

Biosafety Regulatory Systems in the Context of Agricultural Innovation

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SYNOPSIS

Biosafety regulation is a multidisciplinary, multifunctional endeavor that should take into account the broader context of agricultural production and innovation. Investments needed to operationalize a biosafety regulatory system should promote interministerial cooperation, sound and pragmatic policy development, scientifically defensible risk assessment and risk management, rational inspection and enforcement activities, and meaningful stakeholder consultation and public participation. Efficiencies can be gained through the cross-utilization of national or regional expertise, regional harmonization, and ensuring that the design of a biosafety regulatory system takes into account programmatic and operational costs, including opportunity costs that may arise from overregulation.

BACKGROUND AND CONTEXT

To date 22 countries have approved genetically engineered (GE) plants for cultivation or consumption (CERA 2010a). In 2010, 148 million hectares (366 million acres) were planted to GE crops, largely soybeans, cotton, maize, and canola (James 2010). Common to all countries where GE crops are cultivated is a system to regulate these products and especially to ensure that they are evaluated with respect to human health and environmental safety (commonly referred to as biosafety) prior to their commercial release.

The regulation of products of agricultural biotechnology, particularly GE crops, has been identified as a constraint to innovation in this sector, largely because of the costs of meeting information and data requirements prescribed by regulatory authorities for assessing the safety of GE plants (Cohen and Paarlberg 2004; Kalaitzandonakes, Alston, and Bradford 2007; Matten, Head, and Quemada

2008) but also because of inadequate capacity to enforce regulatory compliance (Pray et al. 2006).

The converse may be argued as well, however. A well-defined biosafety regulatory system that is consistent in its application (that is, the assessment, decision-making, and enforcement processes are not arbitrary) can be a powerful stimulus for investments in this area. For example, Brazil has seen public and private investments increase in agricultural biotechnology since it passed the Biosafety Law in 2005 (BrBiotec 2010). The new law clarified the regulatory remits of various ministries and clearly defined the roles and responsibilities of the two regulatory authorities, the National Biosafety Council (CNBS, *Conselho Nacional de Biossegurança*) and the National Biosafety Technical Commission (CTNBio; *Comissão Técnica Nacional de Biossegurança*).

The law ended a five-year moratorium on approvals of GE crops that arose from differences in governmental and judicial interpretation of pre-2005 legislation (Cardoso et al. 2005). The moratorium, in turn, contributed to wide-scale cultivation of illegal (unapproved) GE soybeans. Since 2005, Brazil has approved 20 GE cotton, soybean, and maize lines for commercial cultivation; prior to 2005 it had approved only 1 (CERA 2010a).

A functional biosafety regulatory system is a prerequisite for realizing the benefits that agricultural biotechnology can (and does) provide to poor producers and poor consumers in developing countries (World Bank 2007). Ultimately, environmental and human health protection is the overarching priority of any biosafety regulatory system, and confidence in the decisions that governments make on behalf of the public is a precondition for public acceptance and adoption of agricultural biotechnology products. Strategic investments in programs that foster adaptability, transparency, clarity, and workability in the development and implementation of regulatory systems also foster agricultural innovation.

INVESTMENT NEEDED

Investments in support of biosafety regulation may be needed for any or all stages in the typical progression of events that lead to the development and implementation of a regulatory system. Key issues and policy options for these stages were described in a conceptual framework for biosafety regulation (McLean et al. 2002); World Bank (2003) presented examples for individual countries. In summary, the key stages are:

- **Elaborate a national policy** consistent with other objectives related to economic, social, and rural development, natural resource management, and environmental protection and sustainability.
- **Conduct an assessment and gap analysis** of national development priorities, agricultural policies, existing regulatory regimes, and national and regional scientific and technical means necessary for a biosafety regulatory system to function.
- **Build a strong base of scientific knowledge** in support of the regulatory system and the development of core competencies in biotechnology product evaluation (box 6.22).
- **Develop biosafety regulations to effect specific public policy goals** (as articulated in a national biosafety or even biotechnology strategy).
- **Implement regulations** through the operationalization of the biosafety regulatory system.
- **Address cross-cutting issues** that are common to each stage in the development and implementation of a

Box 6.22 Building Human Resource Capacity for Biosafety Risk Assessment

The type of human resource capacity needed to implement a biosafety regulatory system generally, and its risk assessment function specifically, is particular to each country. No standardized lists of human resource requirements specific to individual disciplines exist. It can be instructive, however, to examine how other countries have approached this issue.

