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THE STATUS AND IMPACT OF BIOSAFETY REGULATION IN DEVELOPING ECONOMIES SINCE RATIFICATION OF THE CARTAGENA PROTOCOL

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THE WORLD BANK

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ABBREVIATIONS AND ACRONYMS

ABDC	Agricultural Biotechnology in Developing Countries Conference
Bt	*Bacillus thuringiensis*
CBD	Convention on Biological Diversity
CILSS	Comité Permanent Inter Etats de Lutte contre la Sécheresse dans le Sahel (Permanent Committee for Drought Control in the Sahel)
EC	European Commission
ECOWAS	Economic Community of West African States
EU	European Union
FAO	Food and Agriculture Organization (of the United Nations)
GE	Genetically engineered
GEAC	Genetic Engineering Approval Committee
GEF	Global Environment Facility
GM	Genetically modified
GMO	Genetically modified organism
INSAH	Institut du Sahel (Sahelian Institute)
LMO	Living modified organism
NBF	National biosafety framework
OECD	Organisation for Economic Co-operation and Development
R&D	Research and development
UNEP	United Nations Environment Programme
USA	United States of America

EXECUTIVE SUMMARY

Common to all of the countries where genetically engineered (GE) crops are cultivated is a system to regulate these products and particularly to ensure their evaluation for human health and environmental safety (commonly referred to as biosafety) prior to any commercial release. This paper explores how the Cartagena Protocol to the Convention on Biological Diversity, as well as other important drivers, have affected the regulation of GE crops in developing countries. It examines the impact of biosafety regulation on research and development of GE crops and on product approvals. Finally, it identifies opportunities to advance biosafety regulation in those developing countries that wish to access the potential benefits of agricultural biotechnology.

The early adopters of GE crops, like the United States, Canada, and Argentina, developed regulatory systems to respond to the impending release of GE crops for cultivation. In most developing countries, however, the establishment of national biosafety regulatory systems was a by-product of the ratification of the Cartagena Protocol on Biosafety and its entry into force in 2003. The Cartagena Protocol is the only international environmental agreement that is concerned exclusively with products of modern biotechnology. Its interpretation and implementation have had a significant impact on biosafety regulation, especially in developing countries. Over the past decade, more than 140 developing countries or countries with transitional economies have received assistance to develop or implement national biosafety frameworks. Only a small number of developing countries have moved beyond these projects to operationalize their biosafety regulatory systems effectively, so that they may be considered functional—that is, they implement regulatory submission, assessment, and decision-making processes in a consistent, transparent, and predictable manner.

As is true for capacity development in other regulatory arenas, progress in biosafety regulation in developing countries is often impeded by limited political and financial commitments from national governments and by insufficient technical, human resource, and institutional capacity for implementation. It is also confounded by competing or redundant capacity-building projects and the absence of products to regulate. Only a limited number of developing countries have substantive public sector research programs in agricultural biotechnology or are considered markets of interest for private sector investments in this area. In effect, there is limited demand to drive regulatory development (or reform) forward, and policy makers' attention is necessarily redirected to other priorities. Private sector developers of GE crops are generally disinterested in entering markets, even those in which farmers demand GE crops, unless the biosafety regulatory system is operational and predictable. More critically, public sector and donor initiatives that focus on improving the productivity of staple crops using biotechnology will be unsuccessful unless there is a clear path for improved crop varieties actually to move from laboratories to field trials to farmers.

Even with these challenges, there are opportunities to advance biosafety regulation in ways that could particularly benefit developing countries. These opportunities include:

- Revisiting the context for biosafety regulation of GE crops to ensure that both the risk assessment and any non-safety considerations that are used to inform decisions are not defined solely by environmental protection goals but also by other development priorities, such as improving agricultural productivity, food security, and rural development.
- Rationalizing environmental risk assessment information and data requirements to focus exclusively on issues that are relevant to assessing plausible adverse environmental impacts of GE crops. Improved and cost-effective approaches to biosafety regulation generally, and risk assessment particularly, can be pursued without compromising environmental protection and management goals.
- Incorporating the assessment of environmental benefits of GE crops in agricultural ecosystems in addition to the standard evaluation of potential adverse environmental impacts.

- Aggressively pursuing harmonization of risk assessment requirements and processes between countries—for example, by recognizing scientific opinions arising from risk assessments by other regulatory authorities, establishing regional approaches to risk assessment, or, more ambitiously, adopting decisions taken by other governments where appropriate.
- Improving biosafety capacity building so that it moves past the development of national biosafety frameworks and associated short-term technical training to pursue sustained commitments to operationalize, monitor, and improve the regulatory systems that are put into place. Capacity-building programs should promote the rationalization of biosafety regulation and opportunities to strengthen the scientific and knowledge base in ways that will provide benefits that extend beyond the often transient need for biosafety risk assessment and decision making.

Chapter 1: INTRODUCTION

The *World Development Report 2010: Development and Climate Change* highlights the link between biotechnology, development, and environment. Aside from recognizing biotechnology's potential to improve crop productivity, increase crop adaptation to climatic stresses such as drought, and mitigate greenhouse gas emissions, the report emphasizes the need to establish science-based regulatory systems "so that risks and benefits can be evaluated on a case-by-case basis, comparing the potential risks with alternative technologies" (World Bank 2010). Safe access to new technologies, including agricultural biotechnology, is also a strategic goal articulated in the *World Development Report 2008* and *Agriculture Action Plan* (World Bank 2008, 2009). Its importance was emphasized again in an array of documents prepared for the Agricultural Biotechnology in Developing Countries Conference (ABDC-10) convened by the Food and Agriculture Organization (FAO), as well as in the final conference report.[1]

All of these documents recognize that agricultural biotechnologies can contribute to poverty reduction and food security in developing countries but that the adoption and deployment of products developed using the tools of modern biotechnology need to be evaluated within a regulatory framework that considers the potential environmental consequences of such releases, including impacts on biodiversity. As a key conclusion of the ABDC-10 Report states, "Governments need to develop their own national vision and policy for the role of biotechnologies, with options and opportunities examined within the context of national economic, social, and rural sustainable development and environmental strategies, objectives, and programmes."

Genetically engineered (GE) plants, the most widely adopted products of agricultural biotechnology, are strictly regulated by governments internationally through the implementation of national biosafety regulatory systems (Box 1.1). The impending release of GE varieties drove the establishment of national biosafety[2] regulatory systems in developed countries, but not in most developing countries. In those countries, the establishment of biosafety regulatory systems was catalyzed when the Cartagena Protocol on Biosafety came into force, along with associated capacity-building initiatives to assist the Parties in meeting their obligations under that international agreement. For many national governments, however, the operationalization of biosafety regulatory systems that meet environmental and agricultural priorities remains elusive.

In 2003, the year the Cartagena Protocol came into force, the World Bank published a review of the key issues and policy options pertaining to the development and implementation of national biosafety systems, illustrated by country-specific examples of biosafety policies and practices related to crop biotechnology. Since then circumstances have altered the political and regulatory context of biosafety regulation (Box 1.2). With the objective of exploring the impact of these circumstances, specifically in developing countries, this document examines:

- The status of biosafety regulation since the 2003 World Bank review.
- How implementation of the Cartagena Protocol has affected biosafety regulation.
- The impact of biosafety regulation on research, development, deployment, and trade of GE crops.

1 Documents prepared for, and arising from, ABDC-10 are available at http://www.fao.org/biotech/abdc/backdocs/en/. Particularly relevant are: "Conference Report," (http://www.fao.org/fileadmin/user_upload/abdc/documents/report.pdf); "Current Status and Options for Crop Biotechnologies in Developing Countries," (http://www.fao.org/fileadmin/user_upload/abdc/documents/crop.pdf); and "Policy Options for Agricultural Biotechnologies in Developing Countries" (http://www.fao.org/fileadmin/user_upload/abdc/documents/policy.pdf).

2 In this document, "biosafety" refers to actions taken to protect biodiversity, including agricultural biodiversity, through the assessment and management of potential adverse impacts associated with the release of GE organisms in the environment. Note that this definition excludes the safety of foods and livestock feeds derived from GE organisms. Interestingly, biosafety is not defined either in the Convention on Biological Diversity or the Cartagena Protocol on Biosafety.

BOX 1.1: Elements of a Functional Biosafety Regulatory System

A functional biosafety regulatory system[a] is a prerequisite for realizing the benefits that agricultural biotechnology can, and does, provide to poor producers and poor consumers in developing countries.[b] Environmental protection is the overarching priority of any biosafety regulatory system, and confidence in the process and decisions that governments make on behalf of the public is a precondition for the acceptance and adoption of agricultural biotechnology products.

There is no best model for a biosafety regulatory system. Each system is necessarily influenced by the social, cultural, economic, environmental, and related development objectives and priorities of a country. A number of common issues must be considered when establishing or revising a biosafety regulatory system, however.

Elaboration of a national policy consistent with other objectives related to economic, social, and rural development; natural resource management; and environmental protection and sustainability. This policy forms the basis for the development of specific legislation and/or regulations, leading finally to the design and implementation of the structural elements necessary for risk analysis, inspection, monitoring, and enforcement.

An assessment and gap analysis of the national development priorities, agricultural policies, existing regulatory regimes, and national and regional scientific and technical means necessary for a biosafety regulatory system to function. This national appraisal provides a means to identify and characterize available resources and regulatory infrastructures, assess their adequacy for supporting a biosafety system, and identify gaps where capacities need to be strengthened.

Building a strong base of scientific knowledge in support of the regulatory system and developing core competencies in biotechnology product evaluation. These activities allow an improved scientific basis for assessments of potential risks and/or benefits, and they strengthen the scientific capabilities for risk management, inspection, and monitoring. This scientific knowledge and skill base, however, needs to be supplemented with complementary capacities in the delivery of extension services and in the seed production and distribution system, particularly capacities that are public sector driven.

The development of biosafety regulations to effect specific public policy goals (as articulated in a national biosafety or biotechnology strategy). Decisions on an appropriate regulatory structure should be informed by the assessment and gap analysis as well as extensive consultation with stakeholders, including the public. This process is particularly vital if a country chooses to incorporate issues external to science (that is, issues other than those used to assess safety, such as economic, social, and/or ethical considerations) into its decision making.

