How Much is the Quality of Life Being Regulated?

Joel I. Cohen and Patricia Zambrano
International Food Policy Research Institute
Washington, DC

Worldwide, genetically modified (GM) crops comprise mainly four species in five countries (James, 2003), produced with GM technologies that have been developed mostly by the private sector in the developed world. Although an active public sector in the developing world is engaged in crop biotechnology (Atanassov *et al.*, 2004), little so far has reached smallholder farmers. Thus, when we discuss biotechnology in the developing world, we can only speak of "potential." Many of the technologies under development have the potential to generate agronomic and environmental benefits or to enhance the nutrition of people in the developing world and to increase income and improve overall well-being. Most of the evaluations of benefits from GM crops in the developing world have been based on *ex-post* data for insect-resistant cotton, which has been approved for use in several countries.

Genetically modified food crops have not met with general acceptance, contrasting sharply with the widespread adoption of high-yielding varieties during the Green Revolution that were regulated under seed- and plant-protection laws still in place today. In the mid-1970s in India, despite a "paralysis that beset the public servants and politicians" (Hopper, 1987, 1999), farmers accessed, traded and sold the goods of the Green Revolution. The impact and longer-term effects of these high-yielding varieties have been studied (Evenson and Gollin, 2003), and their debatable qualities are being modified, some through biotechnology.

Genetically modified cotton and soybean—two of the four major crops grown—have had similar "farmer-first" adoption in developing countries as had the high-yielding varieties of the 1970s. Farmers sought and obtained access to *Bt* cotton before the Indian regulatory system had officially approved it, and interest is increasing in areas where cultivation of GM crops is not yet approved (Sharma, 2004). In fact, approval came months after the GM cotton had been harvested. In Brazil, a similar situation occurred with the planting of an estimated 4 million acres of GM herbicide-tolerant soybean that had not been approved for planting.

Safety standards for crops, as for all food and agricultural products, should not be compromised. However, GM crops now have new regulatory regimes or require 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.

Regulatory decisions on GM crops have been made with varying familiarity as to crop and trait, and with varying uncertainty with respect to risk. So far, they have been deemed safe in a number of global reports (FAO, 2004; Nuffield, 2004), have few negative environmental or health effects, and in certain environments have been proven efficacious.

Regulatory decision making is done country by country and on a case-by-case basis, with little sharing of knowledge, delaying the regulatory and hence adoption process. Additionally, countries adhering to the Cartagena Biosafety Protocol have the option to deny approval for import or use of GM crops by using the precautionary approach, if generally not satisfied with existing scientific knowledge.

These complexities translate to the delaying the approval of GM crops, even in cases where quality-of-life improvements are anticipated. Such improvements potentially 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 by reducing overall health and environmental risks associated with their use,
- increase in yields that can boost local production of food, benefiting local economies and reducing reliance on imports or food shipments,
- implementation of promising technologies that minimize the effects of biotic or abiotic stresses on crop development, such as salt resistance and drought tolerance that are major constraints on marginal 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.

Timeframes for realizing such benefits from GM food crops may be from 5 to 15 years. Like conventionally developed crops, those considered as genetically modified must pass agronomic and safety evaluations. Field evaluations begin with confined trials, often conducted at experiment stations or commercial research facilities, where environmental risk and exposure are minimized, and where seed production/collection can be controlled. Promising lines are advanced to more-open evaluations and multi-location trials and, eventually, are released to farmers.

Safety assessments are inherent to risk assessment and biosafety. Whether these reviews are carried out through a coordinated framework using existing regulatory agencies, through specially created agencies for GM crops, or through national biosafety committees, the same questions arise as to safety and risk. Therefore, it is essential that regulators in neighboring countries facilitate exchange of data, understand where areas of uncertainty and perceived risk exist, and are cognizant of potential benefits.

However, safety considerations generally do not take into account potential benefits including life-enhancing possibilities.

However, safety considerations generally do not take into account potential benefits including life-enhancing possibilities. Commercial entities and public research institutes in developing countries are often ill-equipped to ensure adequate risk assessment. A consequence of research devoted to regulatory requirements is the additional cost, which means that only a few traits are researched and developed, and even fewer reach confined testing in developing countries. Countries may also decide to set multiple regulatory requirements to avoid a decision, rather than approve an unfamiliar trait where risk is uncertain. If 100% confidence in risk assessment is not achieved, the precautionary approach may result in cessation of the approval process.

