Harnessing Biotechnology for the Poor: challenges ahead for capacity, safety and public investment*

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Introduction

Biotechnology provides new opportunities for achieving productivity gains in agriculture. However, mobilizing modern biotechnology to serve agricultural research in developing countries also implies new investments, changes in resource allocations and growing responsibilities for policymakers, research managers, and scientists. These responsibilities include determining the benefits and risks of biotechnology applications, ensuring productivity constraints affecting livelihoods of the poor are addressed, and deciding how national research agendas embrace biotechnology. Government officials assuming these responsibilities play a crucial role in setting policies, research agendas, and developing regulatory capacity for agricultural biotechnology. Their task is made difficult because public budgets for agricultural research are severely constrained, human capacity is limited and extensive international debate on the merits and safety of biotechnology complicate timely decision-making.

As a result of these debates, renewed effort is occurring to enhance developing countries’ abilities to address the constraints and difficulties listed above. Benefits expected from biotechnology for developing countries have been emphasized in recent academic and scientific reports. Implications regarding the safe use and regulation of these technologies are considered in international fora and agreements, such as the Cartagena Protocol on Biosafety. Information and communication technologies are being mobilized to help disseminate new knowledge gained from research, patent databases, and regulatory review. Longstanding and productive international collaboration in biotechnology continues, providing for capacity building, research partnerships, and dissemination of materials and technologies. Finally, developing countries themselves are making important public investments in research, policy and capacity.

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Will existing efforts, such as those already highlighted, ensure that benefits from biotechnology reach those in need, and if not, what additional steps are required? This paper addresses these concerns by first assessing the relevance of biotechnology for agricultural research in developing countries. This is followed by implications regarding safety, participation, and public investments available for biotechnology. Recent development reports, ISNAR research, and examples of international collaboration are summarized. Regarding biosafety, the Cartagena Protocol on Biosafety and related expectations for capacity building, risk assessment, and the precautionary approach are described. A review of regulatory systems, and public investments for biotechnology research in six developing countries is then presented. The paper concludes with policy recommendations regarding capacity, safety and investments that enhance public research and regulatory abilities.

Why Biotechnology?

Background and introduction

For the purpose of this report, biotechnology can be thought of as the application of our knowledge and understanding of biology to meet practical needs. More specifically, with reference to modern biotechnology, emphasis is given to applications based on our expanding knowledge of the genetic code of life (National Academy, 2000). Conventional applications of biotechnology remain important, including plants derived from tissue culture that facilitate elimination of disease, and the propagation of plants in economical forms. Various terms describe modern biotechnology, with the focus of this paper on genetic modification (GM) technology used to create "genetically modified organisms," or, GMOs. Elsewhere, the analogous terms "genetic engineering" or "recombinant DNA technology" are similarly used.

Since it’s beginning in the laboratory during the 1970s, ever more precise techniques have evolved, now permitting the genetic modification of most crops and food plants. New transgenic products already on the market are often categorized as expressing "market-led traits," (National Academy, 2000) or are profit-driven rather than need driven (Altieri and Rosset, 1999). Many of these have become commercially successful, providing greatest benefits to farmers, but often leaving consumers with little appreciation or understanding of production-level benefits.

In addition to market-led traits, biotechnology's tools are increasingly being applied to crops and livestock-related needs of importance to developing countries. They often provide the only or best “tool of choice” for improving the genetic component of agricultural productivity. With the advent of modern biotechnology, scientists can add genes and customize plant genomes for resistance to pests and pathogens in ways not possible previously. In addition, molecular characterization and genomics expand our knowledge of plant and livestock genomes, making new genes available that could not have been isolated before. These genes can then be inserted into plants, using genetic modification technologies, and their utility seen in farmer's fields.
Recent technological advances do not mean, however, that biotechnology has become a panacea. Farmers in developing countries face many problems that biotechnology will not solve, including better market access, improved infrastructure and economic/income policies that address livelihood needs. Despite recognizing that tools and applications of biotechnology are only one means to address productivity, reports continue that highlight "the notion of biotechnology as a magic bullet solution to all of agriculture's ills" (Altieri and Rosset, 1999), providing reasons why biotechnology will not ensure food security, nor protect the environment or reduce poverty.

Such reports often state that agricultural problems today are not those of production. However, as Per Pinstrup-Anderson notes, “The question is not whether there is enough food, but whether people who need the food can get access to it. Since a large majority of such people live in rural areas, their best option is likely to be associated with productivity increases in agriculture, something that supported by modern science and technology” (Pinstrup-Anderson, 2000). Other reports reinforce this message, emphasizing biotechnology’s contribution to sustainable productivity1 (National Academy, 2000) and how research can increase local productivity.

Lipton (1999) provides a number of points to consider when discussing biotechnology and global poverty reduction, emphasizing that, “the poor continue to depend on staples for income and progress, via consumption, prices, nutrition, employment, farm income, and overall rural income.” And that: “GM plant research is a key tool for breeding to improve staples yield potential, stability, spread, sustainability and employment — but is not being used well.” He concludes that public action and institutional innovation in agricultural research is needed to redirect current GM research to address the needs of the poor. Such views are reinforced by Chrispeels (2000), stating that to reach the poor, research has to be created from the bottom up, and that crops are needed that “fit not only the agroecology of the poorest regions, but also fit into the social and economic systems.”

