



Delivering Genetically Engineered Crops to Poor Farmers

Recommendations for Improved Biosafety Regulations in Developing Countries

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Small-scale, resource-poor farmers in developing countries face daily stresses, including poor soils, drought, and lack of inputs. Ongoing trends such as climate change and population growth will likely exacerbate binding stresses. A new generation of genetically engineered (GE) crop research aims to alleviate these pressures through the improvement of subsistence crops—such as cassava, sorghum, and millet—that incorporate traits such as tolerance to drought, water, and aluminum in soils as well as plants with more efficient nitrogen and phosphorus use. However, many developing countries lack the necessary biosafety systems for a timely and cost-effective adoption. This brief focuses on the regulatory reforms necessary for farmers and consumers in developing countries to benefit from GE crops.

One Step Behind the Technology

Before GE crops are released to farmers, technology developers must demonstrate to regulatory authorities that their products are safe by applying widely accepted risk-assessment procedures. Yet as many as 100 developing countries lack the technical and management capacity needed to review tests and monitor compliance (Johnston et al. 2008). A growing number of countries have begun investing in developing national biosafety frameworks, and some have approved confined field trials for GE crops, but progress is still slow. Only two African countries—Burkina Faso and South Africa—have approved a GE crop release for commercial purposes, of which only South Africa has actually released commercial GE crops. Furthermore, if the regulatory safety standards are set to an impossibly high threshold (at zero risk), GE crops are unlikely to be approved.

Even in areas where biosafety systems are in place, many public-sector and university-based scientists cannot afford the regulatory compliance costs,¹ which range from tens of thousands to millions of dollars. In some countries (such as the Philippines), the cost of complying with biosafety regulations can sometimes be greater than the cost of developing a new crop variety (Bayer, Norton, and Falck-Zepeda 2009). As a result, multinational private companies have led GE crop development and transfer in the developing world. Aside from financial resources, large private companies have extensive experience; ample capacity to evaluate risk and comply with regulatory requirements; and the scientific capacity for product development, risk management, and stewardship. However, the private sector does not focus on the crops grown by the poor, finding it difficult to justify paying large regulatory costs for products with limited returns—particularly when facing indefinite delays for regulatory decisions.

Despite these limitations, public-sector research organizations, such as national agricultural research systems and international agricultural research centers, have in recent years invested in research and development for GE crops suited to developing-country farmers (Atanassov et al. 2004). These public organizations are only now facing regulatory requirements and costs of approval. How public organizations address these challenges will determine the impact of GE technologies on food production in much of the world. If regulatory costs are equal to those seen in developed countries for large commercial crops, and if final approval remains uncertain, it is unlikely that many of these potentially useful crops will end up in the hands of smallholder farmers.

In addition to creating regulatory bottlenecks for crops, the high cost of compliance with biosafety regulations can limit investments in developing GE products and thus reduce the flow of potentially valuable crops that reach farmers. Regulatory delays often have a larger negative impact on societal benefits than regulatory compliance costs.

Developing Effective Biosafety Regulations

So far, GE crops released deliberately have a remarkable safety record. No proven or documented damage to human health or the environment has been reported for any of the approved GE crops to date. Many major science academies in Europe and the United States, international agencies, and national and regional regulatory agencies officially endorse this safety record.² However, novel crops and traits that will enter the regulatory pipeline may present a new set of challenges for regulatory agencies and biosafety systems.

Biosafety regulatory systems assess, manage, and communicate the objective risks posed by GE crops to human health, the environment, and biodiversity. Benefits, costs, and implications of the potential introduction of the technology have received only cursory attention from most regulatory systems. Moreover, regulatory agencies have not fully considered the implications of turning down safe and valuable technologies. Failing to approve new technologies that may benefit poor farmers and consumers carries its own set of risks (Nuffield Council on Bioethics 2003). Undesirable conventional agriculture production practices may result in overexposure to chemical pesticides or incomplete pest-damage abatement, negatively impacting food safety and security. Biosafety regulatory systems thus need to balance objective risks to human health and the environment against the potential risk of lost opportunities to increase agricultural production, introduce novel crops, and enhance the livelihoods of poor people.