Implementation of regulations through the operationalization of the biosafety regulatory system. Generally, the central issues around the implementation of biosafety regulations involve the establishment of appropriate mechanisms for risk assessment, risk management, and risk communication. Decisions made during the implementation phase impinge directly on the economic costs associated with assessing and mitigating risks and ensuring compliance. Important considerations include opportunities for international cooperation at a technical level (for example, sharing human and scientific resources and expertise) and establishing scheduled phasing-in of regulations (for example, initial voluntary guidelines entrenched in legislation over time).

Addressing cross-cutting issues that are common to each stage in the development and implementation of a national biosafety system. These issues include public information and participation, which relate to the transparency of the regulatory system, and the degree to which the public has input either into the formulation of regulatory policy or into specific regulatory decisions. Human, financial, and infrastructure resources largely determine the scientific and administrative capacity of any country and so obviously influence any biosafety-related policy or program. Resources must be available to develop and implement a national biosafety system; to support the infrastructure required; to facilitate communication and public participation; to train scientific and regulatory personnel; and to foster the research required to assure that risk assessments are sound. These cross-cutting issues affect the implementation of the system designed to assess biosafety and, perhaps more importantly, those nontechnical factors that are crucial to public acceptance and confidence in the decisions that are made by government on behalf of the people.

Source: McLean et al. 2002; World Bank 2003.
a. In this document, a biosafety regulatory system is considered functional when the regulatory submission, assessment, and decision-making processes are implemented in a consistent, transparent, and predictable manner.
b. World Bank 2008.

BOX 1.2: Key Drivers Affecting Biosafety Policy and Regulation

RATIFICATION OF THE CARTAGENA PROTOCOL ON BIOSAFETY

The Global Environment Facility (GEF) Council adopted the GEF Initial Strategy on Biosafety in November 2000. The strategy was aimed at assisting countries to prepare for the coming into force of the Cartagena Protocol on Biosafety through the establishment of national biosafety frameworks (NBFs). The entry into force of the Protocol in 2003 was followed by a marked acceleration in the number of countries that accessed resources through GEF-funded capacity-building projects (enabling activities) to develop national biosafety regulatory systems.

DEVELOPING COUNTRY INVESTMENTS IN AGRICULTURAL BIOTECHNOLOGY

Countries such as China, India, and Brazil have adopted policies that explicitly recognize the importance of agricultural biotechnology as a driver of their respective economies. Under these policies, significant innovation in agricultural research is taking place in the public sector. China and India have rich pipelines of both commodity and pro-poor GE crops in development and approaching commercialization. Brazil recently approved herbicide-tolerant soybean CV127-9, the first example of a GE product developed and commercialized through a public-private partnership (Embrapa and BASF). The fact that new product development of this kind is no longer the (almost) exclusive purview of private enterprises in the United States, Canada, and European Union has significant implications for both agricultural development and international trade. The imperative of at least some of the product development in countries like China and India is to meet domestic food needs. Considerations related to any trade disruptions that may result if unapproved GE products enter the global value chain may be considered incidental to achieving food security.

APPROVAL AND LARGE-SCALE CULTIVATION OF GE CROPS IN MAJOR GRAIN-EXPORTING COUNTRIES

From 2003 to 2010, the global area planted with GE crops doubled from 68 to 148 million hectares. In 2010, the United States, Brazil, Argentina, India, Canada, China, Paraguay, Pakistan, South Africa, and Uruguay accounted for 98% of the area planted to GE crops.[a] Major commodity exporters of maize, soybeans, and/or cotton cultivate GE varieties of these crops, and there is limited segregation of GE and non-GE harvests in these countries. Globally, governments have taken disparate approaches to regulating GE crops; the resulting asynchronicity in product evaluations and approvals can result in significant and costly trade disruptions.[b] For example, in 2009 trace levels of a GE maize event[c] approved in the United States but not the European Union were detected in U.S. soy shipments, and 200,000 tons of soy was refused entry at European Union ports.[d] Situations like this will become more common as the number of GE crop and trait combinations increases. It has been estimated that over 120 different transgenic events may be commercialized worldwide by 2015, compared with approximately 30 GE events in commercially cultivated crops in 2008, and that half of them will be developed and first approved in India, China, and Brazil.[e]

CATALYSTS FOR NEW PRODUCT DEVELOPMENT

Drivers such as agricultural adaptation to climate change, the food security crisis of 2008–09, and increasing demand for renewable energy have accelerated plant biotechnology research on a range of new traits and new plant species. Drought-tolerant maize, salt-tolerant rice, sorghum that uses nitrogen more efficiently, and soybeans with modified oil profiles are all expected to advance to commercialization within the next decade. Genetic engineering is being applied to improve existing plant sources of biomass for ethanol and biodiesel production and to modify less-familiar, non-food plant species for large-scale cultivation to meet growing demand for biofuel feedstocks. Novel traits for pest and disease resistance are being introduced into many plant species, and the use of these GE plants in integrated pest management systems increasingly is viewed as integral to sustainable agricultural production.[f]

Source: Authors.
a. James 2011.
b. Magnier, Konduru, and Kalaitzandonakes 2009; Gruere 2009; Stein and Rodríguez-Cerezo 2010b.
c. The term "event" is used in agricultural biotechnology to refer to each unique genotype produced from the genetic transformation of a plant species using a specific genetic construct. For example, two varieties of a plant species transformed with the same genetic construct constitute two events. Risk assessments and authorizations for commercial cultivation are for the particular event. This means that lines, varieties, or hybrids derived from an approved event through conventional plant breeding are also approved for the same uses.
d. "Blocking Biotech Feed Harms Farmers: EU Farm Chief," 2009.
e. Stein and Rodríguez-Cerezo 2010a.
f. Romeis, Shelton, and Kennedy 2008; Kos et al. 2009; Chandler et al. 2011; Naranjo 2011.

Chapter 2: THE IMPACT OF THE CARTAGENA PROTOCOL ON BIOSAFETY REGULATION

A number of international agreements affect the regulation of GE crops in the same way that they influence the regulation of other non-GE plants and plant products (for example, in the areas of plant health or trade): Agreement on the Applications of Sanitary and Phytosanitary Measures; Agreement on Technical Barriers to Trade; Agreement on Trade Related Aspects of Intellectual Property Rights; and the International Treaty on Plant Genetic Resources for Food and Agriculture. The most significant multilateral agreement, however, and the only one that directly addresses biosafety regulation, is a supplementary treaty to the Convention on Biological Diversity (CBD), the Cartagena Protocol on Biosafety.

The Cartagena Protocol addresses the safe transfer, handling, and use of living modified organisms (LMOs).[1] It is the only international environmental agreement concerned exclusively with products of modern biotechnology, and its interpretation and implementation have had a significant impact on biosafety regulation in developed and developing countries.[2] The Protocol entered into force on September 11, 2003 and has been ratified by 161 countries.[3]

Pursuant to Article 19, paragraph 3 of the CBD, the Protocol seeks to protect biological diversity from the potential risks posed by LMOs. It establishes an advance informed agreement procedure for ensuring that countries are provided with the information necessary to make informed decisions before agreeing to import LMOs into their territory. The Protocol refers to a "precautionary" approach and reaffirms the precautionary language in Principle 15 of the Rio Declaration on Environment and Development. The Protocol also establishes a Biosafety Clearing-House,[4] an online portal designed to facilitate the exchange of information on LMOs and assist countries in implementing the Protocol.

1 A "living modified organism" is any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. "Modern biotechnology" means the application of: (1) *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (rDNA) and direct injection of nucleic acid into cells or organelles, or (2) fusion of cells beyond the taxonomic family that overcomes natural physiological reproductive or recombination barriers and that is not achieved through techniques used in traditional breeding and selection (Article 3).

2 A detailed explanation of the Cartagena Protocol is available in MacKenzie et al. (2003).

3 As of October 25, 2011.

4 Biosafety Clearing-House, http://bch.cbd.int/.

The Protocol makes clear that Parties must develop or have access to the necessary capacities to act on and respond to their rights and obligations. These capacities are related to legal and administrative matters, policy development and implementation, decision making, and scientific analysis. Successful implementation of the Protocol is contingent on the development of national biosafety capacity in Party countries that have yet to establish, or are in the process of establishing, biosafety frameworks.

The Protocol provides considerable flexibility in how Parties may meet their obligations with respect to decisions related to risk management and their implementation. Article 16, dealing with risk management, states that 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 Protocol, but the Protocol does not specifically prescribe how a country should fulfill this obligation. The Protocol explicitly recognizes that developing country Parties and Parties with economies in transition require assistance (Article 22), including financial support (Article 28), to implement the Protocol.

2.1 GEF-FUNDED CAPACITY BUILDING FOR IMPLEMENTATION OF THE PROTOCOL

Since 2000, when the Cartagena Protocol was adopted, the Global Environment Facility (GEF) has approved or endorsed an array of capacity-building projects to assist eligible Parties:[5]

- Six global projects, including the United Nations Environment Program (UNEP)-GEF Project on Development of National Biosafety Frameworks (Box 2.1) and the UNEP-GEF Project for Building Capacity for Effective Participation in the Biosafety Clearing-House of the Cartagena Protocol.
- Four regional capacity-building projects to promote compliance with the Protocol.
- Fifty-four country-specific projects for the implementation of national biosafety frameworks (NBFs) (Box 2.2).

5 "Biosafety," United Nations Development Programme, http://hqweb.unep.org/biosafety/, accessed April 22, 2011.

BOX 2.1: Project on Development of National Biosafety Frameworks

In 2001, the United Nations Environment Programme (UNEP) initiated the National Biosafety Framework (NBF) development project, which was designed to help signatories to the Protocol prepare to comply with its provisions. The NBF development project had three major activities: (1) to assist countries to establish their biosafety frameworks; (2) to promote information sharing and collaboration, especially at the regional and subregional level; and (3) to promote collaboration with other organizations to assist in building capacity to implement the Cartagena Protocol on Biosafety.[a] Implementation of the NBF development project required participating countries to follow a prescribed process. Phase 1 was Preparatory Activities and Gathering Information (months 1–6); Phase 2 was Analysis and Consultation (months 7–12); and Phase 3 was Preparation of Draft National Biosafety Framework (months 13–18),[b] according to a format proposed by UNEP.[c] Participating countries received a "toolkit" providing practical guidance for starting an NBF project (Phase 0) and the follow-on phases (1–3). The toolkit contained five modules prepared between 2001 and 2004.[d]

The global nature of the NBF development project effectively guaranteed its impact: 123 countries have completed, or are participating in, the development of NBFs.[e] The effectiveness of UNEP's approach—arguably necessitated by the scale of the project—can be questioned, however, if the measure of effectiveness is an active, operational regulatory system. For example, of 38 African countries that completed their NBFs, only 3 have taken decisions about the use of GE plants outside of containment facilities such as laboratories and greenhouses. Tanzania and Nigeria both authorized confined field trials (although Tanzania's first approvals preceded its NBF development project), and Burkina Faso assessed and approved a GE plant for commercial release (insect-resistant cotton in 2008).