With biotechnology's innovations seen as one part of the "sustainable productivity equation," then expectations of benefits from adopting products of traditional or modern biotechnology could include the following:

- Benefit to poor farmers directly by increasing their level of own-farm production. This may involve production of more food for their own consumption, increasing the output of marketed products that increase farm income, and lowering costs per unit of output.
- Improve nutritional status of the poor from increased nutritional contents of targeted crops or animals.
- Benefit small farmers and landless laborers through greater agricultural employment opportunities and higher wages within the adopting regions.
- Improved environmental and health efficiencies/cost reduction, coming with decreased use of chemical inputs.
- Benefit a wide range of rural poor within adopting regions through growth in the local non-farm economy.
- Benefit both urban and rural poor by lowering food prices.
Relevant technologies

Meeting agricultural needs for farmers in developing countries means working with complex agro-ecological systems, often not accessible to modern marketing systems. Such farmers typically work in smallholder areas, depending on a few key commodities, livestock or aquatic resources for food consumption and sale. Many of these areas are remote, with delivery and use of modern agricultural inputs restricted. Farmers have little cash income, meaning that inputs are very difficult to obtain or purchase. From an ecological perspective, many of these areas are rich in agro-biodiversity, with some farmers working in centers of diversity for our major and minor food crops. To impact smallholder communities, products from biotechnology must address the needs and ecological environment of farmers and the poor who are often beyond the reach and opportunity of modern markets.

Recent reports have focused on biotechnology’s ability to serve the poor, by characterizing the types of developments that could be of most use to the farmer base highlighted above. In this regard, recent emphasis (National Academy 2000) is given to products providing:

- **Pest resistance**: offers benefit to farmers in need of genetic control mechanisms, where cultural practices are not effective, and where reduction in pesticides is advantageous;
- **Improved yield**: isolation of dwarfing genes originally used to increase yields of cereals during the green revolution have now been shown to have same effect in other crops, such that this dwarfing technique has potential to increase yields in other crops;
- **Tolerance to biotic and abiotic stresses**: genetic control of the rice yellow mottle virus is one example of how transgenics can accomplish resistance when conventional approaches failed to do so;
- **Nutritional benefits**: traditional breeding has been unsuccessful for increasing nutritional elements of many plant varieties, but recent progress enhancing vitamin A content and elevated iron levels in rice show the potential of such research for developing countries; and
- **Reduced environmental impact**: producing crops that tolerate cultivation in stressful conditions, by introducing traits that control root disease to help farmers cultivate crops where reduced tillage is essential.

A recent example of such benefits and utility for farmers in developing countries has been documented in China. Farmers in Northern China were surveyed regarding use of cotton expressing the Bacillus thuringiensis toxin for control of the cotton bollworm. Chemicals and host plant protection can no longer reliably control the pest. In this study, the GM cotton provided smallholder farmers with significant economic as well as environmental benefits, by substantially reducing pesticide use without reducing output per hectare or quality of cotton. Some farmers reduced pesticide spaying from 30 to 3 times. (Pray et al., 2000).
International collaboration in biotechnology

One means by which developing country partnerships have been established for biotechnology research is through international collaboration. Opportunities are provided for research organisations in developing countries that plan or implement research programmes and build national capacity in agricultural biotechnology. Since 1985, a number of international initiatives in agricultural biotechnology have been established, and they provide an important source of information or assistance (Komen, 2000). International initiatives in agri-food biotechnology are defined as those organisations or programmes that conduct, support, or co-ordinate collaborative biotechnology research that addresses developing-country agriculture.2

In a survey conducted by ISNAR, representatives of international biotechnology programs were asked to indicate progress for their research activities. Progress was charted through seven stages of development. The first three stages described progress achieved in the laboratory and greenhouse. The next three stages include testing, beginning with contained trials moving to large-scale, multi-year testing. Finally, each respondent was asked if a partner, public or private, had been identified with regard to technology transfer and product development. The analysis of research progress shows that the major share of the research activities are in the experimental, laboratory phase or in contained greenhouses. Still, some have resulted in products ready for wider distribution:

1. **Disease-free planting material**: Various tissue-culture techniques are applied to the micropropagation of disease-free planting material: coffee, cocoa, banana, oilpalm and sugarcane.

2. **Biocontrol agents**: The production of biopesticides is undertaken at pilot-scale in India in collaboration with Swiss scientists. Products based on Bacillus thuringiensis and B.sphaericus have been provisionally registered. A pheromone-based attractant decoy for tick vector control was developed at the University of Florida under the International Program on Vectors and Vector-borne Diseases.

3. **Transgenic plant varieties**: Virus-resistant potatoes have been planted in Mexico, in collaboration between CINVESTAV and Monsanto. Field trials of virus-free potatoes are being conducted in Egypt from an international program with U.S. scientists, and for virus-resistant transgenic tomatoes and cucurbits.

4. **New diagnostics and vaccines for livestock diseases**: This appears to be the most significant area for product development to date, with diagnostic tests and rDNA vaccines for rinderpest, cowdriosis (heartwater), theileriosis (East Coast Fever) and foot-and-mouth disease. These are reported to be ready for large-scale testing or product development.

International agricultural research centers

An important source of international expertise in agricultural biotechnology occurs through the international agricultural research centers of the Consultative Group for International Agricultural Research (CGIAR). Of the total of 16 member centers, 11 engage in biotechnology research, with most of this research related to germplasm improvement or with regard to livestock, for animal vaccine development (Morris and Hoisington, 2000). Together, the centers invest about $25 million on biotechnology. This funding supports
extensive partnerships with national agricultural research organizations, as well as with advanced research institutes globally are fostered through such research. The most important activities include genetic diversity studies, gene mapping, gene discovery, tissue culture, genetic engineering, pathogen detection, vaccine development and policy research. With regard to capacity building, two areas are identified: (i) training people, and (ii) building institutions. Together, these inputs represent extensive global investments to help developing countries manage biotechnology (Morris and Hoisington, 2000).