Purpose of this Paper

The purpose of this paper is to review GM crops under development and their regulation, potential benefits and cost of lost opportunities, and the social implications of biosafety. 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 developments are made, the current state of regulation among developing countries is conveyed, and a Conceptual Framework for biosafety systems is introduced. Alternative sources for helping rural communities are interjected, and specific concerns regarding the GM approach are discussed. Suggestions are made for achieving new models for regulation with benefits for public, as well as private, research. Difficulties encountered within a regulatory system, as well as those external to it are described, and aspects of opportunity, costs, benefits and risk are discussed.

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

Currently, for-profit 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, loss of 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 of strong commercial control. However, until recently, no reliable data were available regarding such public research or its regulation.

A recent 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 percentages of these transformation events—distributed by phenotype—are presented in Figure 1. Over half of the 209 events involved single genes that confer either viral or insect resistance. In eleven 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	Sub-total of events
Africa	Egypt	17	
	Kenya	4	
	South Africa	28	
	Zimbabwe	5	54
Asia	China	30	
	India	21	
	Indonesia	24	
	Malaysia	5	
	Pakistan	5	
	Philippines	17	
	Thailand	7	109
Eastern Europe	Bulgaria	8	8
Latin America	Argentina	21	
	Brazil	9	
	Costa Rica	5	
	Mexico	3	38
All			209

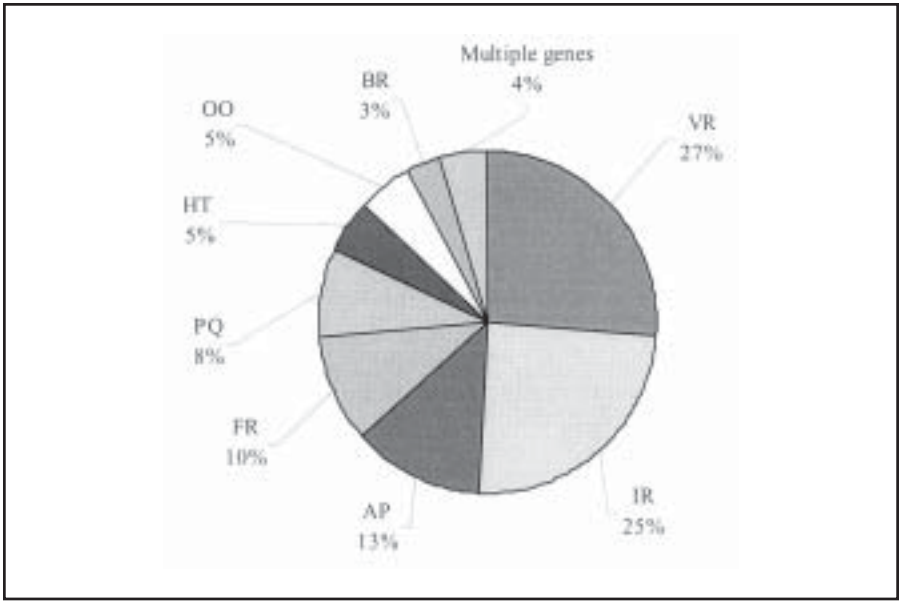

Figure 1. Phenotypic distribution and percent of total events (Atanassov *et al.*, 2004).
AP–Agronomic properties; BR–Bacterial resistance; FR–Fungal resistance; HT–Herbicide tolerance; IR–Insect resistance; OO–Other; PQ–Product quality; VR–Virus resistance.

Transformation events grouped by crop type are shown in Figure 2. Although cereals predominate, significant numbers of fruits, roots and tubers, and vegetables are represented, with each group containing diverse species. Progress in transforming indigenous crops is also significant. Although almost half of all transformation events are for rice, potato, maize, papaya, and tomato, the other half are spread over forty-one 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 to which 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.