This situation is representative of several circumstances: (1) an absence of applications for research and development (R&D), field trials, or commercial release of GE crops to "activate" nascent regulatory systems in many African countries; (2) insufficient resources to sustain biosafety regulatory systems in the absence of support from international donors such as the Global Environment Facility; and (3) the highly precautionary stance of some African countries, such as Zambia and Ethiopia, which developed NBFs or legislation to effectively limit access to living modified organisms.[f] These circumstances also apply to many developing countries outside of Africa.

Source: Authors.
a. "UNEP Biosafety Development Projects," http://www.unep.org/biosafety/Development_Projects.aspx, accessed April 22, 2011.
b. UNEP (2006).
c. UNEP (undated).
d. "UNEP Toolkit for the Development Project," http://www.unep.org/biosafety/Toolkit.aspx, accessed April 22, 2011.
e. Draft NBFs are available at http://www.unep.org/biosafety/National%20Biosafety%20frameworks.aspx, last updated 2 August 2010.
f. The Zambian Biosafety Law was passed in 2007. Ethiopia has a draft biosafety bill under consideration. See also Morris (2008).

GEF grants for these projects have totaled US$ 105,394,357, with an additional US$ 94,271,107 of cofinancing.[6]

In 2005, the GEF Office of Monitoring and Evaluation evaluated GEF support for biosafety capacity building (GEF 2006). While generally favorable to the projects, the report identified a number of limitations related to project design and implementation. The prescriptive, phased approach of the NBF development project was considered "too ambitious in terms of high goals within limited time schedules, and it did not have a sufficient flexibility to adapt the level of funding and the measures of required technical assistance to the needs of each country" (GEF 2006:6).

This "one size fits all" approach to biosafety capacity building is not unique to the NBF development project, and others have also pointed out that tailoring interventions to the specific country context is essential for projects to succeed (Johnston et al. 2008; Chapotin, McLean, and Quemada 2009; Araya-Quesada et al. 2010). Projects to build biosafety capacity should utilize needs assessments and gap analyses to identify and prioritize interventions that will further the operationalization of a functional regulatory system. Although the NBF development project did include a requirement for comprehensive stock-taking, countries were still expected to use the same step-wise approach to complete the development of their NBFs, irrespective of the outcomes of national needs assessments. For example, both the NBF development project brief and the project toolkit[7] were commonly interpreted by national subprojects and UNEP's regional project

6 GEF project and other databases, http://www.gefonline.org/, accessed October 10, 2010.

7 Particularly Phase 3 Toolkit Module Part (I), "Developing the Regulatory Regime," http://www.unep.org/biosafety/Documents/Drafting_the_NBF_Formulation_of_the_regulatory_regime.pdf.

BOX 2.2: Projects Funded by the Global Environment Facility for Implementing National Biosafety Frameworks

The first 12 projects for implementing national biosafety frameworks (NBFs) assisted countries that had developed their biosafety regulatory frameworks prior to the Cartagena Protocol; the projects helped those countries to adapt and/or implement those frameworks to meet their obligations as Parties.[a] This effort included:[b]

- Reviewing NBFs and drafting regulations and guidelines to support their implementation.
- Making regulatory and administrative systems for handling applications and related biosafety matters operational.
- Setting up decision-making mechanisms to handle applications for releases and transboundary movements of living modified organisms (LMOs).
- Developing technical guidelines for risk assessment and risk management, monitoring, and enforcement.
- Strengthening capacity for risk assessment/management, including setting up and/or improving and equipping special laboratories for this purpose.
- Strengthening information systems on LMOs.
- Enhancing public awareness, public education, and participation.
- Setting up of biosafety databases for the purpose of the Biosafety Clearing-House.

Countries had considerable flexibility in the design and execution of the projects, which had varying degrees of success. Six countries (China, Colombia, India, Kenya, Mexico, and Uganda) now have functional regulatory systems, but all 12 countries continue to be challenged to meet all of their Protocol obligations, such as the timely provision of required information to the Biosafety Clearing-House.[c] An additional 42 countries have transitioned, or are in the process of transitioning, from NBF development projects to implementation projects.[d]

Source: Authors.
a. The 12 countries were: India and Colombia (projects implemented by the World Bank); Malaysia and Mexico (projects implemented by the United Nations Development Programme); and Bulgaria, Cameroon, China, Cuba, Kenya, Namibia, Poland, and Uganda (projects implemented by UNEP). The eight countries undertaking UNEP-coordinated projects had participated in the preceding UNEP-GEF Pilot Project on Development of National Biosafety Frameworks in 18 Countries, which ran from 1997 to 2000. See GEF (2000).
b. GEF (2001).
c. Article 20 of the Cartagena Protocol established a biosafety clearing-house to "facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms" (http://bch.cbd.int/protocol/text/article.shtml?a=cpb-20), accessed April 2012.
d. GEF project database, http://www.gefonline.org/, accessed October 10, 2010.

coordinators to require the development of new laws to regulate LMOs (GEF (2006:63–64). This perception resulted in the development of complex regulatory frameworks that were inconsistent with the national capacities identified during stock-taking reviews. Only a limited number of countries pursued alternative approaches, such as adapting their plant health and quarantine regulatory regimes as an interim measure for meeting Protocol obligations in the short term.

International support for establishing biosafety regulatory systems has favored the creation of new regulatory entities under ministries other than agriculture. The Protocol, and more specifically the GEF-funded capacity-building projects in support of the Protocol, has been particularly influential in this regard. The relationship of the Protocol to the CBD means that national grants for NBF development and implementation projects were provided largely to ministries of environment. Agricultural biotechnology regulation intersects the mandates and interests of multiple ministries, especially agriculture, but also ministries of science and technology, environment, health, and trade. Capacity-building projects that seek to support the development of biosafety regulatory systems should explicitly require meaningful interministerial consultation and a clear delineation of roles and responsibilities between competent authorities.

This type of interministerial coordination, while necessary, has been challenging to obtain in practice. As indicated during the 2003 Sub-Regional Workshop for Latin American Countries on the Development of a Regulatory Regime and Administrative Systems, the primary conflict identified for the implementation of NBFs was the coordination of administrative tasks and competencies of the institutions involved in them (UNEP 2003b). This challenge was stressed in a similar workshop for Asian countries, where it was noted that "much of the administrative system seemed to be in place in many countries, and that coordination was the major challenge where different agencies were working separately" (UNEP 2003a). For many countries, both developed and developing, intragovernmental coordination on biosafety policy and regulatory issues remains a challenge (CBD 2009; SCBD 2009; Birner et al. 2007; Reddy 2009).

2.2 ONGOING ASSISTANCE TO PARTIES

A report in 2010 summarized progress under the Action Plan for Building Capacities for the Effective Implementation of the Protocol[8] and the capacity-building needs of Parties (UNEP 2010b). Based on a small pool of countries[9] responding to a questionnaire prepared by the CBD Secretariat, an extensive list of capacity-building needs was identified, which generally corresponded to the elements of the Action Plan, such as risk assessment, risk management, and scientific, technical, and institutional capacity building. The questionnaire did not ask countries to identify critical constraints to the establishment of functional regulatory systems versus less imperative "needs" (such as the construction of contained greenhouses), so priorities for capacity building were not established. Parties are supposed to provide national reports on capacity-building needs and priorities to the CBD Secretariat, but compliance with this requirement has been limited.[10] As with results from the questionnaire, national reports have identified an array of capacity-building needs and have only in some cases prioritized them as immediate, medium-term, or longer-term priorities (UNEP 2010a). Prioritization should be a required element of all assessments of biosafety capacity needs; without this necessary contextual information, managers of capacity-building projects are left to determine where to focus interventions.

Of the many ongoing national, bilateral, and multilateral projects to build biosafety capacity, some are linked directly to the Protocol (as with the GEF implementation projects), and others seek to improve the capacity of developing countries to access, develop, or evaluate GE crops.[11] Most projects focus on developing biosafety regulatory systems and/or provide technical support, particularly in risk assessment and risk management. Recent reports have recommended an assortment of improvements to make biosafety capacity building more effective.[12] The reports all recognize that strategic, longer-term programs are necessary, that sustainable progress requires both political and resource commitments from national governments, and that technical capacity alone is not sufficient to ensure effective biosafety regulation.

The number of national, regional, and global programs implemented to build biosafety capacity over the past decade is impressive, yet their collective effectiveness and particularly their sustainable contributions to operationalizing biosafety regulatory systems are less so. This outcome can be attributed, at least in part, to an absence of project and program coordination. While most donor organizations clearly view coordination as a necessity, it is a challenge to identify a single country where biosafety project coordination has been achieved successfully. For example, the Capacity-Building Coordination Mechanism under the Cartagena Protocol "allows Parties, other governments, relevant organizations and donors involved in implementing and/or funding biosafety capacity building initiatives to share information and experiences on their ongoing initiatives; exchange resource materials and information about existing capacity-building opportunities; identify key biosafety capacity building issues and priority needs and ways to address them; and identify overlaps and potential areas for collaboration,"[13] but it does not actively foster "coordination and interaction between those involved in biosafety capacity-building activities" (UNEP 2007; Johnston et al. 2008).

Coordination is typically considered a responsibility of the various organizations that fund or deliver biosafety capacity-building programs, which may be exactly why effective project coordination has remained elusive. Many donors and implementing agencies with divergent mandates, objectives, and political agendas operate within countries or regions, and it is unrealistic to expect that they will all work together. Instead, the responsibility lies with national governments to ensure that capacity-building programs are designed and delivered to meet pressing national priorities in a cohesive, strategic manner. This level of oversight requires the various ministries involved in implementing an NBF to work collaboratively to develop a national plan for capacity building. The implementation process for such a plan should incorporate mechanisms for carefully analyzing project goals and projected impacts before projects are accepted, as well as for ex post assessments of project effectiveness and sustainability. An approach like this might ensure that the national plan is revisited and revised based on a regular evaluation of progress. It may also potentially require ministries to forgo funding or projects that do not align with the plan, which may be an unrealistic expectation for governments with severe resource constraints.