Many CGIAR research applications and projects are consistent with recommendations found in the combined academy report, (National Academy, 2000), as well as addressing a number of significant and related policy items. In addition, many international biotechnology projects provide access to materials and technologies developed by advanced public and private sector research organizations in industrialized countries. These projects enable the centers to pass research results to developing countries, thus mobilizing science and technology towards the needs of the poor.

Concluding points

The opportunities available through international collaboration in agri-food biotechnology are many, and can contribute to developing-country objectives for agricultural and social development. Hands-on experience gained through collaborative research, training programmes, and international technology transfer projects are critical. However, the ultimate success of the activities presented in this chapter will often be judged on the basis of tangible products in farmers’ fields. This is not a short-term process and will require strong national partners, from the public as well as the private sectors. In addition, collaborating countries will have to review, and possibly adapt, their systems for biosafety review and IPR regulation. Such capacity building implies costs that must be weighed against the expected benefits.

The Cartagena Protocol on Biosafety

Introduction

Concerns about the safety of genetically modified organisms moderate the rate of GMO product development and deployment. National biosafety systems serve as mechanisms for ensuring the safe use of biotechnology products without imposing unacceptable risk to human health or the environment, or unintended constraints to technology transfer. However, establishing and operating a system for biosafety review presents a number of associated challenges. International dialogue regarding concerns for the regulation and review of new agricultural products gave rise to the Cartagena Protocol on Biosafety, which emphasizes the need for capacity building, including “the enhancement of technological and institutional capacity in biosafety.”

For developing countries, functional biosafety systems are key to maximizing the benefits from biotechnology while demonstrating to stakeholders and the public that attendant environmental and health issues are addressed by scientific risk assessments. In this regard, there are many issues for regulatory officials to be cognizant of, some of which are
presented in Box 1. In this section, the Cartagena Protocol on Biosafety will be reviewed and its implications examined. Then, the results of two country studies are presented. These studies highlight policy and management challenges facing regulatory systems in developing countries with regard to the safe use of GMOs.

**Box 1. GMOs: the controversy, an overview (adapted from Burrill 2000).**

| **Pro** | A valuable new technology that can develop more plentiful and nutritious foods |
| **Con** | New scientific technology – harmful side effects may occur, and care should be taken in its implementation, including long-term tests on health and environment. |

**Natural or Unnatural?**

| **Pro** | Extension of traditional breeding, allowing the combination of valuable traits within species |
| **Con** | Uses artificial lab techniques, combining genes that would never occur in nature, altering genetic patterns which have developed over millions of years |

**Have Tests Been Performed?**

| **Pro** | All GMOs have been tested and demonstrated safe prior to reaching the marketplace |
| **Con** | The testing is typically conducted on laboratory animals |

**Is Safety Demonstrated?**

| **Pro** | GMOs have been sold in the U.S. for several years and there is no evidence to indicate that they are harmful to health |
| **Con** | There is also no evidence to indicate they are safe |

**Should There Be Labels?**

| **Pro** | Most people can’t tell the difference between conventional and GMOs so why bother? |
| **Con** | Polls indicated the public would like GMOs to be labeled so they can make informed choices |
On 29 January 2000, delegates from 138 countries reached agreement on an International Biosafety Protocol to help protect the environment and ensure the safe transfer, handling and use of living modified organisms (LMOs). This agreement (Cartagena Protocol on Biosafety to the Convention on Biological Diversity) is designed to ensure that trade in LMO’s does not have a negative impact on biodiversity and the world’s ecosystems. The Protocol was opened for signature in May 2000, and it will remain open until June 2001. The objective of the protocol, carried out in accordance with the precautionary approach, is:

to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, and specifically focusing on transboundary movements.

The Protocol’s development goes back to the CBD, which provided for the “safe transfer, handling and use of living modified organisms derived from modern biotechnology.” Decisions taken at that time reflect: (i) the belief that GMOs require their own trade rules, and (ii) the acceptance of the precautionary approach as a basis for decision-making. However, the following issues remain unresolved (Morris, 2000):

- the relationship between the Biosafety Protocol and the World Trade Organization rules is not clear;
- socio-economic concerns, though mentioned in the Protocol, are not included explicitly in the risk assessment procedure used when countries say no to an import;
- genetically modified products other than seeds are not covered by the Advanced Informed Agreement (whereby exporters have to inform countries of their intention to ship a GMOs in advance, and receive permission to do so before proceeding);
- the issue of liability for damage arising from GMOs has been put off for the present; and,
- no obligation was accepted to separate and clearly label GM commodities.

Preparation for implementing the Protocol, including the capacity to receive and review advanced informed agreements, began with the first meeting of the Intergovernmental Committee for the Cartagena Protocol (ICCP), held in December 2000. The protocol can only enter into force after ratification by at least 50 parties. Final decisions for implementing the Protocol will be taken by the Meeting of the Parties after the Protocol’s entry into force, expected sometime in year 2002. During the interim period, the ICCP will make recommendations that the Meeting of the Parties of the Protocol may later transform into binding decisions.

Despite this time horizon, certain elements supporting biosafety system development already have gained wide agreement as being necessary for implementation of the Protocol. These include the establishment of the Biosafety Clearing-House (Convention on Biological
Diversity, 2000) and the building or strengthening of capacities to deal with the procedures of the Protocol, especially for developing countries and transition economies.

The central operative mechanism of the Protocol provides an advance informed agreement procedure, which would apply to the first intentional transboundary movement of LMOs. This agreement gives importing countries the right to receive information on LMOs intended for introduction into the environment, as detailed in Articles 7-13, prior to their arrival in country. Decisions taken with regard to import of LMOs are to be taken in accordance with Article 15 on risk assessment. This links risk assessment and management capabilities with the decision-making process required for the advanced agreement procedure.