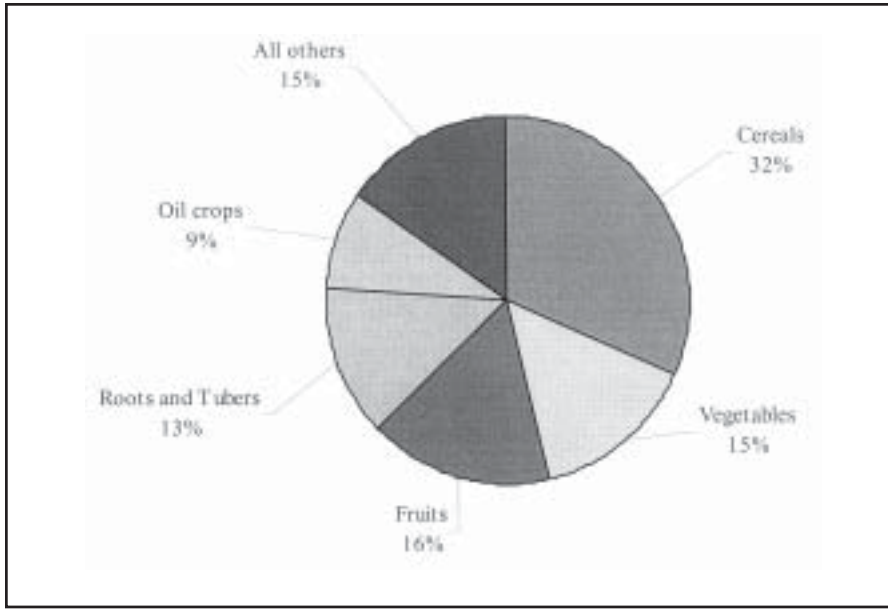

Figure 2. Percent transformation events by crop group (Atanassov *et al.*, 2004).

Many of these GM crops under development target very specific quality-of-life priorities in the countries where they are being developed. In Table 2 we included only those crops that have the greatest potential to improve people's well-being. Strictly we could broaden this to all events, as all the technologies under development by the public sector have at least an indirect effect on producers' or consumers' well-being, which is the purpose of all public research. For example, all fifty-one insect-resistance events under development will have an effect on farmers' quality of life, but we included only the thirty-five specifically developed for lepidoptera as they will have the greatest effect in reducing the impact of insecticide use.

The crops under development 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.

Despite this progress, the primary source of GM crops continues to be the private sector. Multinational companies have invested significant resources in guiding technologies through regulatory processes to production. With the exception of China, public-research products lag behind, eliciting concern because private funds are not being invested in countries, crops, traits or technologies that are most relevant to small-scale, resource-poor farmers.

TABLE 2. QUALITY-OF-LIFE RELATED EVENTS (COHEN, 2005)

Category 1	Category 2	No.	Subtotal
Insect-pest resistance	Lepidoptera	35	35
Disease resistance	Bacteria	8	84
	Fungi	21	
	Viruses	55	
Abiotic-stress tolerance	Drought	7	11
	Salinity	4	
Quality improvement	Nutritional and other	9	15
	Enhancing shelf-life	6	
Other	Vaccines	9	9
Subtotal		154	154
All events			209
% Subtotal over all			74

It is clear that Asia in particular has made a significant commitment to GM-crop research (ADB, 2001). This region contains the largest number of countries engaged in such research as well as the highest percentage of events in the testing phase. Africa, with the exception of South Africa, is seriously lacking in capabilities and resources to consider such research (Alhassan, 2003; UN ECA, 2002); many countries are exploring implications and are considering whether to invest in research on, or importation of, GM crops. Research capacity and potential markets are evolving (*e.g.* for insect-resistant cotton), albeit subject to uncertainties regarding the use of, and trade in, GM crops.

Developing countries are reacting in a precautionary manner regarding approvals of GM food crops, and justifying this approach by referring to the options articulated in the Convention for Biological Diversity and the Cartagena Protocol on Biosafety.

PUBLIC GM RESEARCH AND REGULATORY CONSIDERATIONS

Developing countries are reacting in a precautionary manner regarding approvals of GM food crops, and justifying this approach by referring to the options articulated in the Convention for Biological Diversity (CBD, 2004) and the Cartagena Protocol on Biosafety (Cohen and Paarlberg, 2004). Approaches to regulation that are consistent with the Cartagena Protocol are supported through the United Nations Environment Program Global Environment Facility (UNEP-GEF) pro-

gram on biosafety, which provides training in regulatory policy, frameworks, legislation and capacity building (Briggs, 2001; UNEP-GEF 2004). While significant progress has been made in building regulatory capacity and developing guidelines, biosafety decision-making remains complicated, lacking transparency.