8 "Action Plan" (for Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety), http://bch.cbd.int/protocol/cpb_art22_actionplan.shtml.

9 The countries that had responded by June 2010 were Benin, Côte d'Ivoire, Croatia, Dominican Republic, Egypt, Latvia, Lithuania, Mexico, Niger, Nigeria, Poland, Republic of Moldova, Saint Lucia, Togo, and Venezuela.

10 National reports have been submitted by Barbados, Bulgaria, Cameroon, China, Costa Rica, Croatia, the Former Yugoslav Republic of Macedonia, India, Kenya, Panama, Qatar, Syria, Uganda, and the United Republic of Tanzania; see UNEP (2010b).

11 Biosafety capacity-building projects have been the subject of recent reviews. See Johnston et al. 2008; UNEP (2010a,b); Johnston et al. (2008).

12 See Chapotin, McLean, and Quemada (2009); Araya-Quesada et al. (2010); Johnston et al. (2008); UNEP (2010a).

13 "The Capacity-Building Coordination Mechanism" [for the Action Plan], http://bch.cbd.int/protocol/cpb_art22_actionplan.shtml#coord.

Chapter 3: THE IMPACT OF BIOSAFETY REGULATION IN DEVELOPING COUNTRIES

3.1 BIOSAFETY REGULATIONS AFFECTING RESEARCH AND DEVELOPMENT

The early stages of developing a GE crop (consisting essentially of laboratory and greenhouse work) are constrained only nominally by biosafety regulations but quite significantly by the scarcity of funds to pursue such a program. National agricultural research systems commonly suffer from inadequate investments even in their traditional research and development (R&D) programs. A transgenic research program requires capital-intensive investments in laboratory and greenhouse infrastructure and sustained funding to support research operations, including training and retention of scientific personnel. The need for sustained, significant investment applies not only to the transformation and regeneration work that leads to the development of GE events but to the follow-on programs essential for GE crop R&D, particularly plant breeding. Insufficient or transient investments in R&D, along with other systemic limitations in policies related to agricultural research (intellectual property rights, for example, or participatory approaches to establishing research priorities) collectively make it almost impossible for low-income countries to pursue basic research for GE crop development.

In the later stages of GE crop development (field research), however, biosafety regulations have a significant impact. Without exception, national biosafety regulatory authorities require permits to conduct confined field trials of experimental GE crops. These small-scale trials of experimental plants are essential to the collection of biosafety data for regulatory dossiers. They also provide an opportunity to evaluate agronomic performance in general, ascertain the efficacy of the particular GE trait (information that is necessary for selecting the most promising events), and generate sufficient plant material for required food safety and livestock feed safety analyses. The confined nature of these trials is achieved through a number of management practices that are usually prescribed by the permitting authority.

Highly restrictive requirements for confined field trials have been a common feature of developing country regulatory systems, and they have limited product developers' ability to conduct field research (Spielman, Cohen, and Zambrano 2006). A common misunderstanding is that confined field trials should be subject to essentially the same risk assessment process as for commercial releases, demonstrating that regulators, national biosafety committees, and sometimes capacity builders and trainers do not appreciate that the risk mitigation measures used to confine these trials render more extensive environmental risk assessments unnecessary. A detailed risk assessment is more correctly applied to the environmental release of GE events outside of confinement. This misperception has been exacerbated by the fact the Cartagena Protocol does not differentiate between these two distinct activities[1] and, as a consequence, many NBFs do not either. GE crop development cannot advance past the laboratory stage unless biosafety regulatory systems permit the confined field evaluation of GE plants of uncertain risk.

3.2 BIOSAFETY REGULATIONS AFFECTING PRODUCT APPROVALS

To date, 16 countries plus the European Union have authorized GE events for environmental release[2] (Table 3.1). Another 8 countries (Czech Republic, El Salvador, Malaysia, the Netherlands, Russia, Switzerland, Taiwan, and the United Kingdom[3]) have approved at least one GE event for use in food and/or livestock feed.

Since 2003, when the Cartagena Protocol came into force, only three developing countries have further assessed and approved GE crops for cultivation for the first time (Table 3.1) although the number of events approved globally has been increasing (Figures 3.1 and 3.2) (Stein and

1 The Protocol differentiates between contained use (exempt from the advance informed agreement procedure) and intentional introduction into the environment (the advance informed agreement procedure applies). A confined field trial may be considered as an intentional introduction into the environment and consequently the risk assessment procedures of Article 15 and Annex III apply.

2 Other countries, such as Bolivia, Honduras, and Pakistan, have been identified as permitting the commercial cultivation of GE crops; however, regulatory authorizations in these countries have yet to be publicly disclosed by the competent authorities. Countries such as Chile and Costa Rica have permitted the cultivation of GE events for counter-season seed production for export but differentiate this activity from commercial cultivation, as none of the harvest is permitted to stay in the country.

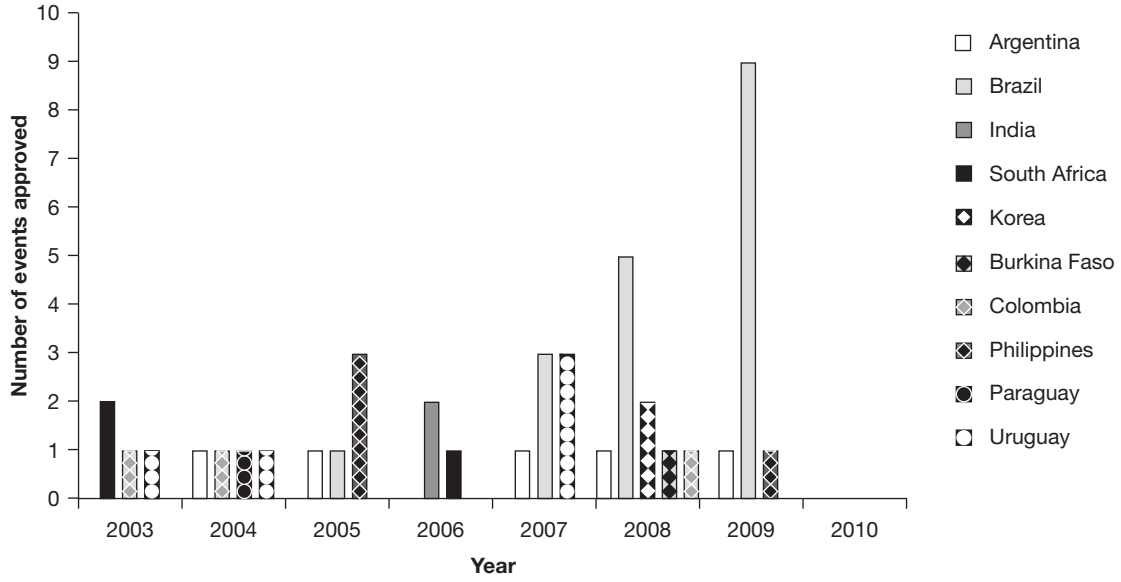
3 Approvals in the Netherlands (1997) and the United Kingdom (1996 and 1997) occurred prior to the implementation of EU regulations.

TABLE 3.1: Summary of Countries That Have Approved at Least One GE Event for Environmental Release

YEAR OF FIRST APPROVAL	COUNTRY	FIRST LINE(S)[a] APPROVED	TOTAL LINES APPROVED TO DATE[a]	CROPS APPROVED TO DATE
1992	United States	Delayed-ripening tomato	81	Canola (*Brassica napus*), chicory, cotton, flax (linseed), maize, papaya, plum, potato, rice, soybean, sugar beet, tobacco, tomato
1995	Australia	Modified flower color carnation	16	Canola (*B. napus*), carnation, cotton
1995	Canada	Herbicide-tolerant canola	60	Alfalfa, canola (*B. napus, B. rapa*), flax (linseed), maize, potato, soybean, sugar beet
1995	Mexico	Delayed-ripening tomato	3	Cotton, maize, soybean
1996	Argentina	Herbicide-tolerant soybean	20	Cotton, maize, soybean
1996	European Union	Male sterile chicory	7	Carnation, chicory, maize, potato
1996	Japan	Delayed-ripening tomato; herbicide-tolerant soybean; insect-resistant maize	55	Alfalfa, canola (*B. napus*), cotton, maize, tomato, soybean, sugar beet
1997	South Africa	Insect-resistant maize; insect-resistant cotton	11	Cotton, maize, soybean
1997	Uruguay	Herbicide-tolerant soybean	8	Maize, soybean
1997	China	Insect-resistant cotton	?[b]	Cotton, maize, rice
1998	Brazil	Herbicide-tolerant soybean	22	Cotton, maize, soybean
2000	Colombia	Modified flower color carnation	4	Carnation, cotton, maize
2002	India	Insect-resistant cotton	3	Cotton
2002	Philippines	Insect-resistant maize	5	Maize
2004	Paraguay	Herbicide-tolerant soybean	1	Soybean
2008	Korea	Insect-resistant maize	2	Maize
2008	Burkina Faso	Insect-resistant cotton	1	Cotton

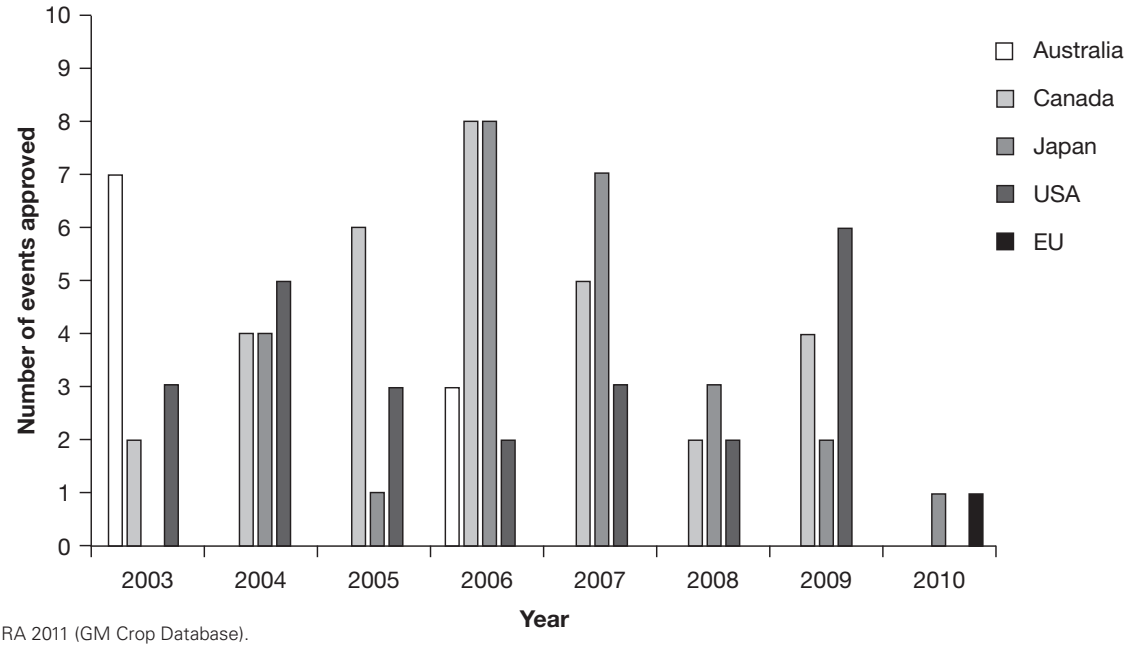
Source: CERA 2011 (GM Crop Database).
a. "Lines" includes primary events developed through genetic engineering and stacked events derived through conventional crossing of primary events.
b. The absence of transparency in decisions taken by the Chinese government prevents an accurate accounting of the number of approved lines.