The Protocol also emphasizes the need to conduct risk assessment “in a scientifically sound manner,” (Article 15) and the need to establish and maintain appropriate mechanisms for risk management (Article 16). Parties signing the Protocol agree to designate one national focal point to work with the CBD Secretariat, as well as designating one or more competent authorities to be responsible for performing the administrative functions required by the Protocol (Article 19).

Article 20 describes the Biosafety Clearing-House (BCH), which would be established in order to:

a. Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and

b. Assist parties to implement the Protocol, taking into account the special needs of developing country Parties.

A meeting of experts was held at the CBD headquarters in September 2000 to consider the technical questions related to the establishment and operation of the BCH. Background papers prepared for this meeting indicates that the BCH would provide improved and integrated access to information sources, promote the exchange of information, knowledge and best practices, and provide a forum for the exchange of views and information on biosafety.

Article 22 of the Protocol focuses on capacity building, stating that Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of the Protocol. In this regard, an indicative framework for capacity building under the Protocol was considered by the ICCP, covering these among other issues:

- Identification of the needs and involvement of Parties;
- Overview of completed activities in the field of biosafety;
- Overview of existing programs / projects / activities and possibilities for cooperation;
- Multilateral, regional and bilateral cooperation and the need for common understanding and harmonization;
- Elements of capacity building with respect to risk assessment and management in accordance with Articles 15 and 16 and Annex III of the Protocol; and
- Financial and technological resources required.
Attention was also given to public awareness and participation (Article 23), such that these would be promoted, along with education, for the safe transfer, handling and use of living modified organisms as related to conservation and sustainable use of biological diversity, while taking into account risks to human health.

The Global Environment Facility (GEF) was identified to provide a financial mechanism for the Protocol under the CBD and is being called on to provide assistance to countries to implement provisions of the Protocol. At the third meeting of the Conference of the Parties to the CBD, the Parties approved the GEF to provide financial resources to developing countries for country-driven activities and programs for capacity building in biosafety, including the implementation by developing countries of the UNEP International Technical Guidelines on Safety in Biotechnology.

In response to this, GEF financed a pilot “biosafety enabling” project, with its objective to assess the types of needs that recipient countries might have in this area, and determine the level of financial support needed to address these needs, and to help GEF determine a program for biosafety. The project had two components:

- Preparation of National biosafety frameworks in each of 18 participating countries, including a survey of capacity for both biotechnology and for safety assessment
- Organization of 8 workshops exploring risk analysis and management, and trans-boundary movement of living modified organisms.

As stated in the project’s evaluation report (Kinderlerer, 1999), 17 of the initial 18 countries were able to prepare National Biosafety Frameworks and identified national systems needed to ensure safe adoption and application of the products of biotechnology. These countries now require support for capacity building initiatives that enable them to implement these frameworks in light of the Protocol on Biosafety. A new biosafety capacity-building project, working with UNEP for the development of national biosafety frameworks, is beginning. It aims to strengthen national capacity to implement biosafety procedures and maximize the potential of biotechnology. It will do so by preparing national biosafety frameworks; promoting regional and subregional collaboration on biosafety related issues; and establishing a global biosafety support program (Convention on Biological Diversity, 2001).

GEF has prepared a strategy “for assisting countries to prepare for the entry into force of the Protocol” that was accepted by the ICCP in December. While implementation of the Protocol is several years away, steps are being taken now to prepare countries for its coming into force. These steps include, among others, the development of a Biosafety Clearing-House, assessment of country needs as conducted by the UNEP/GEF Pilot Biosafety Enabling Activity Project, and a GEF strategy for building and strengthening of national capacity.

The precautionary principle

Few policies regarding risk management created as much controversy as the Precautionary Principle. Emerging from European environmental policies in the late 1970s, the principle
has been used in numerous international treaties and declarations and is the basis for European environmental law, playing an increasing role in environmental health policies as well. Despite widespread political support, the Precautionary Principle engendered controversy as its critics have interpreted "precautionary" decisions as veiled forms of trade protectionism (Morris, 2000). In relation to the Protocol on Biosafety, the principle gives a country the right to ban import of products lacking complete scientific evidence attesting to the safety of products produced through biotechnology.

Some countries have made their position on the application of the Precautionary Principle clear, such as that of Canada’s Environment Minister David Anderson on January 29th, 2000, stating that, "The Protocol agreement meets the challenge of establishing effective science-based risk assessment and regulatory regimes while respecting the concerns of the developing world. Canada recognizes the right of every country to restrict the import of LMO's that would harm its biodiversity. That is why Canada supports the precautionary approach which allows nations to take action even in the absence of full scientific certainty," (Morris, 2000).

However, many other groups and countries are concerned with the risks such a principle poses to innovation. “Focusing on the risks of the new, they ignore the off-setting risks that food shortages might become severe, that existing vaccines might become ineffective, even when the evidence on these risks is not conclusive;” (Smith, 200). The automatic application of such a principle, with a strong bias against innovation, could prevent useful products from reaching beneficiaries in the developing countries.

As the Protocol process advances, specific tensions between delegates regarding the implications of the precautionary principle emerge. These include concerns regarding innovation versus precaution, the need for scientific information versus timely regulatory approvals, and the demand for human capacity development and related funding needs versus global concerns regarding trade implications.

Regulatory systems and the developing world: capacity and efficiencies

ISNAR, Virginia Polytechnic Institute and State University and partner institutions in developing countries established a collaborative research project to assess the efficacy of biosafety systems by reviewing policies and procedures associated with the introduction of genetically engineered crops. The specific objectives of the studies are to:

1. assess the efficacy of biosafety policies and procedures associated with the introduction of biotechnology products;
2. develop recommendations for enhancing the operation of each country’s biosafety system and minimizing potential constraints to technology transfer;
3. identify areas where international organizations can provide further assistance.