In India, the Risk Assessment Unit of the proposed Biotechnology Regulatory Authority of India will be permanently staffed by a multidisciplinary team of scientists responsible for undertaking science-based risk assessments of specific products. The Risk Assessment Unit will comprise thematic cells. The expertise for the two cells pertinent to the regulation of genetically engineered crops is:

- **Core characterization:** Molecular biologist, toxicologist, microbiologist, biochemist, bioinformatics specialist, biostatistician.
- **Plant biotechnology:** Plant physiologist, plant pathologist, entomologist, agronomist, and plant breeder.

In Brazil, the National Biosafety Technical Commission (CTNBio, Comissão Técnica Nacional de Biossegurança) provides technical support and advice to the federal government “in the formulation, updating, and

implementation of the National Biosafety Policy for GMOs and derived products, and for establishing technical safety standards and technical opinions regarding the authorization of activities that involve research and commercial use of GMOs and derived products.” CTNBio is comprised of 27 members:

- Twelve specialists (PhDs recommended by scientific organizations).
- Nine government officials appointed by the following agencies: Ministry of Science and Technology; Ministry of Agriculture, Livestock, and Food Supply; Ministry of Health; Ministry of the Environment; Ministry of Development, Industry, and Foreign Trade; Ministry of External Relations; Ministry of Agrarian Development; Ministry of Defense; and Special Office of the President for Aquaculture and Fisheries.
- Six members appointed as follows: one specialist in consumer rights by the Ministry of Justice; one specialist in human health by the Ministry of Health; one specialist in environment by the Ministry of the Environment; one specialist in biotechnology by the Ministry of Agriculture, Livestock, and Food Supply; one specialist in family agriculture by the Ministry of Agrarian Development; one specialist in worker’s health by the Ministry of Labor.

Source: DBT 2008; Government of Brazil 2005.

national biosafety system, especially the human, financial, and infrastructure resources to: develop and implement a national biosafety system; support the infrastructure required (such as buildings, equipment, and computers); facilitate communication and public participation; train scientific and regulatory personnel; and foster the research required to assure that risk assessments are sound.

POTENTIAL BENEFITS

Investments in support of developing biosafety regulatory capacity have the potential to provide many positive spillovers into related areas. These areas include public agricultural research, extension services, and plant health and quarantine programs.

Private developers of GE crops, particularly multinational companies, are generally disinterested in entering markets, even where there is farmer demand for these crops, unless an operational (and predictable) biosafety regulatory system is in place. More critically, publicly funded and donor-funded initiatives that focus on improving the productivity of staple crops using biotechnology will be unsuccessful unless there is a clear path forward that ensures improved crop varieties will actually move from laboratory to field trials to farmers. (Although when the technology does reach farmers, the impact can be significant; see box 6.23.)

Highly precautionary regulations may be the most significant barrier to innovation in agricultural biotechnology, as they price the technology out of the hands of the public sector and SMEs. These costs include the direct costs of regulatory compliance as well as indirect costs associated with

unanticipated events, such as trade disruptions that can occur as a result of accidental (or sometimes deliberate but illegal) transboundary movement of GE commodities into a jurisdiction where there is no approval for that GE crop or derived food. For example, continued delays in the deployment of pro-vitamin A rice (“Golden Rice”) have been attributed exclusively to biosafety regulation by the product developer (Potrykus 2010).