Box 1—Risk-Assessment Principles

- It is not possible to “prove” that anything is 100 percent safe.
- Society must determine an acceptable level of safety or risk.
- Risk cannot be characterized in absolute terms; rather, risk assessment needs to be comparative. Potential risks associated with transgenic organisms should be evaluated by comparison to risks posed by the nonmodified recipient or parental organism, in the likely environment of the release. For example, a GE product (or products derived from them) should not present a risk greater than its non-GE counterpart.
- Regulatory procedures need to be specific, as most safety issues that arise with GE crops are different from those related to GE animals or vaccines. Safety issues related to an experimental field release under supervision of technical experts are different from those related to a general release in the hands of farmers.

Source: 2009. *Enabling national biosafety systems in COMESA countries: A roadmap towards implementation*. A Program for Biosafety Systems Report, prepared under the Regional Approaches to Biosafety and Biotechnology Regulations (RABESA) II project.

The key to delivering safe, valuable, and appropriate GE technologies to farmers in poor countries is to design smart and efficient regulatory systems that countries with lower scientific and financial capacity can readily implement. Developing countries need smart and efficient biosafety regulations that protect society from unsafe products—though not necessarily more regulation. Regulatory agencies need to base such regulations on risk-assessment procedures with a history of success in other countries. Many international documents, such as Annex III to the Cartagena Protocol on Biosafety, articulate principles of biosafety, risk assessment, and risk management. Furthermore, establishing sensible regulations does not have to be complicated as long as the process is robust, transparent, and participative. Most importantly, biosafety needs to be a process trusted by society. A number of policy and regulatory system options are available for improving biosafety processes.

1. Match the level of regulation to the level of risk

The foundation of many biosafety systems has been the Cartagena Protocol on Biosafety, an implementing international agreement that is part of the Convention on Biological Diversity. The text of the Cartagena Protocol introduces the use of the precautionary approach,³ giving regulators the active responsibility of anticipating and minimizing harm to the environment and human health. Countries have interpreted the precautionary

approach in different ways, with some focusing on unlikely hypothetical risks and asserting that no level of risk is acceptable. Other countries have established functional systems in which the scope of the precautionary approach fits within the framework of modern risk-assessment methods and objective decisionmaking standards.

The scope of risk assessment and management efforts needs to be directly proportional to the actual level of risk presented by a GE crop. Regulators should balance risks by applying biosafety assessment approaches that are scientifically sound and thorough but do not impose unnecessary burdens on crop developers based on unrealistic assessments of risk. GE-crop events or constructs with assessed low risk do not require increased regulation. Countries can consider a variety of regulatory approaches, such as “fast tracking” crops with traits that have received regulatory approval in other countries and focusing only on the specific issues that may pose an objective risk domestically. As a result, a GE-crop event or construct could be approved after a simplified risk assessment and proceed to the next stage of approval.

2. Adopt flexible regulatory frameworks

Biosafety regulatory frameworks have to be sufficiently flexible, so they can be readily implemented. For example, national regulatory systems could accept data generated elsewhere on a new technology. The scope for this approach is greater in assessing food safety than environmental safety, as local conditions more frequently determine the latter.

Institutional organizations also can contribute to efficient biosafety systems. For example, a “single window–single regulator” mechanism, as adopted in Australia and proposed in India, can centralize decisionmaking and ease the regulatory process for applicants. The use of formal evaluation frameworks may also be helpful. The biosafety conceptual framework of the International Service for National Agricultural Research/International Food Policy Research Institute (IFPRI) and the Food and Agriculture Organization of the United Nations can serve as a guide to examine such issues as a country’s inventory of human, physical, and financial resources as well its institutional capacity. The framework clearly spells out the various trade-offs and options in designing, implementing, and revising a national biosafety system.

Regulators should adopt novel approaches to risk assessment and decisionmaking. They might use environmental modeling tools based on similar environmental conditions, or examine regulatory experience with similar crops in similar environments in order to yield important lessons for regulating a specific GE crop in a specific location. Adopting new regulatory paradigms for novel crops such as bananas or sweetpotatoes⁴—where regulators examine gene constructs rather than events—will help expedite the process without a significant decrease in safety. Ultimately, governments can enable the risk-assessment process by using a variety of means to reach the regulatory objective.