The studies, beginning in Egypt and Argentina (Madkour et al., 2000; Burachik and Traynor, 2001), examine four common elements of biosafety systems: guidelines, people, the review process and mechanisms for feedback (Traynor, 1999). Information is collected regarding: (1) the organization, membership, and operations of national biosafety committees; (2) the nature and availability of information on biosafety procedures and
requirements; (3) the regulatory review paths and necessary approvals leading to commercial release; (4) the extent of public involvement in biosafety matters; and, (5) the personal experiences of applicants and reviewers in dealing with the biosafety system.

Country studies - synthesis and findings

Argentina and Egypt are among the more advanced developing countries in terms of current and intended use of genetically engineered crops and products derived from them. Egypt has approved several dozen field test releases and is on the verge of its first GM crop commercialization. Argentina has been exporting commercial GMO commodities since 1996. Several common characteristics are found between the two countries regarding their handling of biosafety matters. For both countries, the first step in establishing a biosafety system was the drafting of guidelines for ensuring the environmental safety of GMO releases. National guidelines were formulated after a thorough examination of regulatory documents from Canada, Australia, the US and other countries, with appropriate adaptations to national agricultural parameters. In contrast, application, review and approval procedures for food safety and seed registration, typically subsequent steps in the path to commercialization, were built on a framework of pre-existing laws and authorities.

Mechanisms for evaluation and approval evolved over time in both countries. As the first few GMO products reached each stage leading to commercial production – field-testing, food safety review, seed registration and commercial sale – the necessary guidelines, committees, and processes for each stage were implemented on an as-needed basis. In this way, successive regulatory procedures could be functionally coordinated with previous steps and with other Ministries and regulatory authorities. The drawback to this approach is that it tends to create delays; applications may be put on hold until procedures for the next step are worked out.

In Egypt and Argentina, the Ministry of Agriculture is the lead government entity overseeing agricultural biotechnology. It is within this Ministry that environmental safety evaluations are conducted; the Ministry of Environment has a lesser role, if any. Food safety evaluations are conducted through the Ministry of Health. Both countries have constituted advisory committees that conduct technical reviews and make recommendations for approval of individual release applications. The national biosafety committees are empowered to deny a request or to hold it pending receipt of additional information from the applicant. Final decision making authority to allow field tests or commercial releases, however, rests with the Minister of Agriculture. All evidence would suggest that Ministry officials in both countries respect the work of their biosafety committees, as there have been no cases in which advisory committee recommendations were ignored, nor instances in which Ministerial approval was granted in the absence of a proper biosafety review and recommendation.

Both countries have advanced research institutes where Ph.D.-level scientists assisted by highly competent staff conduct state-of-the-art biotech research. Thus, there are pools of qualified individuals who may serve on national biosafety committees or as ad hoc technical advisors.

Nonetheless, the biosafety systems in Argentina and Egypt are very near to exhausting the available expertise having competence in biosafety. This is evident in the degree of redundancy among members of the various review committees in Egypt, and in the
difficulty in identifying additional independent experts in Argentina. One of the most consistent messages heard throughout both studies was the immediate need for biosafety training that would build technical competence in risk assessment and risk management.

Biosafety evaluations in Argentina and Egypt, as in almost every other country, focus on risk in a proposed release. The task is to identify any potential risk and explore potential means for managing identified risks. Ostensibly, evaluations compare predicted impacts of the GMO with those of the equivalent non-GMO variety. Genetically modified varieties that present no greater risk than the referenced conventional variety are deemed acceptable for testing and eventual commercial release. As elsewhere, however, neither country includes a benefit assessment (nor assessment of the risks of not proceeding with the GMO) in the equation. Benefit assessments are a crucial part of the information needed for a comprehensive and balanced review, and generate important information needed by the public.

Membership on a biosafety committee typically is an unpaid position added to each person’s regular duties. Whether university faculty, public or private sector scientist, government agency representative or research administrator, all have to adjust their schedules in order to accommodate the extra workload. In spite of this, none of those interviewed in the two studies expressed any sense of being burdened with an unwanted responsibility. Rather, they took pride in the scientific rigor and fairness of their reviews, and felt that their biosafety work was important and valuable.

In many other respects, Argentina and Egypt have taken different approaches to biotechnology adoption and regulation. Egypt’s effort to address environmental safety for products of biotechnology was set in motion in 1992 by the terms of collaboration between the Agricultural Genetic Engineering Research Institute (AGERI) and a research and policy development project supported by the U.S. Agency for International Development. Among its objectives the project sought to facilitate the development of genetically engineered crops tailored for Egypt’s needs. From the outset, it was understood that transgenic products developed under the agreement would not be transferred and tested in Egypt unless there was an adequate mechanism for biosafety review. In a sense, strong interest in the collaboration and its possible benefits to Egypt created internal pressure to begin developing a biosafety system.

In Argentina, the impetus for building biosafety infrastructure came in the form of external requests from transnational companies seeking a place to grow bulk commodities and for off-season seed production. Thus the country’s introduction to GMOs was in the form of imported transgenic soybean and maize varieties grown almost exclusively for export.