POLICY ISSUES

Key policy considerations include:

- **Coordination of biosafety laws and regulations** with existing legislation related to environmental protection, human health, agricultural production, IP protection, and trade.
- **Interministerial coordination** to ensure that concerns and remits are carefully considered during the establishment of a biosafety regulatory system. Responsibilities and mandates of all involved ministries should be clearly communicated.
- **Multilateral environmental agreements**, particularly the Cartagena Protocol on Biosafety, must be considered during the development or revision of biosafety legislation (box 6.24).
- **Trade:** Biosafety legislation should not promote practices that may be considered or may result in impediments to trade.
- **Resources**—financial, human, and institutional—need to be considered before developing the regulatory system because they can, and should, influence its construction.

Box 6.23 Who Benefits from Agricultural Biotechnology?

It is difficult to quantify the benefits of regulating products of agricultural biotechnology, but the economic impact from commercializing many genetically engineered crops has been studied. Brookes and Barfoot reported that in 2007, the total cost farmers paid for genetically engineered soybean, maize, cotton, and oilseed rape was equal to 24 percent of the technology gains (inclusive of farm income gains plus the cost of the technology payable to the seed supply chain, comprised of sellers of seed to farmers, seed multipliers, plant breeders, distributors, and the providers of

genetically engineered technology). According to this study, farmers in developing countries paid 14 percent of technology gains, whereas farmers in developed countries paid 34 percent of their gains. The higher share of total technology gains accounted for by farm income gains in developing countries relative to the farm income share in developed countries reflected factors such as IPRs in developing countries and the higher average level of farm income gain on a per-hectare basis derived by developing country farmers relative to developed country farmers.

Source: Brookes and Barfoot 2009.

- **Regional coordination and harmonization of elements of the regulatory system** should be considered and/or pursued, as harmonization has the potential to: reduce regulatory disparities between countries; reduce the regulatory burden on national governments and the regulated community; and facilitate trade within region (see IAP 3).

LESSONS LEARNED AND RECOMMENDATIONS FOR PRACTITIONERS

The previous sections have described the often complex interface between agricultural innovation and biosafety regulations. Lessons related to developing and implementing biosafety regulations can be summarized briefly:

- Building capacity to develop and implement biosafety regulatory systems requires a multiyear commitment.
- Interministerial coordination is a prerequisite for successful development of a biosafety regulatory system.
- Investments in biosafety regulatory capacity can be strategically applied to benefit other regulatory programs.
- Biosafety regulatory systems should incorporate provisions for change.
- Investments to develop biosafety regulatory systems should accompany investments in agricultural biotechnology research.

- Biosafety regulation can be rationalized through the promotion and acceptance of international risk assessment standards.

The next sections address each of these points in detail.

Building capacity to develop and implement biosafety regulatory systems requires a multiyear commitment

Workshops, symposia, and conferences can be valuable in raising awareness or catalyzing discussions that may inform the development of strategic programs, but they cannot replace continued and meaningful engagement with those who are tasked with the responsibility of actually developing and implementing the regulatory framework (a task requiring considerable time, coordination, and expertise; see box 6.24 for an example from India). Identifying in-country partners and investing in longer-term capacity building for key individuals, including policy makers and opinion leaders, contributes to systemic versus transient gains. Experience has shown that the willingness of these individuals to understand the impact of, and provide an enabling environment for, (cost)effective biosafety regulation is critical (see box 6.25 for an example from Uganda).

Box 6.24 The Development of Genetically Engineered Food Safety Assessment Guidelines in India

The South Asia Biosafety Program (SABP) has assisted the Governments of Bangladesh and India to further strengthen their institutional governance of biotechnology since 2004. In India, the program started with stakeholder consultations and a gap analysis of the current biosafety regulatory system. The analysis identified the need for comprehensive safety assessment guidelines for foods derived from genetically engineered plants and for technical training in conducting food safety assessments according to international standards.

The Indian Council of Medical Research (ICMR), the technical arm of the Ministry of Health and Family Welfare, in partnership with SABP, undertook a series of activities over the next several years aimed at meeting this need. It began with an international conference on safety assessments for foods derived from genetically

engineered plants. The conference offered an opportunity for stakeholders and technical experts from a number of sectors to exchange experiences and views.