3. Enact performance-based rather than prescriptive regulations

Most regulatory systems establish a set of prescriptive regulatory processes with which the applicant must comply. In most cases, however, prescriptive regulatory systems have little flexibility to adapt to accumulated knowledge and experience with the specific crop and gene construct or with GE crops in general. In contrast, performance-based regulations concentrate on regulatory outcomes or results rather than prescribed techniques, procedures, or processes. These types of regulations give applicants the flexibility to comply with safety standards in innovative ways while respecting the goals of the regulatory process.

4. Make greater use of innovative risk-assessment methods for regulatory purposes

An efficient biosafety system implies a risk-assessment process based on confined field trials to evaluate potential impacts on biodiversity and food/feed safety, taking into account other characteristics such as history of safe use, biology and physiology of the organism, and food-safety assessments. Developing countries must ensure that the implementation process is both feasible and focused on the right questions.

Environmental risk assessments tend to be quite specific to a particular agroecological area, and data generated elsewhere therefore tends to be less applicable for specific agroenvironmental locations. Tiered approaches can reduce regulatory burdens. In tiered approaches, risk analysts compare the GE crop's risk profile in a particular area with the risk profile of the same GE crop in a similar agroecological zone. For example, in Hancock's (2003) procedure, a preliminary assessment of the environmental risk of GE crops compiles data on the geographical range of compatible relative species, determines the invasiveness of the crop and its relatives, and describes the modified crop's properties. As a result, regulators can define the type of experimentation that developers need to conduct before the crop's approval for environmental release. Other internationally accepted approaches available for use in developing countries can also reduce the regulatory burden.⁵

5. Rationalize the application process

When a developer proposed a GE cassava for a confined field trial in Nigeria, the application form consisted of 150 questions. The completed application form totaled 60 pages and required significant human and financial resources—beyond the capacity of many public-sector institutions. After several consultations with relevant stakeholders, the IFPRI-led Program for Biosafety Systems managed to reduce the number of questions to those relevant to making an appropriate decision for confined field trials while eliminating other unnecessary information requirements. This rationalization process reduced significantly the regulatory burden needed to comply with biosafety regulations without sacrificing safety, by concentrating solely on those questions relevant to the risk-assessment process.

6. Understand the effects of regulation

Regulators and policymakers need to understand regulatory policies in terms of costs, benefits, and safety trade-offs for both approval and nonapproval of GE crop technologies, as well as the cumulative (and, in some cases, unanticipated) impacts of regulation. They should also be sensitive to the constraints that applicants and technology innovators are likely to face in dealing with the regulations, while contributing to an environment that enables collaboration among all stakeholders and ensures the overall success of biosafety regulations.

Policymakers and regulators must keep in mind that regulation entails costs and benefits, beginning with budgeting for the development and maintenance of institutions, procedures, and management tools for implementing biosafety. Other relevant costs include the cost of compliance with biosafety regulations and risk-management conditions, as well as the economic, environmental, and health costs related to delayed access to new technologies and products and their associated benefits. Decision-makers must also recognize that, while new GE crops may be risky, they may also have significant net benefits to society. In the end, the regulatory authority must consider all the risks and benefits of approval or rejection of the proposed technology, by comparing the technology to the counterfactual case before rendering a decision.

Box 2—Design Principles for Biosafety Regulatory Design

- Measures to regulate and manage a particular GE crop should be proportional to the level of risk.
- Availability of information in-country or elsewhere may open other regulatory processes, including accepting data generated elsewhere or fast-tracking a specific event through the regulatory approval process.
- Maintain the case-by-case, step-by-step approaches in risk assessment and management. This has proven to be an effective tool to ensure that the latest information available is considered and to adapt assessment and management procedures and resource allocation effectively to changing circumstances.
- The type of information relevant and required for the assessment of environmental releases of genetically modified organisms has been laid down in a number of international guidance documents—originally, in the Organisation for Economic Co-operation and Development (OECD) Blue Book—which have proven to be a sufficient basis for environmental risk assessments.

Source: 2009. *Enabling national biosafety systems in COMESA countries: A roadmap towards implementation*. A Program for Biosafety Systems Report, prepared under the Regional Approaches to Biosafety and Biotechnology Regulations (RABESA) II project.