The 30-member Egyptian national biosafety committee is comprised of seven representatives of the Ministries of Agriculture, Health, Environment, Industry, and Commerce; a representative of the Egyptian Academy of Science and Technology; twelve members from academic institutions, an attorney, eight people from government research institutes, and a seeds expert. The Minister of Agriculture selects members; the private sector has no role in review and decision-making. Even with such a large committee, some questions of risk may not adequately be addressed in the review process. For example, applications to commercialize Bt maize varieties have successfully passed environmental biosafety review, yet the risk of accelerated emergence of Bt-resistant pest populations, and
possible management strategies to reduce the risk to an acceptable level, were not addressed during the discussions. In the future, experience and more forward thinking may help reviewers anticipate longer-term risk problems and options for suitable management solutions.

The 19-member Argentinean biosafety commission includes people from private sector organizations (though not individual companies) as well as government agencies and academic institutions. The major consideration for membership is the candidate’s qualifications in the desired area of expertise. Institutions represented on the Commission submit the curricula of three candidates, two of whom are selected for consideration and eventual approval by the Secretary of Agriculture. Conceivably these factors contribute to the more technical nature of the Argentinean review committee. When combined with years of accumulated experience, differences noted here may also contribute in part to the more comprehensive review achieved in the Argentinean system.

The potential for conflict of interest is an inherent part of Argentina’s biosafety system. Nearly all biosafety reviewers conduct applied research at public institutions (leading to field tests and possibly commercial products), work collaboratively with biotechnology companies, or belong to industry organizations. Even those in the first group often have ties to private sector companies. The prevalence of these relationships makes it common for a Commission member to excuse himself from taking part in a decision. Such connections also make it difficult to find independent, disinterested members to review applications containing confidential business information.

Although not a priority in Egypt, Argentina is considering seriously to draft biosafety legislation that would include stringent measures to ensure compliance. Although such a step would likely make future revisions much more difficult, the loss of flexibility in the biosafety system is considered less important that the gain in legal authority and increased public visibility of a vigilant biosafety system.

**Regulatory systems – management lessons**

From the two country studies (Egypt and Argentina), recommendations emerged that would strengthen regulatory systems, stimulate scientific risk assessment, and advance efforts in the areas of public acceptance, technology transfer and regulatory harmonization. Key topics include:

- **Revising national biosafety guidelines**: provide greater clarity by stating purpose and objectives of biosafety reviews; outline procedural and facility requirements; provide a clear "road map" of approval processes and examine the relationship between approvals and legal authority with sanctions to ensure compliance;
- **Enhancing the effectiveness of National Biosafety Committees**: stimulate open and effective dissemination of information; promote cooperation with national and international bodies; and provide database listings of applications;
- **Improving biosafety procedures and decisions**: increase the scientific base for decision-making; identify research needs and collect data to support risk assessment, and adhere to realistic time frames for application decisions;
Building public awareness: information campaigns and educational outreach activities;
Strengthening institutional roles: define and clarify responsibilities among entities sharing responsibility for environmental, food safety and marketing reviews; and
Enhancing transparency and efficiency: clarify review procedures to all stakeholders; distribute responsibility for review of confidential business information between at least two biosafety officials; and organize "customer service" meetings for stakeholders.

Dynamics of participation

The public controls the fate of biotechnology in its willingness or refusal to accept products produced through genetic modification, thus it is essential to inform the public about all aspects of biotechnology. The first step is to develop a strategy for building public awareness, preferably before misinformation from other sources takes root in public opinion. From the beginning, communications efforts should recognize that the public is a full partner in deciding if, when, and how the technology is to be used.

Fostering broad participation in the regulatory system is thus a key to effectiveness and transparency in biosafety decision-making. This is especially true as biosafety policies and procedures affect a diverse group of stakeholders beyond consumers and the general public (Traynor 1999). Scientists engaged in field research are directly subject to biosafety regulations. The private sector has a stake in how the system is implemented and how it operates. Local and multinational companies want a regulatory environment that is reasonable, transparent and consistent. They have a stake in how commercial use of GMOs will be regulated in terms of application and approval procedures, environmental safeguards, consumer issues such as labeling, and matters of trade and import. Government agencies concerned with issues associated with applications of biotechnology to agriculture and the food supply play a role in how the system is set up and run. National biosafety committee members and technical reviewers are the human face of the biosafety system. Their decisions are subject to local, national, and even international scrutiny.

The public’s concerns about biotechnology’s environmental effects and food safety are based in part on past experience with scientific advances whose immediate benefits were trumpeted before longer-term negative effects were realized. This, and concerns raised by environmental groups and consumers’ organizations, need to be addressed. One way to secure public input is to solicit public comment on proposed actions regarding release applications via national government publications or local notifications. A respected community member with a suitable technical background could serve on the local institutional biosafety committee. Other mechanisms should be identified. A system that actively seeks public input and openly addresses the risk-benefit issues is, in the long run, one of the most effective ways to build public acceptance of biotechnology and its products.

Emphasis on participation and the regulatory process was highlighted by the National Research Council report (National Research Council, 2000), stating that to improve transparency, regulatory systems need to expand the quantity, quality and public accessibility of information on the regulation of transgenic products.

In studying the Egyptian biosafety system (Madkour et al., 2000), it was noted that in Egypt, as in most developing countries, there is no official information strategy for informing
the public about GMOs and biosafety. The normal difficulties of mounting a public information campaign, such as determining who should do it, what approaches would be most effective, and who should pay for it, are compounded in Egypt where nearly 40% of the people are illiterate. Furthermore, there is no strong tradition of public empowerment in which consumers demand information and assert their “right to know” about genetically engineered foods. Similar hurdles will have to be overcome in most developing countries.