ICMR then hosted a multisectoral stakeholder consultation that achieved consensus on making the safety assessment of genetically engineered foods in India consistent with the internationally accepted Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants adopted by the Codex Alimentarius in 2003. ICMR formed a drafting committee with representation from several ministries and departments and formulated draft “Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants.”

The draft guidelines were circulated to technical experts for input and reviewed by India’s Review

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Box 6.24 The Development of Genetically Engineered Food Safety Assessment Guidelines in India (continued)

Committee on Genetic Manipulation and Genetic Engineering Approval Committee before being posted for public comment. Stakeholders' comments were addressed, and the guidelines were reviewed once again by both committees before their final adoption in 2008. The end result is a guidance document that is consistent with internationally accepted practices for assessing the safety of genetically engineered food.

ICMR also collaborated with SABP to conduct technical workshops providing in-depth, hands-on training about key requirements for the safety assessment of foods derived from genetically engineered plants. The training ensured that scientists and regulators, as potential risk assessors and science advisors, understood the

concepts and principles of genetically engineered food safety assessment and the methodology outlined in the new guidelines.

From inception to completion, the process of developing new food safety guidelines and ensuring their implementation under existing authority in India took four years. The long-term collaborative relationship between ICMR and SABP contributed to the success of this endeavor. SABP, particularly through strong in-country partnerships, supported ICMR's commitment to developing new guidelines by providing not just technical expertise on food safety assessment, but also institutional support to ICMR and Indian regulatory committees as they took the guidelines through review, adoption, and implementation.

Source: McLean 2010; CERA 2010b.

Box 6.25 Advancing Agricultural Biotechnology in Uganda: It Takes More Than Good Science

Uganda has spent almost fifteen years working to develop a functional biosafety regulatory system that will promote an enabling environment for research, development, and deployment of genetically engineered crops. The country was an early recipient of Global Environment Facility support to develop a National Biosafety Framework. The process started in 1998, three years before Uganda ratified the Cartagena Protocol on Biosafety and five years before the Protocol came into force.

Since then, the Ugandan regulatory and science communities have benefitted from significant national and international investments that have supported both human and institutional resource development, such as enhanced technical capacity for product development, management of confined field trials, and premarket risk assessment. The incremental gains achieved through these interventions have been confounded by continued delays in operationalizing the regulatory system, particularly the passage of national biosafety legislation.

Uganda provides an all too common example of a country where innovation in agricultural biotechnology is not necessarily limited by science but by political, social, and market barriers. It is generally accepted that

product commercialization will not advance in Uganda until the national Biosafety Bill is promulgated. The process of preparing the Biosafety Bill began in 2003. The Bill was finalized in 2007, approved by the Cabinet in 2008, and currently awaits submission to Parliament. An analysis of the reasons for this protracted process found that a combination of market, policy-political, and sociocultural factors are hindering progress, such as:

- Lack of sustained and coordinated political champions to move the bill forward.
- Lack of clarity among ministries regarding regulatory roles and responsibilities.
- Influence of antibiotechnology organizations.
- Complex and diverse institutional players.
- Poor product development strategies, leading to delays in driving the operationalization of the biosafety regulatory system.

The last bullet may now be a significant catalyst for movement on the Biosafety Bill. Using existing legislation, Uganda has approved confined field trials of genetically engineered cotton, banana, and

(Box continues on the following page)

cassava. These and other pipeline products such as drought-tolerant maize are all considered important for Uganda's agricultural productivity and sustainability. Having farmer-supported, genetically

engineered crops approaching commercialization may be the incentive needed to achieve multistakeholder, and consequently political, support for the Biosafety Bill.

Source: Horna et al. 2012, forthcoming; AATF 2010.