FIGURE 3.1: Approvals of GE Events by Developing Countries since 2003



Source: CERA 2011 (GM Crop Database).

FIGURE 3.2: Approvals of GE Events by Developed Countries since 2003



Source: CERA 2011 (GM Crop Database).

Rodriguez-Cerezo 2010a; CERA 2011). While it would appear that the majority of the world's countries have been attempting to establish biosafety regulatory frameworks, only a minority have made, or had an opportunity to make, biosafety regulatory systems operational, and even fewer have taken decisions relative to commercial approvals of GE crops or foods.

3.3 THE ROLE OF RISK ASSESSMENT AND NON-SAFETY CONSIDERATIONS IN BIOSAFETY DECISION MAKING

National biotechnology policies must integrate an array of political, social, ethical, health, economic, and environmental considerations and translate these into a strategy for how decisions will be made regarding the safe and appropriate use of biotechnology methods and products.

National biosafety regulatory systems include a science-based risk assessment process as a prerequisite to commercialization of a GE event. The national, regional, and international approaches for assessing the risk of GE crops currently in use vary in their application of legislative triggers, guidance, and terminology (World Bank 2003). Some approaches are highly prescriptive, whereas others offer greater flexibility to regulatory agencies and decision makers. Internationally developed standards or guidance for biosafety risk assessment, as developed by the Organisation for Economic Co-operation and Development (OECD) Working Group for the Harmonization of Regulatory Oversight in Biotechnology[4] or under the auspices of the Cartagena Protocol, have established risk assessment benchmarks that are commonly imbedded in national regulatory systems. Arguably, it is not the risk assessment in itself that has led to the adoption or non-adoption of GE crops on a country-by-country basis, but factors other than safety, as discussed below.[5]

Economic, social, and other non-safety concerns are often the most important considerations in the public's acceptance of new biotechnology applications. Consequently they can play a determining role in whether a government approves a GE event for commercial use (Box 3.1).

When examining how non-safety considerations are addressed in national biotechnology policy, it helps to differentiate policies related to promoting or guiding innovation from those related to the commercialization of biotechnology

4 OECD, "Environmental Biosafety," http://www.oecd.org/document/10/0,3746,en_2649_34385_47257482_1_1_1_1,00.html, accessed April 2012.

5 In this document, "non-safety" issues include all regulatory issues required to be addressed by developers of a GE event that go beyond issues of evaluation of potential harm to human, animal, and plant health and the receiving environment. Such non-safety issues have primarily focussed on the economic and socio-economic impacts from the cultivation of transgenic crops, such as the loss of export markets, increased costs of commodity segregation, or the reduction of product value through commingling. Other non-safety issues may be considered in regulatory decision making, however, such as ethics, culture, or public opinion.

BOX 3.1: The Case of Bt Brinjal in India

Transgenic brinjal (eggplant, *Solanum melongena*) was developed by the Indian seed company, Mahyco, to confer resistance to the Lepidopteran pest *Leucinodes orbonalis* (fruit and shoot borer). In October 2009, India's apex regulatory authority, the Genetic Engineering Approval Committee (GEAC), approved Mahyco's Bt brinjal event EE1 for environmental release and use in food and feed after three years of deliberation, including two expert panel reviews of the safety-related data submitted to GEAC by Mahyco. As the first transgenic food crop to be approved in India, Bt brinjal was extremely controversial and was popularly characterized in the media as unsafe for human health and the environment. Immediately following GEAC's approval of Bt brinjal, India's Minister of Environment and Forests undertook a series of regional consultations and additionally reached out to the international scientific community to solicit opinions on the safety of Bt brinjal. In February 2010, the Minister took the unprecedented action of ignoring GEAC's risk assessment and decision to approve Bt brinjal when he unilaterally placed a moratorium on its commercial release. The Minister stated, "It is my duty to adopt a cautious, precautionary principle–based approach and impose a moratorium on the release of Bt-brinjal, till such time independent scientific studies establish, to the satisfaction of both the public and professionals, the safety of the product from the point of view of its long-term impact on human health and environment, including the rich genetic wealth existing in brinjal in our country."

Source: Authors; MoEF 2010a,b.

products. In the case of innovation policy, ethical, moral, social, and economic concerns all influence policy deliberations through dialogue and debate at the national level. In the case of commercialization, market and trade considerations are the most significant drivers, and they are influenced by national priorities as well as international trade-related agreements, such as the agreements on Sanitary and Phytosanitary Measures and Technical Barriers to Trade and the Biosafety Protocol, which limit the types of non-safety considerations that can be legitimately used to affect trade in biotechnology products. Technological innovations in agricultural biotechnology have not been subject to the same degree of scrutiny or government intervention as, for example, research into stem cells. Instead, it is the products of agricultural biotechnology research, and not the research itself, that have been most affected by non-safety considerations (Box 3.2).

BOX 3.2: Examples of Non-Safety Considerations for GE Crop Approvals

Although functional regulatory systems are largely science based, product commercialization may be determined by other factors, as seen in the following examples.

Argentina: An explicit review of the economic impact on national agricultural production and marketing is included prior to GE crop approvals. This review is separate from the food and environmental safety risk assessment and is required only for commercial cultivation.

Australia: State and Territory governments have authority over land use and have used it to institute moratoria on the cultivation of certain approved GE crops, primarily based on economic considerations.

European Union: Member countries have invoked a safeguard clause to prohibit cultivation of certain GE events, citing potential risks. They have maintained the prohibition even after the European Food Safety Authority has provided scientific opinions that the risks are not significant.

South Africa: The Genetically Modified Organism Amendment Act, passed in 2006 to give effect to the Cartagena Protocol, requires the inclusion of both safety and socio-economic considerations in product-specific decision making. The criteria for assessing the socio-economic impacts of a GE crop release have yet to be clearly described in guidance, yet non-safety considerations are affecting product approvals. In 2009, South Africa's Executive Council for Genetically Modified Organisms rejected a permit application for the general release of SpuntaG2, a potato that is resistant to the potato tuber moth. SpuntaG2 was jointly developed by the South African Agricultural Research Council and Michigan State University specifically for smallholder farmers. The Executive Council indicated its primary reason for not authorizing the potato "had to do with the fact that both commercial and small-scale farmers will be unlikely to switch to the GM potato."[a] Potatoes SA, representing the South African potato industry, opposed the release of SpuntaG2 on the grounds that it would affect domestic consumption of potatoes as well as international trade, particularly with the European Union.

Source: Authors.
a. Mannak (2009).

3.4 ASYNCHRONOUS AND ISOLATED FOREIGN APPROVALS OF GE CROPS

Differences in governments' approaches to biosafety regulation and decision making can have significant impacts on global trade. One example is the effects of asynchronous and isolated foreign approvals (see also Box 1.2).

Asynchronous approvals occur when a country of export approves a GE event for cultivation before its trade partners have done so, meaning that seed or commodity exports may contain GE events not yet approved by the recipient country.[6] In such cases, the exported shipment is deemed by the importing country to have regulated or "illegal" content, and it may be embargoed or returned to the point of origin. To avoid this problem, private sector product developers seek approvals in key markets and delay large-scale commercial cultivation until they are obtained. The least efficient regulatory system becomes rate limiting, and delays of even one year between approvals in key markets can mean tens of millions of dollars in lost revenue.

Isolated foreign approvals occur when a product developer that has received approval of a GE event for cultivation in one country has no intention to seek approval in other areas of the world. For example, the Government of China has made no submissions to other national regulatory authorities for approvals of GE crops that it has developed for its domestic market and that are currently in cultivation. Isolated foreign approvals may prove a more challenging reality to address than asynchronous approvals. Governments in countries of import will have to decide to either forgo testing of commodity or seed shipments that could potentially contain unapproved events understood to be in widespread cultivation in the country of export (in other words, don't look for what you don't want to find) or implement extensive and expensive testing programs and take action (such as a trade embargo) if unapproved events are discovered.

6 The presence of unapproved GE events in seed, food, and feed exports can also arise when: (1) GE seed is smuggled into a country and cultivated illegally in absence of any regulatory approvals (one example is the illegal cultivation of GE cotton in India before 2002; see Sadashivappa and Qaim 2009); (2) when an event is released accidentally into the value chain (for example, the detection in commercial rice samples of GE rice event LL601, grown in field trials from 1998 to 2001 in the United States but never submitted for regulatory approval, affected the United States rice export market; see Li et al. 2010); or (3) when there are asynchronous approvals within a country (StarLink maize, approved in the United States for use in livestock feed but not for human consumption, was detected in processed maize food products, resulting in food recalls and lost sales of United States maize to markets like Japan and South Korea; see Taylor and Tick 2001).

3.5 THE COST OF BIOSAFETY REGULATION

It is widely held that biosafety regulation is a significant constraint to realizing the benefits that GE crops may afford developing countries, both in terms of the direct costs of meeting regulatory requirements and in terms of the indirect or opportunity costs. Such costs may include forgone profits to farmers, product developers, and other actors in the agricultural production and value chains; costs associated with the use of alternative crop production practices and their environmental impacts; and market or trade disruptions. High regulatory costs such as those reported in Box 3.3 impede both innovation and commercialization of GE technologies by all but the large multinational companies and, in particular, exert a chilling effect on research in minor crops, such as pro-poor staple food crops, and in countries where market size cannot justify the fixed-cost investments (Qaim 2009).