A Conceptual Framework[1] (McLean *et al.*, 2002) has been developed to bring together regulatory policy, procedures and capacity (Figure 3). It starts by acknowledging that no single biosafety regulatory system fits the needs of all countries. This is shown as countries adopt different approaches for implementing biosafety systems, regulations and policies[2]. Individual countries have different capacities and needs for biosafety regulation. One of these needs is to become compliant with the articles of the Cartagena Biosafety Protocol that one-hundred and ten countries have ratified.

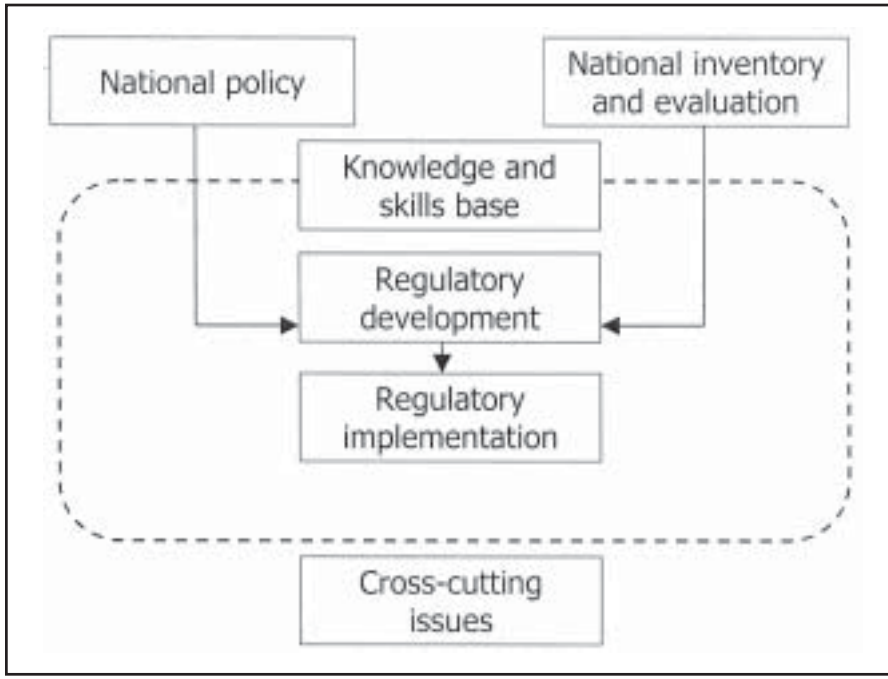

Figure 3. Basic elements of a Conceptual Framework for implementing biosafety frameworks and their interconnections (McLean *et al.*, 2002).

[1]The Conceptual Framework recognizes five elements central to a regulatory system: policy, national inventory, knowledge and skills base, regulatory development, and regulatory implementation.

[2]Major differences between countries are explained by overall economic development level, available human and technical resources, governments' implicit or explicit perspective on biotechnology and genetically modified organisms (GMOs), and whether policies governing the use of GMOs are promotional, permissive, precautionary or preventive.

The Cartagena Protocol on Biosafety speaks both to risk management and to risk assessment (Article 16, and Annex II and III) by which regulators can assess safety, but also consider (explicitly or not) the levels of risk they are willing or able to tolerate. Little data are available to help regulators balance risk analysis and risk perception with the advantages of releasing a promising new technology, and with analysis of cost of regulation. In addition, the Protocol does not specify the different requirements for confined or limited testing versus approvals for commercial release. This tends to confuse both the scientists and the regulators as per the type of trial requested.

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.

Fifteen traits remain stable in small-scale, single or multi-location confined trials. These trials are contained to prevent any environmental damage, thus the regulatory standards are different from those established for subsequent stages.

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 to examine 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, forty-four are in confined trials, twenty-two are in scale-up testing (mostly in China), and seven are at the commercial release stage (Figure 4).

Events at the stage of confined testing represent the most promising public research on GM crops. These forty-four events will decline in number during their evaluation. Of those listed, only 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.