A shortcoming of many capacity-building projects is that they support the drafting of biosafety frameworks, legislation, or related documents but do not provide the follow-on support to finalize, adopt, and then implement the system(s) prescribed in these documents (Chapotin, McLean, and Quemada 2009). For example, 123 countries participated in the Project on Development of National Biosafety Frameworks sponsored by the United Nations Environment Programme and Global Environment Facility (UNEP-GEF). Designed to help countries comply with the Cartagena Protocol, the project was active from 2001 to 2009. Of the 38 African countries that completed their national biosafety frameworks under this project, only three have regulatory systems that can be considered operational: Tanzania and Nigeria have authorized confined field trials (although Tanzania's approvals pre-dated their National Biosafety Frameworks project) and Burkina Faso has assessed and approved a GE plant for commercial release (insect-resistant cotton in 2008). The transition of countries from the framework development projects to the follow-on UNEP-GEF Project on Implementation of National Biosafety Frameworks was limited to 19 countries.

Interventions should be tailored to country needs, but many large capacity-building programs, such as the National Biosafety Frameworks project, implement a common project model. Investments should first support a comprehensive needs assessment and gap analysis to identify and prioritize interventions that will further the operationalization of a functional regulatory system. In addition to evaluating the national situation, it is important also to critically consider capacity building or related initiatives that may be happening regionally or internationally and whether these may assist or constrain follow-on activities. The needs assessment should also take into account the broader context of agricultural production and innovation, because biosafety regulation is but one part of that larger system.

Interministerial coordination is a prerequisite for successful development of a biosafety regulatory system

International support for the establishment of biosafety regulatory systems has favored the creation of new regulatory entities under ministries other than agriculture. Particularly influential in this regard is the Cartagena Protocol. Because of its relationship to the Convention on Biological Diversity, the Protocol has largely been implemented through 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.

Investments in the development of biosafety regulatory systems should explicitly require meaningful interministerial consultation and a clear delineation of roles and responsibilities between competent authorities. Otherwise, different ministries develop parallel and often redundant or conflicting regulatory requirements that ultimately increase the regulatory burden on product developers. Rational regulation is achievable if the overarching purpose of biosafety regulation (that is, human and environmental safety) drives the development of the regulatory system and is not tied to political or financial gain by specific ministries.

Interministerial coordination, while necessary, is difficult 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 national biosafety frameworks was coordination of the administrative tasks and competencies of the institutions involved in them (UNEP 2003a). This issue was also 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 2003b) (box 6.26 presents an example

Box 6.26 Interministerial Coordination in the Biosafety Regulatory System of Bangladesh

In Bangladesh, the biosafety regulatory system is still in a developmental stage, although institutional procedures cover R&D and the review and approval of foods derived from transgenic plants. The system is based on a National Biosafety Framework document, developed with UNEP-GEF funds in 2004–06, which draws on a set of Biosafety Guidelines initially published by the Ministry of Science and Technology in 1999. With the ratification of the Cartagena Protocol by Bangladesh in 2004, responsibility shifted to the Ministry of Environment and Forests (MoEF), and the Biosafety Guidelines were redrafted to incorporate certain obligations of the Cartagena Protocol. The revised guidelines were published in 2007.

Under the Biosafety Guidelines, the competent authority is the interministerial National Committee on Biosafety (NCB). The subordinate Biosafety Core Committee operates as a scientific review body and so far has been asked by the NCB to provide input into all its decisions. To lend enforcement power to MoEF, a Biosafety Rule has been drafted that incorporates the Biosafety Guidelines and brings them under the formal jurisdiction of the Environment Conservation Act. This Biosafety Rule was prepared by a drafting committee convened by MoEF that sought to proactively include

inputs from key ministries. Because of this action, no further government debate is considered necessary for approval.

Guidelines for confined (experimental) field trials of genetically engineered plants have also been prepared through the cooperative efforts of the Department of Environment (DoE in MoEF) and the Bangladesh Agricultural Research Council, Ministry of Agriculture (MoA). The guidelines include procedures for applications, standard operating procedures, and a guide for inspections of confined field trials by officials appointed by MoEF. These guidelines have been approved by the NCB and published as an annex to the Biosafety Guidelines. In 2009 guidelines for genetically engineered food safety assessment were prepared that are consistent with Codex (2003). NCB approved them in 2010, and they will be published as an appendix to the Biosafety Guidelines.