BOX 3.3: Costs in 10 Markets of Regulatory Approval of a GE Event Developed by the Private Sector

Direct compliance costs to obtain regulatory approval of a private sector–developed GE event in 10 markets (Argentina, Australia, Canada, China, the European Union, Japan, Korea, the Philippines, Taiwan and the United States) were estimated to range from US$ 7.1 million to US$ 14.4 million for insect-resistant maize and US$ 6.2 million to US$ 14.5 million for herbicide-tolerant maize.[a] The differences in costs across product developers were attributed to:

- Different strategies taken as product developers attempted to anticipate the effect of evolving regulatory guidance (for example, the appropriate number of confined field trials required for data generation or the kinds of studies that should be submitted in the regulatory dossier).
- Costs associated with specific types of testing, including production of plant tissue for analyses, compositional assessment, protein production and characterization, and molecular characterization).
- Overhead costs for facilities and management.

These costs did not take into account indirect compliance costs associated with early research and development or unanticipated delays that can arise during the regulatory approval process.

Source: Authors.
a. Kalaitzandonakes, Alston, and Bradford (2007).

It is a reality that public sector product developers, like their private sector counterparts, must contend with the costs of bringing a GE product to commercialization in a global marketplace (Box 3.4). These costs are often cited as the primary deterrent for public sector investments in agricultural biotechnology, especially in developing countries (Qaim 2009; Graff, Hochman, and Zilberman 2009).

In addition to costs associated with meeting biosafety regulatory requirements in the country where a GE event is to be cultivated, product developers must also consider the potential consequences of unanticipated actions, such as trade disruptions that can occur as a result of accidental, or sometimes deliberate but illegal, transboundary movement of GE seed from a jurisdiction where it is approved for cultivation to one where it is not (Box 3.5). This consideration is particularly significant in relation to developing countries, where border controls restricting the movement of viable plant material may be limited and where seed of improved varieties is commonly informally exchanged within and across borders. The major multinational product developers have adopted product launch policies to undertake a market and trade assessment to identify key import markets prior to the commercialization of any new GE event and to meet applicable regulatory requirements in these key markets (BIO 2007). While this consideration is also valid for product developers in the public sector, it will add costs to product development and commercialization. An alternative to individual product developers seeking country-by-country approvals is to encourage national governments to adopt regional approaches to biosafety risk assessment and possibly decision making, which could mitigate some of the costs and potential consequences of inter-country movement of GE events (see Chapter 4). Regional approaches may be particularly helpful to developers of pro-poor crops, which because of their particular traits or farmers' preferences may already have limited geographic distribution (in other words, they are not globally traded commodity crops like soybeans, maize, or rice).

BOX 3.4: Examples of Regulatory Costs for GE Plants in the Philippines

Direct regulatory costs for four GE events (Bt eggplant, virus-resistant tomato, Bt rice, and virus-resistant papaya) currently being advanced by public institutions in the Philippines were reported to range from US$ 249,500 to US$ 690,680.[a] These costs are significantly lower than the USD $2.6 million estimated for the technical and commercial development of Monsanto's insect-resistant maize event MON810 in the Philippines. The discrepancy can be attributed to the fact that the direct costs for the four public sector events are for a very limited set of activities taking place in the Philippines and exclude research and development, technology transfer, and compliance testing for these events or their novel proteins that took place outside of the Philippines or had already been completed for like products. The cost for MON810 commercialization in the Philippines reflected the studies and activities conducted from the gene discovery phase to the first set of laboratory and greenhouse experiments in the United States, as well as in-country costs.[b]

Source: Authors.
a. Bayer, Norton, and Falk-Zepeda (2010).
b. Manalo and Ramon (2007).

BOX 3.5: Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol

In October 2010, the Nagoya–Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol was adopted. This Supplementary Protocol was the culmination of six years of contentious discussion about how liability and redress for damage to biological diversity resulting from the transboundary movement of living modified organisms (LMOs) should be managed. The Supplementary Protocol provides international rules and procedures that countries may incorporate as they develop their own national approaches to establishing compensation mechanisms. It remains to be seen how the Supplementary Protocol will be implemented and how it will interact with other international treaties on trade. The private sector has developed a contractual mechanism, the Compact, which provides States with recourse in the event of damage to biological diversity caused by LMOs. It has been signed by the six major multinational developers of GE plants and is open to other private or public organizations that meet the requirements for membership, which includes the financial capacity to respond to damages. Neither the Supplementary Protocol nor alternative mechanisms for dealing with liability and redress, like the Compact, alleviate the post-commercial costs that a public sector product developer may consider when deciding to pursue the development of GE crops (or a government may consider when allocating resources to agricultural research and development). *Source*: Authors.

3.6 THE EFFECTIVENESS OF THE REGULATORY PROCESS

The costs of meeting regulatory requirements leading to the commercialization of a GE event can be quantified, but it is much more challenging to measure the effectiveness of a biosafety regulatory system in meeting its objectives. Over the course of the development continuum for a GE product, biosafety regulatory authorities have multiple points of engagement, including but not limited to: permits for importation of experimental plant materials; licensing of R&D facilities where recombinant DNA research takes place; permits for confined field trials; pre-market environmental, food, and feed safety assessments and approvals/disapprovals; post-market environmental monitoring; and inspection and enforcement activities during all of these stages. Regulatory authorities often publish the number of licenses or permits that they have issued, information about compliance infractions resulting from inspections, and (most commonly) summary decisions about GE event risk assessments or authorizations for commercial use which demonstrate, at least in part, the outcomes of these regulatory activities. These sorts of information are poor metrics for evaluating the effectiveness of a biosafety regulatory system, however. If regulatory processes provide real value—for example, in providing significant environmental safeguards—then the monetary costs of their implementation may be considered justified. If these interventions are redundant with other regulatory operations, are applied inconsistently or discriminately, or are used as barriers to technological access, innovation, or trade, then biosafety regulation is significantly more costly than described in Section 3.5.

Chapter 4: OPPORTUNITIES TO ADVANCE BIOSAFETY REGULATION

Maintaining crop productivity at current levels is already challenged by urbanization and its attendant competition for land and water, increasing demand for non-food products (such as feedstocks for biofuels), access to water for irrigation, and limited scope for agricultural land expansion without significant negative impacts on biodiversity. These challenges will be exacerbated by the impact of climate change, particularly in developing countries, where crop yields are projected to remain static or decrease by as much as 14 percent in irrigated rice and 28 percent in irrigated wheat, with sub-Saharan Africa and South Asia being particularly hard hit across most important crop species (Nelson et al. 2009). Agricultural adaptation to constraints on production requires many kinds of interventions, and one of the most important is the ability to maintain, let alone increase, crop yields under current and future biotic and abiotic stress scenarios. The breeding and selection of adapted plant varieties require integrated approaches ranging from conventional breeding with landraces and crop wild relatives to more advanced methods such as marker-assisted selection and genetic engineering.

Biosafety regulation, properly applied, should provide developing countries that choose to access the potential benefits of agricultural biotechnology with an effectual process for doing so. As described in Chapters 1 and 2, however, only a small number of the many developing countries that have developed NBFs have operationalized them, and even fewer have actually taken biosafety-related decisions such as permitting confined field trials or authorizing GE events for cultivation. As noted in the conference report from ABDC-10:

> *Both the lack of policies and regulatory mechanisms as well as overly stringent regulations hinders development of, and access to biotechnologies. Effective and enabling national biotechnology policies and science-based regulatory frameworks can facilitate the development and appropriate use of biotechnologies in developing countries; and ongoing reviews, improvement and harmonization of existing biotechnology policies and regulatory frameworks can keep them current and rational.*
>
> *FAO (2010)*

There are opportunities to advance biosafety regulation in ways that could particularly benefit developing countries. Some of these are introduced below.

4.1 REVISIT THE CONTEXT FOR BIOSAFETY REGULATION OF GE CROPS

Ratification and implementation of the Cartagena Protocol have significantly raised both the profile and importance of biosafety regulation as a contributing element to biodiversity conservation. As discussed, the Protocol has also situated the biosafety of LMOs, first and foremost, as an environmental issue, which affects how biosafety is considered by national governments as they attempt to meet their Protocol obligations. Biosafety is typically the responsibility of ministries of environment and natural resources, as evidenced by the fact that 71 percent of the national focal points for the Cartagena Protocol are situated in ministries of environment and natural resources (11 percent are in ministries of agriculture and 17 percent in other ministries) (SCBD 2011).

GE crops, the only significant class of LMOs in international trade, are by default the organisms first considered when developing country governments establish and implement biosafety regulatory systems. The challenge, however, has been to ensure that the regulatory context for these crops is relevant to their use in agriculture. More specifically, both the risk assessment and any non-safety considerations that are used to inform decisions should not be defined exclusively by environmental protection goals but by additional development priorities, such as improving agricultural productivity, food security, and rural development.

Many countries have framed biosafety regulatory systems to consider GE crops only in the narrow context of environmental harm. In some cases, this was a deliberate action in support of a policy decision to ban GE crops. In others, it was perhaps the unintentional consequence of following an approach advocated for NBF development without due consideration of the potential trade-offs that would arise when highly precautionary language (effectively impeding access to the technology) was imbedded in laws or regulations. Countries developing NBFs in the early 2000s, as many did with GEF funding, may not have viewed GE crops as a potentially useful tool for agricultural development. At that time, commercially available GE events were limited almost exclusively to commodity crops developed for industrialized agricultural production systems. GE crop and trait combinations suitable for smallholder farmers in developing countries were limited primarily to a few public sector R&D projects, and governments might

reasonably have assumed that this controversial technology would have limited applicability to their own agricultural systems. A decade later, the scenario has changed (as described in Box 1.2), and governments that have been apathetic or even antagonistic to agricultural biotechnology are reevaluating its potential as a tool to improve crop production and management practices and thus contribute to improved food security and agricultural sustainability. In these cases, governments may need to reconsider biosafety (and other) regulatory systems to ensure that they encourage innovation in agriculture while still ensuring adequate environmental protection.

