VR)	Insect resistant (IR)	Agronomic Properties (AP)	Fungal resistance (FR)	Product quality (PQ)	Herbicide tolerant (HT)	Multiple genes	Bacterial resistance (BR)	Other	All
	No.	*Number of transformation events*									
Asia	30	27	39	11	6	10	2	4	6	4	109
Africa	20	18	11	8	7	5	4		1	0	54
Latin America	12	8	1	3	8	2	4	5		7	38
East Europe	4	2		4			1		1	0	8
All	46	55	51	26	21	17	11	9	8	11	209

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5. GM Crops and Regulatory Development

Clearly the extent and purpose of the research summarized above is remarkable, yet the public sector has had only limited success in getting its biotechnology projects out of the laboratory and through regulatory systems. Meeting the various requirements of regulatory systems can be demanding and time consuming, requiring additional expertise and experience. That is, institutional and national biosafety committees can require extensive amounts of data early on. Costly tests may be required to approve even preliminary glasshouse or contained field trials, with some countries requesting increasing amounts of data before a permit is issued. These tough requirements limit the number of trials that a research institute can conduct.

This raises the issue of benefits and costs of regulation. The most important benefit of biosafety regulation is ensuring that biotechnologies deployed in a country are safe and effective. In addition, a well functioning regulatory system will instill confidence in the public that the risk assessment used to evaluate new technologies, including biotechnologies, are sound and science-based. As the cost of the assessment is usually borne by the notifier, well-designed and sensible regulations will facilitate selection of the best public technologies available for resource poor farmers. Consequently, biosafety systems can incur additional costs to that of research and development. In some cases, a biosafety system having too many and diverse requirements may create additional costs to the notifier and society. These may include for example, the opportunities lost when biotechnologies having a potential high social value, may not be able to provide its net benefits to society.

Analyzing the costs of biosafety regulations is largely an unexplored area. In the study presented by Atanassov et al. (2004) and Cohen (2005), preliminary findings on this topic are provided. Data from Brazil, for example, were included on compliance costs for the regulatory approval of one event. Cost estimates include the initial greenhouse and field screening, field testing for environmental impact, and food safety measured in US$. The average per year cost of compliance per event varied from US$ 140,000 in the case of virus-resistant papaya, to US$ 800,000 for herbicide-resistant soybeans. The higher cost per event for herbicide resistant soybeans is mainly due to the requirement of performing complete animal studies.

The crops analyzed in the IFPRI study are in various stages of regulatory review in their respective countries. The total number of events decreases as lines are cut that do not convey sufficient agronomic efficacy, or if safety requirements cannot be met. For this reason, “regulatory stage” categories were defined and used to group each transformation event recorded in the study of public sector GM-crop research. Respondents were asked to indicate the stage of regulation for their respective events. Those in the experimental stage contain stable research products derived from multiple generations, beginning in the laboratory and moving to the greenhouse. In this stage, the stable expression of the gene of interest is confirmed.

The scale-up stage occurs when products advance from confined to pre-commercial trials, requiring the ability to increase seed amounts and larger areas for testing purposes. These tests may be conducted for environmental safety purposes or agronomic efficacy, or both. Finally, products are made available to farmers after commercial release, through privately or publicly owned seed companies or other institutional mechanisms. The data show a total of

127 events at the experimental stage, 44 are in confined trials, 22 are in scale-up testing (mostly in China), and 7 are at the commercial release stage (Figure 3 below; plus 8 for Bulgaria that are not classified and 1 that is "permit pending).

Events at the stage of confined testing represent the most promising public research on GM crops. These 44 events will decline in number during their evaluation. Of those listed, five countries have five or more such trials in place. However, the public sector must go beyond confined trials for safety and efficacy. It must also guarantee seed supplies to evaluate product performance on a large scale, and include experiments designed specifically for safety evaluation. However, many of the events recorded have been in multiple years of testing and now await approvals for scale-up or pre-commercial trials.