For these crops, regulatory decision-making is needed for advancement and approval. To efficiently review public GM crops, it is necessary to first analyze and then strengthen regulatory decision-making. This necessitates actions internal and external to the biosafety system itself as described in the Conceptual Framework. Efficient processes essential for timely application review can be neutralized by external factors, including political, trade and activist positions, and, especially, difficulties when encountering European markets that are essentially closed to GM imports or use (Cohen and Paarlberg, 2004).

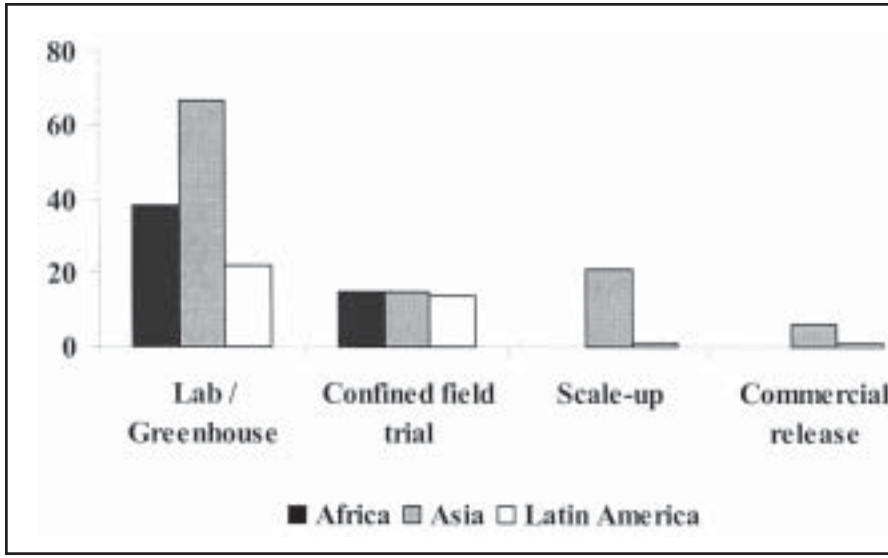

Figure 4. Public events classified by regulatory stage and region (Atanassov *et al.*, 2004)
Note: Eight transformation events for Bulgaria are not included, as the regulatory stages were not disclosed at the time of survey.

No uniform roadmap is available for working externally, facing political, trade, environmental concerns, anti-GM lobbies, moratoriums, and non-governmental or activist influence.

Developing actions that will impact on advocacy voices external to the regulatory system is difficult. No uniform roadmap is available for working externally, facing political, trade, environmental concerns, anti-GM lobbies, moratoriums, and non-governmental or activist influence. 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.

Social and Opportunity Costs for Biosafety Systems

There are at least three consequences for countries using alternative paths to implement biosafety systems. First is the potential for lack of coordination between neighboring countries, creating a patchwork of regulatory systems that hinders trade and discourages technology transfer. Second is the potential for duplication of effort coupled with resource depletion. Third is the potential for jurisdictional arbitrage to seek those countries with the least stringent environmental regulations. Therefore regional regulatory approaches offer the possibility of creating greater efficiency and safety. Even the most dissimilar of biosafety systems will have in common the need for scientific expertise; ability to distinguish confined from open trials, communications infrastructure, appropriate facilities, and suitably educated personnel.

The challenge is to ensure safety while facilitating new opportunities for farmers. Such an outcome recognizes that there is a real social cost for not having efficient biosafety regulatory systems in place.

Regulatory systems are required that, while addressing safety, take account of national agricultural objectives, implications of international treaties [WTO-Sanitary and Phytosanitary (SPS) Agreement and the Cartagena Protocol on Biosafety], and potential to facilitate regional harmonization. On a more technical level, using a country's own interim processes[3] can keep the regulatory process moving, particularly for authorization of confined/experimental field-testing.

A new initiative addressing these matters—the Program for Biosafety Systems (PBS)[4]—will use regionally focused discussions regarding specific commodities, knowledge of existing regulatory systems, and a sub-set of multi-sector issues for analysis. This will explore trade-offs between options and decisions involved in the design of a biosafety regulatory process from a multi-country perspective, identify specific areas where data and regulatory approval can be shared, and guide the development of these areas over the life of the project. This analysis will ultimately help shape new models for biosafety regulatory systems that take into account likely opportunity costs and variations of the risk-benefit-cost calculation. The ideas discussed look for participatory development of new models for biosafety systems to be implemented in a local context of expertise, resources, regulations, political and social realities, and trade constraints.