4.2 RATIONALIZE RISK ASSESSMENT

Biosafety regulatory systems in all countries are dynamic. The flexibility to accommodate change is essential, as a regulatory system must be able to adapt quickly to both premarket and post-market perturbations. Such perturbations include rapid advances in biotechnology research and their effects on product development, assessment, adoption, and stewardship; they also include the trade impacts that occur after product commercialization, such as changes in market access or the consequences of detecting unapproved GE material in grain or seed shipments. Effective management of such changes is a challenge for all biosafety regulatory systems, which is why key regulatory functions like risk assessment should be continually reevaluated and improved.

The establishment of new biosafety regulatory systems and the reform of existing systems should reflect the accumulated experience with the cultivation of GE crops, so that risk assessment and risk management (that is, decision making) are commensurate with the actual level of risk associated with GE crop production (Falk-Zepeda, Cavalieri, and Zambrano 2009). Unfortunately, this goal seems to remain at once obvious yet elusive, as governments have largely failed to realize opportunities to rationalize biosafety regulations and guidance. Instead, the emergence of new analytical tools, particularly in molecular biology, has led to the addition of new information or data requirements for environmental risk assessment, although no evidence of adverse environmental impacts with the cultivation of GE crops has emerged. For example, the European Commission has published two compendia of the results of 25 years of European Union–funded research on GE crops (EC 2000, 2010). The most recent compendium stated that "there is no scientific evidence associating GMOs [genetically modified organisms] with higher risks for the environment or for food and feed safety than conventional plants and organisms." Despite this accumulation of scientific knowledge and experience, environmental risk assessment guidance published by regulators in the European Union and countries such as Canada, Australia, and Japan remains relatively unchanged, with the possible exception of molecular characterization data requirements, which have become more elaborate and costly over the past decade.

Private sector product developers, particularly multinational companies, have the resources to respond to new data requirements, irrespective of their applicability to risk assessment and environmental safety. Arguing against requests for new studies can delay decision making and time to market. The cost of complying with ad hoc or new requests is nominal when compared with forgone profits from missed seed sales, and so product developers are inclined to acquiesce when such requests arise. Over time, precedents for new studies have become established requirements in guidance, the costs of regulatory compliance have risen, and it has become increasingly difficult for the public sector and smaller enterprises to pursue GE crop commercialization (as evidenced by Table 4.1). If the environmental, development, and economic benefits of GE crops, especially pro-poor GE crops, are to be realized, then the rationalization of risk assessment information and data requirements must be

TABLE 4.1: GE Events Developed by Public Organizations and Approved for Environmental Release in at Least One Country

CROP	EVENT	DEVELOPER	DESCRIPTION	APPROVALS (COUNTRY AND YEAR)	COMMERCIALLY AVAILABLE IN 2011
Flax (linseed)	FP967	University of Saskatchewan (Canada)	Sulfonylurea herbicide tolerance	Canada, 1996 USA, 1999	No
Papaya	55-1/63-1	Cornell University (USA)	Resistance to papaya ringspot virus	USA, 1996	Yes
	X17-2	University of Florida (USA)	Resistance to papaya ringspot virus	USA, 2008	No
Plum	C5	U.S. Department of Agriculture (USA)	Resistance to plum pox virus	USA, 2007	No
Soybean	BPS-CV127-9	Embrapa[a] (Brazil)	Imidazolinone herbicide tolerance	Brazil, 2009	No

a. Developed jointly with BASF.

Source: CERA 2011 (GM Crop Database).

pursued aggressively. It can, and should, be led by developing country policy makers, with technical inputs from regulatory authorities and scientists involved in risk assessment. This task will be particularly challenging to accomplish in the context of the highly polarized dialogues/debates around risk assessment that take place under the auspices of the Cartagena Protocol, but opportunities for meaningful bilateral and regional discussions exist (see the discussion in Section 4.4). Improved and cost-effective approaches to biosafety regulation generally, and risk assessment particularly, can be pursued without compromising environmental protection and management goals.

4.3 CONSIDER RISK AND BENEFIT ASSESSMENT

It is often assumed that the potential adverse environmental impacts of GE crops will be greater for developing than developed countries (Qaim, Subramanian, and Sadashiviappa 2009; Heinemann et al. 2009). Concerns have been raised that shifts in agricultural practices or in the selection and genetic diversity of cultivated crops could affect natural biodiversity or compromise the genetic resource base provided by centers of origin for domesticated crop species. An additional concern is that many developing countries still face inadequate technical capacity to undertake the environmental risk assessments that inform the decision to approve or deny the environmental release of a GE crop. Arguably, however, the potential environmental benefits afforded by GE crops may also be greatest for developing countries, although this possibility is seldom considered in biosafety regulatory systems.

The paradigm for environmental risk assessment that has been established in countries with mature biosafety regulatory systems focuses on identifying potential adverse impacts that might be associated with the environmental release of GE plants. Only rarely are potential environmental benefits taken explicitly into account as part of the risk assessment. One example is the Environmental Protection Agency in the United States, which regulates GE plants with pesticidal traits such as Bt crops (named for *Bacillus thuringiensis,* the bacterium from which the pest resistance is transferred) under the Federal Fungicide, Insecticide, and Rodenticide Act, which is a risk benefit statute. This missed opportunity is particularly punitive in the context of developing country agriculture, where alternative strategies for managing biotic or abiotic productivity constraints may not exist or may have negative environmental (and health) effects (see Box 4.1).

BOX 4.1: Example of Environmental Benefits from GE Crops

Benefits of engineered herbicide tolerance: Crops that have been genetically engineered to tolerate the herbicide glyphosate have had both direct and indirect environmental benefits. The direct benefits have come with a shift in the types and pattern of herbicide use.[a] The indirect benefits are associated with the widespread adoption of conservation tillage practices, which aid in conserving soil moisture and improving soil structure and water quality. The shift from conventional tillage to low-till or no-till systems has been facilitated by the introduction of herbicide-tolerant soybeans, maize, cotton, and oilseed rape.[b] These benefits may eventually be compromised, as the widespread adoption of glyphosate-tolerant crops has been associated with shifts in weed populations and the selection of weeds that are also tolerant to herbicide.[c]

Benefits of Bt crops: Significant reductions in insecticide use, and the resulting human health and environmental benefits, have been attributed to the adoption of Bt cotton in almost every country where it has been grown.[d] Bt maize and Bt cotton have become important components of integrated pest management programs, because the reduction in pesticide use improves opportunities for both natural and introduced biological control of other maize and cotton pests.[e]

Source: Authors.
a. Dill, CaJacob, and Padgette (2008).
b. Givens et al. (2009); Gusta et al. (2011); Frisvold, Boor, and Reeves (2010).
c. Owen (2008).
d. Fitt (2009).
e. Hellmich et al. (2008); Naranjo et al. (2008).

4.4 HARMONIZE BIOSAFETY RISK ASSESSMENT

As discussed, biosafety regulation is often pursued as a national activity, and it becomes particularly challenging in countries lacking sufficient human, institutional, and financial resources to operate a regulatory system that may be used only intermittently. In such cases, a regional or subregional approach to risk assessment may be the most practical, cost-effective option. It could include recognizing scientific opinions arising from risk assessments by other regulatory authorities, establishing regional approaches to risk assessment, or—more ambitiously—adopting decisions taken by other governments. Harmonization of risk assessment requirements and processes within a subregional or regional bloc of countries could also serve as an enticement for product developers to invest in the resulting common market, if the costs of achieving regulatory compliance become competitive. Smaller countries might then have access to otherwise unavailable technologies and products, potentially at a better price if competition between

product developers improves. Regulatory harmonization may also be the most effective means of mitigating the trade consequences of asynchronous approvals.

Many developing country governments recognize that developing a comprehensive national capacity in biosafety regulation is neither feasible nor desirable if cooperation in harmonizing risk assessment criteria, information requirements, evaluation standards, and, to some extent, legal and regulatory systems provides a more sustainable alternative. The Economic Community of West African States (ECOWAS) has developed a draft regulation for regional risk assessment (Box 4.2), and the Common Market for Eastern and Southern Africa has developed draft regional biosafety guidelines for

BOX 4.2: Regulatory Harmonization Efforts in West Africa

The potential value of a subregional approach to biosafety regulation in West Africa was first explored in a five-country study of human resource capacity, infrastructure, and the general awareness of biosafety in Cameroon, Côte d'Ivoire, Ghana, Nigeria, and Senegal in 2000; a follow-on study in 2002 added Burkina Faso and Mali.[a] In 2004, the Institut du Sahel (INSAH) completed a stock-taking exercise in each of the five member countries of the Permanent Interstate Committee for Drought Control in the Sahel (CILSS) plus Ghana, to gain a better understanding of the structure of the seed sector in each. This exercise led to the development of the Framework Convention Instituting Common Regulations for Conventional and Transgenic Seeds in the CILSS Area (the CILSS Convention). The preambles to the convention recognize that modern biotechnology has both benefits and potential risks and that a subregional approach to biosafety regulation should be undertaken, as "each country is neither able to individually take advantage of the known and potential benefits of genetically modified organisms (GMOs), nor cope with their known and potential risks."

In 2005, the Economic Community of West African States (ECOWAS) published an action plan with three operational objectives for the development of biotechnology and biosafety in the subregion, one of which was to develop a subregional approach to biosafety regulation.[b] The action plan accepted that such an approach would make it possible to pool resources; facilitate the exchange of experiences, information and data; and maximize the potential of the subregion's limited human, institutional, financial, and technical resources for biosafety. This approach was considered consistent with the goals of other West African subregional organizations like CILSS, the West African Economic and Monetary Union, and the West and Central African Council for Agricultural Research and Development, and it was also consistent with Party obligations under the Cartagena Protocol. In March 2007, the ECOWAS Agriculture and Environment Ministers reached an agreement to adopt a subregional biosafety program which would be based on the CILSS Convention. The operational model, selected during the Preparatory Meeting to Launch the Regional Consultative Committee on Biosafety in July 2007, was a mechanism whereby the science-based risk assessment function would be undertaken by a subregional body, but all decisions (GE product approvals) would remain at the national level. The subregional body would be responsible for undertaking risk assessments for specific types of applications (such as confined field trials, GE food safety assessment, and environmental risk assessment of GE plants) and would provide scientific opinions to the member countries.