Bangladesh's biosafety regulatory system, while still young, has made significant progress. Confined field trials are now being approved and applications for commercial release are considered imminent. Interministerial cooperation, particularly between DoE of MoEF and the Bangladesh Agricultural Research Council of MoA, has been integral to the success achieved to date.

Source: Author.

from Bangladesh). For the majority of countries, both developed and developing, internal coordination between competent authorities remains a significant issue that has yet to be resolved.

Investments in biosafety regulatory capacity can be strategically applied to benefit other regulatory programs

The shared nature of many of the regulatory functions of plant health and quarantine programs and biosafety programs (such as risk assessment, monitoring, and inspection) means that there is an opportunity to apply investments for biosafety regulatory capacity building to strengthen plant health and quarantine systems (and vice versa) so that the objectives of both can be achieved without building redundant administrative and operational services. For example, the Government of Canada recently combined the risk assessment functions for GE plants and plant health into a

single Plant and Biotechnology Risk Assessment Unit. This action was taken to align biosafety and phytosanitary risk assessments, leverage complementarities in the scientific expertise required for both, and improve procedural consistencies (P. Macdonald, personal communication).

Investments should 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 per se, because regulatory authorities may receive an application for a field trial or premarket approval only once a year or once every few years. Investments in education and research in the scientific disciplines that support biosafety risk assessment and regulation, especially in the agricultural sciences, will have wide-reaching payoffs, however. Efficiencies can be gained through the cross-utilization of expertise within a country or even through pooling human resources with neighboring countries.

Biosafety regulatory systems should incorporate provisions for change

The regulation of products of modern biotechnology is a relatively new arena for governmental oversight. Advances in biotechnology processes and products, experience gained in regulatory operations over time (both nationally and internationally), the globalization of agricultural trade, and the influence of multilateral agreements and international standard-setting bodies require biosafety regulatory systems to accommodate change (box 6.27). For example, embedding detailed technical provisions about risk assessment into laws versus guidance impedes regulators' ability to accommodate new knowledge or advances in risk assessment approaches, as revising legislation is considerably more burdensome than amending guidance.

Investments to develop biosafety regulatory systems should accompany investments in agricultural biotechnology research

Implementation cannot be meaningfully initiated unless applications related to GE products are ready to "prime the

regulatory pump," such as applications for R&D activities in laboratories, field trials of experimental GE products (transgenic plants, insects, or fish, for example) or applications for environmental, food, and/or livestock feed safety assessments prior to marketing a product. Of the 38 African countries mentioned previously, few have substantive public research programs in agricultural biotechnology, and many are not considered priorities for private biotechnology investment.

The lack of substantive private or public R&D, even more than resource constraints, may explain why so few countries have implemented national biosafety frameworks. In effect, there is an absence of demand to drive regulatory development (or reform) forward, and policy makers' attention is redirected to existing priorities (with notable exceptions, as in Burkina Faso; see box 6.28). Another definite requirement is the political will to move the regulatory system forward so that decisions, particularly about product-specific approvals, are actually taken.

Biosafety regulation can be rationalized through the promotion and acceptance of international risk assessment standards

The building of sufficient risk assessment capacity is a particular problem in countries that do not have a base of scientific expertise in biosafety. The development of a regional or subregional approach to risk assessment may be the most practical and cost-effective option in such cases. This approach can be facilitated by the active participation of competent authority representatives in international forums such as the Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology and the OECD Working Group on Harmonization of Regulatory Oversight of Biotechnology, where criteria for risk assessment harmonization are discussed and guidance or standards established. Vietnam developed its own practical approach (in this case to assess risks of GE food), based on a review of risk assessments conducted in other countries (box 6.29).

Rationalization can also be achieved during the design of a biosafety regulatory system. Policy options should be evaluated to take into account not just the government's overarching human health and environmental protection goals but also the costs of sustaining a system that can realistically achieve those goals. These costs include the opportunity costs associated with overregulation. Identifying the funding mechanisms required to sustain a regulatory system can be an effective tool in rationalizing its complexity.