Policymakers will have an opportunity to examine the consequences of having a biosafety process that is too lengthy or expensive, to look at how this can reduce opportunities for domestic companies and public-sector R&D institutes to reach

[3]Interim processes can be defined as steps that allow countries to manage issues of immediacy while providing policymakers with experience that can be used to guide the development of a rational statutory process under either new or adapted legislation.

[4]PBS management is based at the International Food Policy Research Institute. Further details in its policy approach to regulation are under development. http://www.ifpri.org/themes/pbs/pbs.htm.

the farmers' hands, and to examine how this can bias the system toward multinational firms. The use of interim processes offers one way of achieving a new model for regulatory implementation. These processes offer a way to reduce lag time for the introduction of biotechnologies, while formal legislation is being formulated.

Two philosophies about risk assessment and management currently prevail in relation to transgenic organisms: the benefit-cost approach, and the precautionary principle.

Assessing Risk and Loss Calculations

Two philosophies about risk assessment and management currently prevail in relation to transgenic organisms: the benefit-cost approach, and the precautionary principle, as used by the European Union (Vogel, 2001) and by the Cartagena Biosafety Protocol. However, both these approaches have generally agreed on the same scientific criteria to be used in risk decision-making for transgenic organisms. The PBS will analyze the implications of these different approaches and develop decision models using a new methodology that integrates benefit-cost and risk analysis. Under this approach, the EU's precautionary approach becomes a special case with zero or negligible risk.

The development of new decision models for PBS involves integrated quantitative risk assessments and benefit-cost analyses. These two approaches are used in a complementary manner, providing different information about decisions to release transgenic organisms. Integration of both approaches is needed to assess where to implement costly regulations for small benefit in terms of reduced risk.

The analysis will be conducted around a series of country case studies of crop-trait combinations and will involve an assessment of the costs, benefits and risk of these combinations under the regulatory conditions existing within each country. The country-specific biosafety regulations will affect the costs (opportunity, timing, *etc*.) incurred and the level of risk assumed

Therefore, changes to the regulatory environment can be assessed as far as they impact the receipt of benefits, or the increase in costs and various potential risks.

Can Quality of Life Come From Elsewhere?

GM research requires human, institutional and financial resources. Each country determines if it is able to make and sustain such 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.

Furthermore, GM-free zones are being widely advocated or forced on countries by trade agreements. 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, infrastructure and markets (Oxfam, 1999).

One industry developer has seen its regulatory costs reach between $10 million and $20 million for each crop event. These costs have grown substantially since the developer began GM research in the early 1980s.

Safety is key for the deregulation of GM crops. However, one industry developer has seen its regulatory costs reach between $10 million and $20 million for each crop event. These costs have grown substantially since the developer began GM research in the early 1980s. Overall, this means that crop research using GM technologies is *a priori* severely limited and such production costs can be justified only with crops with the highest potential profit. The same considerations apply to public research; ways must be found to meet the costs of addressing safety and regulation.

Another issue is whether a GM approach should even be considered, 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).

Closing Statement

Safety is a foremost concern while we develop a track record of familiarity with GM crops and traits. However, the Cartagena Biosafety Protocol presents a precautionary approach when science is new. 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 larger trials. This complexity means that, presently, there is little chance of public GM food crops reaching the farmer. 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.

References

Alhassan, W.S. (2003) Agrobiotechnology Application in West and Central Africa (2002 Survey Outcome). Ibadan: IITA.

Asian Development Bank (ADB) (2001). Agricultural Biotechnology, Poverty Reduction, and Food Security. Working Paper. Manila: Asian Development Bank.

Atanassov AA *et al*. (2004) To Reach the Poor. Results from the ISNAR-IFPRI Next Harvest Study on Genetically Modified Crops, Public Research, and Policy Implications. EPTD Discussion Paper 116. Washington, DC: International Food Policy Research Institute. http://www.ifpri.org/divs/eptd/dp/eptdp116.htm.

Briggs, C. (2001) Planning for the Development of Nearly 100 National Biosafety Frameworks. Paper presented at the international consultation A Framework for Biosafety Implementation – A Tool for Capacity Building, organized by the International Service for National Agricultural Research (ISNAR) and Virginia Polytechnic and State University, Washington, DC, July 23–26.