7. Pursue regional approaches to risk assessment and facilitate knowledge exchange

A relatively easy and cost-effective way to assess, manage, and communicate the biosafety of GE crops is to share data and experience on risk-assessment efforts regionally and globally. The Biosafety Clearinghouse of the Cartagena Protocol on Biosafety facilitates the exchange of knowledge by maintaining a depository of regulatory decisions and other regulatory-related knowledge and enabling data-sharing among countries that are parties to the Protocol. Bilateral and multilateral mechanisms can also pool human and financial resources and expertise: the Common Market for Eastern and Southern Africa is currently implementing the Regional Approaches to Biosafety and Biotechnology Regulations.

Expanded use of internationally accepted consensus can promote the acceptance of regional approaches to regulation. Examples include the OECD document on the scientific aspects of risk assessment, as well as guidelines issued by international standard-setting bodies such as the International Plant Protection Convention and the Codex Alimentarius.

Conclusion

A new generation of GE crops now in development—especially by the public sector in developing countries—has the potential to benefit poor farmers and ultimately reduce food insecurity and poverty. Developing countries will need to develop and implement effective approaches for assessing and managing

the potential benefits and risks of GE crops. However, a poorly designed biosafety assessment and management process can discourage the development of valuable technologies (including GE crops) through costly regulatory delays that can compromise technology delivery; or it may constitute a barrier to public-sector developed products by imposing high biosafety regulatory compliance costs. Such regulatory delays and excessive compliance costs are most burdensome for public-sector and small private firms in developing countries, which are the firms most likely to develop GE-crop technologies of particular value in meeting local needs.

Many innovative approaches for cost-effective risk assessment are available to developing-country policymakers and regulators. Flexible and efficient biosafety systems will help developing countries benefit not only from the GE crops currently in the pipeline, but also from the unforeseen agricultural technologies that will emerge in the future. Innovative approaches are required to meet the challenges of increasing food production to support growing populations in a sustainable manner. Additional policy priorities and constraints complicate technology's role in broader agricultural development goals as the need exists to reduce environmental impact, increase resiliency, and improve livelihoods, while also considering the impacts of climate change. It is prudent, then, for developing countries to explore and critically assess all options available—including both established agricultural practices and emerging technologies, such as GE crops—and integrate them into efficient, locally adapted farming systems.

¹Biosafety regulatory compliance costs add to the chronic underinvestments in overall science, technology, and innovation. In the wake of this serious underinvestment, countries may not have sufficient capacity to establish well-functioning biosafety regulatory systems or to ensure that their public-sector research organizations are able to meet regulatory requirements for new technologies. This, of course, is a call to increase investments in innovation, product transfer, and the establishment of functional biosafety systems that will support delivery of appropriate products.

² This includes the national scientific academies of the United States, the United Kingdom, and Germany, as well as the Society of Toxicology, FAO, OECD, US Food and Drug Administration, European Food Safety Authority, Australia/New Zealand Food Safety Authority, national regulatory agencies in different countries, and others. Furthermore, new genomic research has revealed that conventional plant breeding has a larger genetic impact than GE crops (Baudo et al. 2006; Batista et al. 2008).

³ Annex III of the Cartagena Protocol on Biosafety (paragraphs 5.7–5.10) defines the precautionary principle as follows: "lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk." Since there are multiple interpretations of how to implement this principle, we concur with Nuffield Council on Bioethics (2003) in using the phrase "precautionary approach" to describe a process that is comparative—that is, selecting the course of action with the least overall risk. This is the rationale for the use of the phrase "precautionary approach" in the text of this brief.

⁴ According to biotechterms.org (<http://biotechterms.org/sourcebook/index.phtml>), "construct" is an engineered chimeric DNA designed for transfer into a cell or tissue. Typically, the construct comprises the gene or genes of interest, a marker gene, and the appropriate control sequences. A repeatedly used construct may be called a cassette (FAO Dictionary). "Event" refers to each instance of a genetically engineered organism. For example, the same gene inserted by man into a given plant genome at two different locations along that plant's DNA would be considered two different events. Regulators consider two different genes inserted into the same locus of two same-species plants as two different events. The world's regulatory agencies confer new biotech-derived product approvals in terms of events.

⁵ An example of an innovative approach for GE stress-tolerant crops is Nickson (2008).

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