Public and private investment decisions

Comprehensive strategies are needed to ensure that biotechnology serves developing country agricultural objectives and targets communities most in need (Cohen et al., 1998). The need for such strategies is emphasized in IFPRI’s 2020 Vision for Food, Agriculture and the Environment. In the summary of recommendations, the following points were emphasized:

- Developing countries need a clear policy on and agenda for biotechnology research
- Partnerships should be forged between developing countries, international research institutions and public and private research institutes in industrialized countries
- Incentives should be provided to the private sector for undertaking biotechnology research targeted at the problems of poor farmers (IFPRI, 1995).

Strategies supporting research agendas require human, financial and institutional resources that increase each country’s ability to target benefits towards smallholder farmers. Developing countries are continually challenged to finance the development of basic capabilities and tools of modern biotechnology supporting national research and the public sector. These investments are particularly important for agriculture, which is often the largest economic sector in developing countries—with a vital role in terms of income and employment generation (Pinstrup-Anderson and Cohen, 2000) as well as foreign exchange earnings.

Resources available for agricultural investments are one indicator of efforts to strengthen or create these capabilities. In addition, information on the size, structure, and content of public research is needed to improve policy decisions, clarify roles of the public and private sectors, and support public sector implementation of biotechnology research. To capture this information, ISNAR initiated a survey-based study on research indicators for agricultural biotechnology. Its overall objective is to determine how relevant resources are mobilized and used to implement agricultural biotechnology. Each country survey strengthens the capacity to compile research indicators and identifies gaps and needs with regard to the implementation of biotechnology programs and the mobilization of required resources.

Table 1 shows the percentages of research expenditures among various sectors conducting agricultural biotechnology research. Public-sector organizations accounted for almost 92% of research expenditures during the period of analysis. The average 8% for the private sector, however, showed higher annual growth than did the public universities (except in Indonesia). Moreover, the universities showed a significant decline in research expenditures, which is probably due to economic recession and a drop in donor funding.
Public research institutes showed not only the highest share of financial resources but also the highest annual growth rate (Mexico and Kenya 9%, Indonesia 30%, Zimbabwe 70%). This explains why financial resources are concentrated in only a few public research institutes: KARI in Kenya (70% of total expenditures in 1996), BRI in Zimbabwe (80% in 1998), three research organizations in Indonesia (70% in 1997), and three Mexican research organizations (55% in 1997). This is in sharp contrast to most developed countries; in the USA, in 1992 70% of the financial resources in agricultural biotechnology research came from the private commercial sector (Fuglie et al., 1996).

Table 1. Research expenditures in agricultural biotechnology (percent of 1985 research expenditures).

<table>
<thead>
<tr>
<th>Sector</th>
<th>Mexico</th>
<th>Kenya</th>
<th>Indonesia</th>
<th>Zimbabwe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public research institute</td>
<td>50</td>
<td>60</td>
<td>47</td>
<td>72</td>
</tr>
<tr>
<td>Public university</td>
<td>50</td>
<td>28</td>
<td>49</td>
<td>24</td>
</tr>
<tr>
<td>Private noncommercial</td>
<td>0</td>
<td>4</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Private commercial</td>
<td>0</td>
<td>8</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

Source: Falconi 1999.

In Colombia, the public sector accounts for 61% of the total expenditures, from 1985-1997, while the participation of the private sector is around 39%. This difference reflects stronger development of the private sector in Colombian biotechnology enterprises than in the other four countries previously surveyed. However, government funding still constitutes the highest share of overall funding, showing about 50% of the expenses in 1997 (Torres and Falconi, 2000).

**Personnel**

The number of researchers in biotechnology at least doubled, while the number of PhDs has at least tripled. This growth may be explained by the significant increase of the number of postgraduate programs in biotechnology, the establishment of specialized research organizations that required more scientists trained in biotechnology, and special grant programs that encourage scientists to become involved in biotechnology research. The scientists are concentrated in only a few research organizations: in Kenya some 45% in KARI. In Mexico, 60% in only four research organizations. In Indonesia, 60% in three research organizations, and in Zimbabwe, 70% are in three research organizations.

Downer et al. (1990) has suggested a minimum efficient size for research groups in agricultural biotechnology. For genetic engineering and tissue culture a ratio of one researcher to two support personnel (technicians) was recommended. In the four countries there’s an average of one technician for every two researchers. Most of the research organizations show a low technical support – researcher ratio, which could affect the potential development of research outputs.
Financing

Table 2 presents the sources of funding for agricultural biotechnology research for the five countries. The main recipients of donor’s funds have been public research institutes; KARI in Kenya accounted for nearly 85% of total donor support in 1996 and BRI in Zimbabwe for almost 90% in 1998. The sustainability of these levels of funding will be compromised in the medium term if there is no effort to obtain funding from local sources.

Table 2. Sources of Funding for Agricultural Biotechnology (in %).

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Government</td>
<td>28</td>
<td>60</td>
<td>93</td>
<td>34</td>
<td>47</td>
</tr>
<tr>
<td>Sales of products</td>
<td>3</td>
<td>12</td>
<td>4</td>
<td>16</td>
<td>25</td>
</tr>
<tr>
<td>Contracts</td>
<td>0</td>
<td>4</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Donors</td>
<td>67</td>
<td>24</td>
<td>2</td>
<td>50</td>
<td>13</td>
</tr>
<tr>
<td>Levies</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>14</td>
</tr>
<tr>
<td>Total</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>


Some public research institutes and universities fund their biotechnology research activities from nontraditional sources of funding, such as sales of products and services and contractual arrangements. Although these sources of funding are still minimal, they increased during the period of analysis. Contracts and levies fund biotechnology research done out by private noncommercial organizations, while private commercial organizations are financed by the sales of their products.