Cohen JI (2005) Poorer nations turn to publicly developed GM crops. Nature Biotechnology 23 27–33.

Cohen JI and Paarlberg R (2004) Unlocking crop biotechnology in developing countries – a report from the field. World Development 32(9): 1563-1577.

Convention on Biological Diversity (CBD) (2004) The Cartagena Biosafety Protocol. http://www.biodiv.org/biosafety/signinglist.aspx?sts=rtf&ord=dt.

Evenson RE and Gollin D (2003) Assessing the impact of the green revolution, 1960 to 2000. Science 300: 758–762.

Food and Agriculture Organization of the United Nations (FAO). (2004) The State of Food and Agriculture 2003-04. Rome: FAO.

Hopper WD (1987) An interlude with Indian development. In: Policy and Practice: Essays in Honour of Sir John Crawford (Evans LT Miller JDB Eds), Sidney: Australian National University Press.

Hopper WD (1999) Introduction, The Future: Social Research. Pages 1-4. New School for Social Research in association with The Gale Group and LookSmart.

Independent Science Panel (ISP) (2003) The Case for A GM-Free Sustainable World. http://indsp.org/ISPreportSummary.php.

James, C. (2003) Preview: Global Status of Commercialized Transgenic Crops. International Service for the Acquisition of Agri-biotech Applications (ISAAA).

McLean MA *et al*. (2002) A Conceptual Framework for Implementing Biosafety: Policy, Capacity and Regulation. ISNAR Briefing Paper 47. The Hague: The Netherlands.

Nuffield Council on Bioethics. (2004) The Use of Genetically Modified Crops in Developing Countries. London: Nuffield Council.

Oxfam (1999) Biotechnology in Crops: Issues for the developing world A report compiled for Oxfam GB by Laura Spinney. http://www.oxfam.org.uk/what_we_do/issues/livelihoods/biotech_gm.htm.

Pinstrup-Andersen P Schioler E (2000) Seeds of Contention. World Hunger and the Global Controversy over GM Crops. Baltimore: Johns Hopkins University Press.
Sharma AB (2004) Demand for Bt cotton takes root. The Financial Express (India) May 12.
United Nations Economic Commission for Africa (UN ECA) (2002) Economic Report on Africa 2002. Tracking Performance and Progress.
United Nations Environment Program Global Environment Facility (UNEP-GEF) (2004) Project on Biosafety. http://www.unep.ch/biosafety.
Vogel D (2001) Ships Passing in the Night: The Changing Politics of Risk Regulation in Europe and the United States. EUI Working Papers RSC No. 2001/16. San Domenico, Italy: European University Institute.

JOEL COHEN is a Senior Research Fellow, as of April 2004, in the Environment and Production Technology Division of the International Food Policy Research Institute (IFPRI). He is also Director of the Program for Biosafety Systems, an international consortium enhancing regulatory policy and system development in Africa and Asia that was founded in May, 2003. This appointment followed eleven years as project leader in Management of New Technologies for Agricultural Research at the International Service for National Agricultural Research (ISNAR). Simultaneously, he served as director of ISNAR's Biotechnology Service.

Dr. Cohen recently authored papers on the public production of genetically modified (GM) crops in sixteen developing countries and their regulatory implications; the policy setting for food-safety assessments in the developing world; regulatory concerns and GM crops; and, realities/possibilities for crop biotechnology to mitigate or cope with effects of climate change.

Prior to joining ISNAR, Cohen worked for the US Agency for International Development as senior biotechnology specialist in the Office

of Agriculture, before which he was with Dekalb Plant Genetics. His doctoral degree was in plant breeding and molecular genetics from the Department of Plant and Soil Sciences, University of Massachusetts, Amherst. He also served as a rural extension agent in Nepal, as part of his Peace Corps volunteer experience.

Patricia Zambrano is a Senior Research Assistant at IFPRI. A native of Colombia, she joined IFPRI as a senior research assistant in 1999. Her work focuses on biotechnology and research and development policy issues. Zambrano earned an undergraduate degree in economics from the Universidad de Los Andes, Bogotá, Colombia, and an MA in economics from the University of California, Davis.