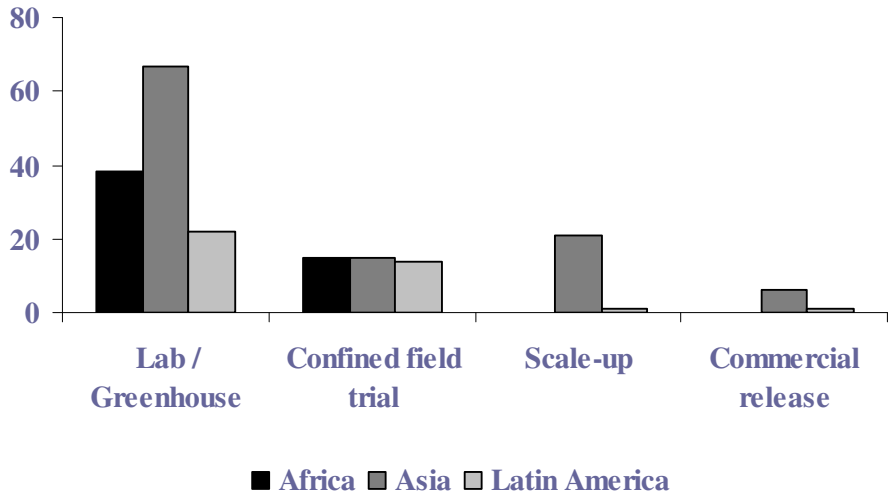


Figure 3. Public events classified by regulatory stage and region (Atanassov *et al.*, 2004)

Note: Eight transformation events for Bulgaria are not pictured in this figure, as the regulatory stage was not disclosed at the time of survey.

6. Biosafety regulations and risk assessment: Evolving national and international instruments

Designing and implementing an efficient regulatory system for decision making on GM products involves several challenges. Different countries have implemented their national biosafety systems in different ways, and a few have gained considerable expertise in reviewing and, in some cases, approving the large-scale release of GM crops. Recent studies analyzing national biosafety systems in Egypt, Argentina and Kenya document the expertise that has been gained in handling GMO applications, but also point to a number of common weaknesses in developing countries, including:

- The lack of a clear legal framework and associated regulatory and enforcement authority;
- The need to revise and re-issue biosafety guidelines, to improve their clarity and breadth;

- The need to improve the operations, and support to the National Biosafety Committees, who usually consist of unpaid "volunteers";
- Improved procedures are needed for the review of applications and decision-making, with clear timelines for response;
- The scientific basis of GMO reviews need strengthening, and with a broader pool of qualified reviewers;
- Adequate funding and access to scientific information is often not provided.

Ideally, a biosafety system would be developed from a comprehensive plan and with clear objectives in mind. However building such a system and making it operational is complicated by the fact that there is neither single best approach, nor standard that reflects national environmental, cultural, political, financial, and scientific heterogeneity. Recent studies (McLean *et al*. 2002; Traynor and Macharia 2003) apply a five-element framework for effective national biosafety system implementation:

- Clear national policies, strategies and research agendas regarding biotechnology and biosafety;
- National inventory and evaluation of priorities, agricultural policies, existing regulatory regimes, and national scientific and technical means;
- The knowledge, skills and capacity base to develop and implement a biosafety system;
- Development of regulations; and,
- Implementation of regulations—the establishment of appropriate mechanisms for risk assessment, risk management, and risk communication.

Together, these elements should form the foundation of an effective national biosafety system. The most common components of a functional national biosafety system are the following:

1. The legal framework: A biosafety law, or a (set of) relevant existing law(-s), complemented with detailed regulations and/or guidelines;
2. A detailed process for handling requests for, and issuing of permits (covering the various stages of the R&D process and commercial release); it should provide clear guidance and responsibilities for the administrative processing of applications, risk assessment procedures (including the designation of advisory committees), and decision making (including the designation of a competent authority);
3. Provisions to ensure compliance with laws and regulations, and — if so required — for the monitoring of environmental and health impacts;
4. Mechanisms for public information and participation.

A clear legal framework (biosafety law, relevant existing laws, or ministerial decrees) is necessary to ensure adequate enforcement and instill public confidence in any decisions taken. Countries developing a mandatory biosafety system have two choices for establishing legally binding regulations: (1) they can develop a new act and regulations to specifically address GMOs, or (2) they can regulate GMOs under the auspices of existing legal instruments such as acts, regulations, and ministerial or presidential decrees. In some countries (e.g., South Africa) regulatory oversight of GMOs began with nonbinding, voluntary guidelines. The designated authorities developed information guidelines and technology developers abided by these, and there is no evidence that the management of GMOs under voluntary regimes has compromised environmental safety. The benefits of voluntary guidelines include the speed by which they can be put in place and the flexibility they allow to adopt revisions incorporating new information requirements without delay.