Box 6.27 Adaptability in Biosafety Regulation: The Gene Technology Act in Australia

In 2001, the Gene Technology Act, 2000 introduced a national scheme for the regulation of genetically engineered organisms in Australia. It included a statutory requirement (Section 194) for an independent review of the operation of the act, including the structure of the Office of the Gene Technology Regulator (the OGTR), by the fifth anniversary of the act coming into force. The review was based on issues raised during extensive national public and stakeholder consultations, submissions made in response to the terms of reference for the review, site visits to laboratories and field trials, experience gained by OGTR personnel during the first four years of the act's implementation, international developments in biotechnology, and related reports and literature. The review found that the act's flexibility to deal with changing circumstances and emerging technologies was sufficient but that the act should be reviewed again in five years to ensure that it continues to accommodate emerging trends.

Source: GTRS 2006.

Box 6.28 The Approval of Bt Cotton in Burkina Faso

Burkina Faso is sub-Saharan Africa's largest cotton producer. Cotton accounts for 30–50 percent of the country's export earnings and is the main source of foreign exchange. In many rural areas where poverty is high, the sale of cottonseed is the main or only source of cash revenue for Burkinabe farmers. Insect control is a key factor in cotton yield; insect infestations can damage up to 90 percent of the crop. Farmers typically apply 6–8 applications of insecticide per growing season, but yield losses of 30–40 percent persist.

An alternative insect management approach is to plant insect-resistant, transgenic cotton varieties (Bt cotton). Transgenic varieties from the United States were evaluated in confined field trials in Burkina Faso from 2003 to 2005. These Bt varieties had significantly reduced larval populations of cotton bollworm and cotton leafroller, with a commensurate improvement in seed cotton yields and lint quality. After the insect resistance trait was bred into local varieties, further field trials were planted in 2006–07. Precommercial seed production began in 2008, the same year two transgenic

cotton varieties were approved by Burkina Faso's National Biosafety Agency (ANB, Agence Nationale de Biosécurité) for commercial release. Comparisons in 2008 and 2009 showed that Bt cotton yielded 30 percent higher than conventional varieties, and only two insecticide applications were necessary.

Burkina Faso's biosafety regulatory system has developed relatively quickly and smoothly compared to those of other African countries such as Kenya, Uganda, and Nigeria. In 2005 Burkina Faso completed its National Biosafety Framework with resources from the United Nations Environment Programme and Global Environment Facility. In 2006 the ANB was established under Law No. 005-2006 "Pertaining to the security system in regard to biotechnology in Burkina Faso."^a However, it was the joint commitment of the Ministers of Environment and Agriculture, who publicly championed the economic benefits of Bt cotton to the Burkinabe economy, that effectively catalyzed the rapid operationalization of the ANB, which was achieved in only two years.

Source: Héma et al. 2009; D.J. MacKenzie (personal communication).

(a) Loi N° 005-2006/AN, Portant régime de sécurité en matière de biotechnologie.

Box 6.29 Practical Regulation of Genetically Engineered Foods in Vietnam

In June 2010, the Government of Vietnam issued Decree No. 69/2010/ND-CP on Biosafety for Genetically Modified Organisms, Genetic Specimens, and Products of Genetically Modified Organisms. With respect to the use of genetically engineered organisms as food or animal feed, the Decree permits a written certification of eligibility for use as food if the subject of the application satisfies "either of the following conditions: 1. The dossier of application for a written certification of their eligibility for use as food has been appraised by the Genetically Modified Food Safety Council, which concludes that such genetically

modified organisms have no uncontrollable risks to human health. 2. They have been permitted by at least five (5) 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. It recognizes that the Vietnamese Ministry of Health considers the biosafety regulatory systems of certain other countries to be consistent with that of Vietnam and that the risk assessment and approvals undertaken by those countries may be considered equivalent to and therefore sufficient to obtain a certificate of eligibility by the Ministry of Health.

Source: Government of Vietnam 2010.