In August 2008, the Experts Group Meeting on ECOWAS Biosafety Regulation was attended by environment and agriculture representatives from 14 ECOWAS countries. The meeting concluded with a request to INSAH-CILSS to revise the CILSS Convention; to circulate the revisions for consideration by all countries; to make final revisions; and then to submit the documents for adoption by ECOWAS. During a series of four subregional meetings, and with additional bilateral inputs from engaged ECOWAS country representatives, the CILSS Convention was substantively rewritten in an effort to address the activities of the subregional process consistently and without duplication. The contained, confined, and unconfined uses of GE organisms were clearly differentiated, and the regulatory responsibilities for each of these activities were defined. The technical annexes, which describe the technical information required for applications to the regional scientific review panel, were more clearly aligned with the types of applications that will be received in the subregion and, importantly, with existing international standards and guidance related to the regulation of GE organisms as established by Codex Alimentarius, the Organisation for Economic Co-operation and Development, and the Cartagena Protocol. The resulting ECOWAS document, "Regulation C/Reg.1/12/08 Establishing a Procedure for the Review and Authorisation of Products of Modern Biotechnology within the ECOWAS," awaits signature and implementation.

Source: Authors.
a. Alhassan (2002, 2003).
b. ECOWAS (2005).

its member states. The Government of Vietnam has pursued a different model for harmonization, as it permits a written certification of eligibility for use of GE organisms in food if the subject of the application has been permitted by at least five developed countries for use as food and no risk has been seen in these countries. This approach to regulatory approvals is both practical and scientifically defensible; the Vietnamese Ministry of Health considers the biosafety regulatory systems of certain other countries to be consistent with that of Vietnam, and it regards the risk assessment and approvals undertaken by those countries as equivalent to those undertaken in-country.

While achieving regional harmonization for risk assessment is possible (the European Food Safety Authority's GMO Panel,[1] the CILSS' Common Regulation for Pesticide Registration[2]), it is not a simple process. For example, ECOWAS was critical of the slow progress in achieving a subregional biosafety framework in West Africa, which it attributed to "an absence of political support in the field of biotechnology and biosafety; lack of communication between stakeholders, even within the same country; lack of coordination between the concerned ministries in the member countries; and poor subregional co-operation on the subject" (ECOWS 2005). These constraints apply as much to developed countries as to developing countries, as evidenced by the United States and Canada, countries that engaged in harmonization efforts earliest (Box 4.3).

Subregional and regional harmonization could also serve as a means for trading partners to mitigate the lack of progress in achieving international consensus on guidance or standards for the environmental risk assessment of GE. Negotiations within a smaller group of countries, particularly if they share economic and development goals, could avoid the divisiveness that occurs in international fora where the ideological differences between the United States and Europe tend to dominate discussions and inhibit progress. For example, the Cartagena Protocol provides an obvious point of departure for promoting risk assessment harmonization, particularly the language in Article 15 and Annex III. Efforts to elaborate Annex III by the Online Expert Forum and an Ad Hoc Technical Expert Group on Risk Assessment and Risk Management yielded a draft document, "Guidance on Risk Assessment of Living Modified Organisms,"[3] but its content and utility for risk assessors in developing countries are debated.[4] The OECD Working Group on Harmonization of Regulatory Oversight of Biotechnology continues to expand its extensive body of consensus and guidance documents in support of environmental risk assessment harmonization.[5]

BOX 4.3: Harmonization between Canada and the United States Remains a Missed Opportunity

In 2001, the Canada-United States Bilateral Agreement on Agricultural Biotechnology harmonized technical requirements for environmental risk assessment of GE crops, but this agreement has not resulted in any appreciable gains in efficiency or effectiveness within or between the representative regulatory agencies. Cooperation in joint reviews of regulatory dossiers remains extremely limited (simultaneous reviews remain the standard practice), although the 2001 Agreement stated "The results of this meeting, and other activities, may lead to considering mutual acceptance of assessments in the future." Mutual acceptance of the scientific opinions arising from regulatory risk assessments has yet to occur, and mutual recognition of decisions to approve or deny approval of a specific GE event may be simply unattainable in absence of political support for doing so.

Source: Authors.

1 The GMO Panel carries out risk assessments (based on reviews of scientific information and data to evaluate the safety of a given GMO) to produce scientific opinions and advice for decision makers (http://www.efsa.europa.eu/en/gmo/aboutgmo.htm). Conclusions from these risk assessments, which have typically found that the GE plant in question is "unlikely to have adverse effects on human health and the environment, in the context of its intended uses," have had little effect on authorizations for cultivation in the EU.

2 The Common Regulation for Pesticide Registration in CILSS countries served both as an impetus and a model for the development of the Framework Convention Instituting Common Regulations for Conventional and Transgenic Seeds in the CILSS Area. According to INSAH (http://www.insah.org/protectiondesvegetaux/csp/RCenglish.pdf), "The main objective of this Common Regulation was to combine the expertise on pesticide evaluation and management of all CILSS Member States for pesticides registration. The Sahelian Pesticide Committee (CSP), the common pesticide registration body, became operational in 1994. It assesses registration dossiers submitted by the agro-chemical industry and grants sales permits valid for all its Member States."

3 According to the CBD (http://www.cbd.int/decision/mop/?id=12325), the objective of the guidance is "to provide a reference that may assist Parties and other Governments in implementing the provisions of the Protocol with regards to risk assessment, in particular its Annex III and, as such, this Guidance is not prescriptive and does not impose any obligations upon the Parties." The guidance document is available from the Biosafety Clearing-House (http://bch.cbd.int/onlineconferences/ra_guidance/testing.shtml).

4 Biosafety Clearing-House, "Archived Discussions," http://bch.cbd.int/onlineconferences/archived_discussions_ra.shtml, accessed April 2012.

5 OECD, "Documents on Harmonization of Regulatory Oversight in Biotechnology and the Safety of Novel Foods and Feeds, http://www.oecd.org/document/55/0,3746,en_2649_34385_2500215_1_1_1_1,00.html, accessed April 2012.

The Working Group comprises OECD member countries, OECD accession countries (Russia), OECD enhanced engagement countries (Brazil, India, Indonesia, People's Republic of China, and South Africa), and other countries such as the Philippines that participate through the OECD Global Forum on Biotechnology. The limited participation of developing country representatives in Working Group meetings means that alternative perspectives on the prevailing biosafety regulatory and risk assessment paradigm are not being sufficiently integrated into the harmonization agenda. This situation needs to be rectified so that the potential impact of guidance or recommendations on the development of GE crops of relevance to non-industrial countries is explicitly considered during document development.

4.5 INTEGRATE CAPACITY BUILDING INTO INVESTMENT PROGRAMS

Only a limited number of developing countries have substantive public sector research programs in agricultural biotechnology (Argentina, Brazil, China, India, and South Africa are examples) or are considered markets of interest for private sector investments in this area. The paucity of strong biotechnology research programs, in addition to human and institutional resource constraints, may explain why so few countries have implemented NBFs. In effect, there is an absence of demand to drive regulatory development (or reform) forward, and policy makers' attention is necessarily redirected to existing priorities. As a result, countries may develop "model" biosafety regulatory systems that are disengaged from agricultural, environmental, or development realities, and any improvements in human resource capacity are transient, because personnel have no opportunity to implement what they have learned.

Biosafety capacity building must therefore move past the development of NBFs and the concurrent short-term technical training. Investments in the development and deployment of GE crops should be accompanied by a parallel and sustained commitment to operationalize, monitor, and improve the associated regulatory systems that are put into place to deal with agricultural biotechnology. Improving a government's capacity for biosafety regulation, including risk assessment, risk management, and communications capabilities, might be more sustainably achieved if product-related applications are ready to "prime the regulatory pump." These applications may be for laboratory activities related to R&D; field trials of experimental GE products (including transgenic plants, insects, and fish); or pre-market applications for environmental, food, and/or livestock feed safety assessment.

Consequently, biosafety capacity building initiatives can have more value and impact if they are implemented in the context of investments that are already planned or underway in wider economic and social development plans. For example, the design of the GEF-funded West Africa Regional Biosafety Program under the World Bank was driven by the fact that three of the proposed beneficiary countries were already implementing important projects and policy reforms on agricultural diversification, research, and extension with the World Bank; the Bank was supporting institutional reforms, producer organizations, strengthening of nascent food supply chains, and export promotion for agricultural products. An additional factor was that all of the countries had actively sought support in developing their cotton sector, including the regulatory aspects.

Capacity-building programs should also pursue opportunities to strengthen the scientific and knowledge base in ways that will provide benefits that extend beyond biosafety risk assessment and decision making. Many developing countries have only a transient need for biosafety risk assessment, given that regulatory authorities may receive an application for a field trial or pre-market approval only once a year or once every few years. However, investments in education and research in the scientific disciplines that support biosafety risk assessment and regulation can have wide reaching payoffs for risk assessment and risk management programs that deal with related issues, such as sanitary and phytosanitary systems and environmental impact analysis. Efficiencies can be gained through the cross-utilization of expertise within a country or through the pooling of human resources with neighboring countries.

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ADDITIONAL RESOURCES

ABDC-10: Documents prepared for, and arising from, ABDC-10 are available at http://www.fao.org/biotech/abdc/backdocs/en/. Particularly relevant are:

- Conference Report (http://www.fao.org/fileadmin/user_upload/abdc/documents/report.pdf)
- Current Status and Options for Crop Biotechnologies in Developing Countries (http://www.fao.org/fileadmin/user_upload/abdc/documents/crop.pdf)
- Policy Options for Agricultural Biotechnologies in Developing Countries (http://www.fao.org/fileadmin/user_upload/abdc/documents/policy.pdf)

Biosafety Clearing-House:

- Website: http://bch.cbd.int/
- "Action Plan" (for Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety), http://bch.cbd.int/protocol/cpb_art22_actionplan.shtml
- "Guidance on Risk Assessment of Living Modified Organisms," http://bch.cbd.int/onlineconferences/ra_guidance/testing.shtml

CERA (Center for Environmental Risk Assessment), GM Crop Database, http://cera-gmc.org/index.php?action=gm_crop_database

GEF (Global Environment Facility) project and other databases, http://www.gefonline.org/, accessed October 2010

OECD (Organisation for Economic Co-operation and Development), "Environmental Biosafety," http://www.oecd.org/document/10/0,3746,en_2649_34385_47257482_1_1_1_1,00.html

UNEP (United Nations Development Programme):

- "Biosafety," http://hqweb.unep.org/biosafety/, accessed April 2011.
- UNEP Toolkit for the Development Project, http://www.unep.org/biosafety/Toolkit.aspx, accessed April 2011
- Draft NBFs are available at http://www.unep.org/biosafety/National%20Biosafety%20frameworks.aspx, last updated 2 August 2010

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