However, in the absence of a legal instrument, the public may not have confidence that the government is adequately regulating these products, or that developers are complying with voluntary guidelines. Additionally, enforcement powers may be limited in a voluntary system.

National biosafety systems are instrumental in implementing government obligations to comply with international agreements and standards that affect biosafety decision making. The main international instruments that influence the development of national biosafety systems are summarized in the following sections.

In January 2000, over 130 governments reached agreement on the **Cartagena Protocol on Biosafety** (CPB), which now regulates the transboundary movement of *living modified organisms* (LMOs)[1] resulting from modern biotechnology. The ultimate goal of the agreement is to ensure an adequate level of protection to potential adverse effects from LMOs on the conservation and sustainable use of biological diversity, taking also into account their possible risks to human health. The protocol entered into force on September 11, 2003, 90 days after receipt of the 50th instrument of ratification[2].

The two cornerstones of the CPB are the concepts of *Advance Informed Agreement* (AIA) and the *Precautionary Principle*. AIA enables an importing country to subject all first imports of LMOs to risk assessment before taking a final decision on import. The Protocol provides details on the whole process of notification, acknowledgment and decision, which is supposed to be completed in 270 days. However, it is stated that the absence of a response is not to be interpreted as implying consent. Detailed information will have to be provided by the importer on notification and LMOs should be clearly identified by accompanying documentation. In addition, the precautionary approach, as applied in article 11 of the Protocol, asserts that

> *"Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects."*

In plain terms, including this principle allows countries to block imports of, for example, seeds of genetically modified plant varieties on a precautionary basis even in the absence of sufficient scientific evidence of their harmfulness. The protocol does not apply to processed foods derived from LMOs. For bulk commodities containing an LMO component, documentation will have to state that the shipment "may contain" LMOs and that the contents of the shipment are not intended for planting.

In addition, the CPB makes clear that Parties to the Protocol must develop or have access to "*the necessary capacities to act on and respond to their rights and obligations*". The Protocol

[1] Living modified organisms (LMOs) are organisms whose genetic material has been altered through modern biotechnology and which are capable of propagation. As such, they can be considered as a specific sub-set of GMOs.

[2] For a complete overview of ratifications and accessions, see: http://www.biodiv.org/biosafety/signinglist.aspx?sts=rtf&ord=dt

provides considerable flexibility with respect to how importing countries may meet their obligations with respect to risk assessment and LMO decision-making, and the implementation of these decisions. As stated in Article 16, which deals with Risk Management, each Party has an obligation to "*establish and maintain appropriate mechanisms, measures and strategies to regulate manage and control risks identified in the risk assessment provisions*". Parties have agreed to carry out these risk management functions under the CPB, but how a country fulfills this obligation is not clarified and only loosely defined in an Annex to the Protocol. It is also recognized that developing country Parties and Parties with economies in transition will require assistance to achieve this, including financial support.

It remains to be seen whether the provisions and standards laid down in the CPB complement or conflict with existing trade agreements that may affect GMOs, such as those governed by the **World Trade Organization** (WTO). Within the WTO, biosafety of GMOs falls mainly under the Agreement on Sanitary and Phytosanitary Standards (SPS). The SPS Agreement is very important in reference to GMOs as it deals with laws and regulations that concern food and feed safety, and animal and plant health. SPS allows WTO member countries to take restrictive measures to protect a country from food safety risks and invasive species risks from GMOs. SPS requires that such measures be based on scientific risk assessment, and that they do not arbitrarily or unjustifiably discriminate between countries. The agreement allows for *provisional* precautionary measures in cases where scientific information is insufficient. They would be obliged to actively seek additional information for a more comprehensive risk assessment, and to review the provisional measure within a reasonable period. This approach could be in conflict with the more "generous" interpretation of the precautionary approach in the CPB. In addition to SPS, the WTO Agreement on Technical Barriers to Trade (TBT) may apply to GMO labeling. The TBT Agreement is intended to ensure that WTO members do not use technical regulations and standards as disguised measures to protect domestic industries from foreign competition. The TBT Agreement allows governments to adopt technical regulations if they serve to protect health or the environment. Such measures should not be unnecessary trade-restrictive, and not discriminatory.

How GMOs and associated trade disputes are handled by WTO is not yet entirely clear. This is due to be clarified through the WTO dispute settlement procedure initiated by the USA, Canada and Argentina in May 2003, with the aim to lift the European Union's moratorium on the release of GM products. This procedure usually takes about 3 years to complete, and the European moratorium may not be in place anymore at that time. The SPS and TBT Agreements encourage the use of international standards. The SPS Agreement recognizes the standards developed by 3 relevant organizations: the FAO/WHO Codex Alimentarius Commission[3], the *Office international des epizooties* (OIE – the World Organisation for Animal Health)[4] and the International Plant Protection Convention (IPPC)[5]. These standard-setting bodies all have their working groups on safety aspects of GMOs and GM foods, and the resulting standards, recommendations and guidelines will become international standards through the relevant WTO agreements.

[3] http://www.codexalimentarius.net/biotech.stm
[4] http://www.oie.int/eng/en_index.htm
[5] http://www.ippc.int/

7. Concluding Remarks

GM research requires additional human, institutional and financial resources for agricultural research programs. Human capacity and impact from research will benefit from a strategy to foster biotechnology, including priority setting and research agendas. Governments need to make strategic decisions at the national level with a clear understanding of the costs, benefits and risks of biotechnology and its potential to help meet national goals. Policy makers need tools for planning and priority setting to help make informed trade-offs among commodities and research problems. Each country will have to determine if it is able to make and sustain additional commitments in the face of competing claims for funding. Such funds could otherwise be invested in irrigation, organic production methods, clean water development, or human disease prevention and eradication.

While capacity is evident, developing further management and analytical capacity is needed for public institutions that set agendas and priorities for biotechnology. These are particularly needed to ensure existing capacity serves rural community needs. Existing personnel will require further support as they are called to contribute to public awareness, and spearhead collaboration with the private sector on product development and diffusion.

In addition to research capacity, the public sector or government is also responsible for regulatory decision making for biosafety. In fact, many research scientists go on to become regulatory officials, or part of the regulatory process, or serve on institutional biosafety committees. While much has been achieved in building regulatory capacity, further work is needed not only within the system, but to effectively deal with external pressures to the regulatory system from external factors, such as trade and markets (Cohen and Paarlberg, 2004). This additional capacity will strengthen the probability that efficient, timely and safe regulatory decisions can be made.

Safety is key for the deregulation of GM crops. However, technology developers have witnessed sharply rising regulatory costs for each crop event. Overall, this means that crop research using GM technologies is currently *a priori* limited and such costs can be justified only for crops with high potential profits. The same considerations apply to public research; ways must be found to meet the costs of addressing safety and regulation.

Furthermore, GM-free production may be deemed advantageous for trade considerations, especially for developing countries exporting to the EU. Consequently, at this time, GM crop production may not be timely; rather it may be more advisable for countries to focus on enhancing food distribution, rural infrastructure and markets (see, for example, Oxfam, 1999). Another viewpoint is whether a GM approach should be considered at all, as it may be naively seen as a panacea for increasing national food security or productivity. Such a philosophy dictates that GM approaches be dropped as they may result in precipitous development and adoption of GM crops, avoiding full appraisal of potential or presumed risks (ISP, 2003).

Different options for cutting hunger have been voiced (Sanchez and Swaminathan, 2005) that focus on attaining the Millennium Development Goals. The authors advocate increasing productivity for food-insecure farmers by placing a heavy emphasis on restoring soil health, improving nutrition, and increasing income and making markets work for the poor.

Informed discussion regarding biotechnology's benefits and potential risks is needed—in the context of specific GM crop examples, political governance and advocacy concerns, and including farmer perspectives. Among concerns over process, procedures, compliance, and trade, quality-of-life benefits can be unclear. While many farmers benefited immediately from Green Revolution varieties and, more recently, from insect-resistant GM cotton, their voices within regulatory circles and in the Conference of the Parties for the Cartagena Protocol on Biosafety have been otherwise absent.

All of the research and regulatory issues ahead leave developing countries at a difficult juncture, as complexities exist to approve either confined or large-scale field trials. This complexity means that presently, there is little chance of public GM food crops reaching the farmer soon. Without such access, determining if quality of life can be more than just a "potential" is not possible. Without such impact, many will argue that there are more certain and successful alternatives to improve quality of life or livelihoods than agricultural biotechnology.

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