The limited funding from nontraditional sources for public research institutes and universities indicates a minimal interaction between public entities and the private sector. In a study of the poor interaction between these sectors in Mexico, Wagnor (1998) concluded that (1) the private sector can import technology more cheaply, (2) the government neglects the use of science to foster economic development, (3) the regulatory framework confuses foreign and local companies in introducing biotechnology products, (4) the basic research orientation of scientists impedes the collaboration between scientists and businessmen, and (5) the lack of funding mechanisms to bring the two sectors closer to each other.

Thus, for all five countries studied, it is clear that funding and execution of biotechnology research is highly dependent on the public sector. The participation of the private sector is very limited, with the greatest extent of commercial involvement seen in Colombia. Significant policy development in each country preceded the expenditures noted, including setting priorities and establishing biotechnology research centers, creating post-graduate programs, and formulating a regulatory framework for biosafety and intellectual property rights. However, comprehensive development strategies are lacking, as are mechanisms that encourage public-private sector collaboration.
The case of China

Recent investments trends for biotechnology in China stand in sharp contrast to the five countries summarized above as well as most developing countries. The current goal for Chinese investments is to create a modern, market-responsive and internationally competitive biotechnology research and development system. Public investments are being made to make this happen, as show in the table below, with much smaller financial resources coming from contracts, donors or commerce (Huang et al., 2001). These levels of finance are meant to improve the innovative capacity of national biotechnology R&D, reform the current research system by providing better support to key institutions and incentive mechanisms, and promoting development and commercialization of biotechnology, thereby increasing investment in research.

Table 3. Plant biotechnology research budget among sampled Chinese institutes, 1986-99.

<table>
<thead>
<tr>
<th>Year</th>
<th>Core</th>
<th>Project</th>
<th>Equipment</th>
<th>Commerce</th>
<th>Consultant</th>
<th>Contract</th>
<th>Donors</th>
<th>Others</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mill. yuan in 1999 price</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1986</td>
<td>4.2</td>
<td>5.4</td>
<td>4.9</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>1.5</td>
<td>0.0</td>
<td>16.0</td>
</tr>
<tr>
<td>1990</td>
<td>4.1</td>
<td>13.3</td>
<td>8.1</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>2.1</td>
<td>0.0</td>
<td>27.7</td>
</tr>
<tr>
<td>1995</td>
<td>4.8</td>
<td>20.3</td>
<td>3.3</td>
<td>0.1</td>
<td>0.0</td>
<td>0.0</td>
<td>2.6</td>
<td>1.5</td>
<td>32.7</td>
</tr>
<tr>
<td>1999</td>
<td>14.4</td>
<td>60.0</td>
<td>8.1</td>
<td>0.3</td>
<td>1.0</td>
<td>0.1</td>
<td>6.9</td>
<td>2.0</td>
<td>92.8</td>
</tr>
<tr>
<td>1999a</td>
<td>19.4</td>
<td>86.9</td>
<td>10.9</td>
<td>0.3</td>
<td>1.3</td>
<td>1.1</td>
<td>7.6</td>
<td>3.3</td>
<td>130.8</td>
</tr>
</tbody>
</table>

Composition (%)

<table>
<thead>
<tr>
<th>Year</th>
<th>Core</th>
<th>Project</th>
<th>Equipment</th>
<th>Commerce</th>
<th>Consultant</th>
<th>Contract</th>
<th>Donors</th>
<th>Others</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1986</td>
<td>26</td>
<td>34</td>
<td>31</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>9</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>1990</td>
<td>15</td>
<td>48</td>
<td>29</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>8</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>1995</td>
<td>15</td>
<td>62</td>
<td>10</td>
<td>0.3</td>
<td>0</td>
<td>0</td>
<td>8</td>
<td>5</td>
<td>100</td>
</tr>
<tr>
<td>1999</td>
<td>16</td>
<td>65</td>
<td>9</td>
<td>0.3</td>
<td>1.1</td>
<td>0.1</td>
<td>7</td>
<td>2</td>
<td>100</td>
</tr>
<tr>
<td>1999a</td>
<td>15</td>
<td>66</td>
<td>8</td>
<td>0.3</td>
<td>1.0</td>
<td>0.8</td>
<td>6</td>
<td>3</td>
<td>100</td>
</tr>
</tbody>
</table>

Research budget by institute and university in 1999a

| Source: Huang et al. (2001). |
The figures presented in Table 3 indicate a scale of investment not common to developing countries, as China positions itself to become one of the world leaders in biotechnology. As this capacity grows, coordination among institutions and consolidation of agricultural biotechnology programs will become necessary to create an even stronger program in the future (Huang et al., 2001). However, success will also depend on the regulatory climate. However, for release and acceptance of GM products, which has not caused delays in the past, but may now temper the speed at which new products, especially those of food crops, reach growers and consumers.

Synthesis and recommendations: safety, capacity and investments

This paper examined investments, international research collaboration, and national biosafety systems providing for the use and regulation of biotechnology. While issues of safety and the environment dominate international debates, other matters equally deserving of attention were highlighted in this paper. These are summarized below, followed by recommendations, where appropriate.

Building a strong foundation in the public sector

Capacity for research and regulation of biotechnology is supported in many developing countries. But more progress is needed to further management, analytical, and technical capacity for responding to the issues highlighted in this paper. This implies support be provided for public institutions that play essential roles in formulating agendas and priorities for biotechnology, particularly needed to serve rural communities and contribute to livelihood expectations. In addition, and requiring further support, public institutions will be called on to ensure environmental safety, contribute to public awareness, and spearhead collaboration with the private sector on product development and diffusion.

As shown for the six developing countries surveyed, funding and execution of biotechnology research is highly dependent on the public sector. While such support is necessary, and should be encouraged, additional attention is needed to broaden opportunities for the private sector, especially so in developing countries themselves.

Coupling technology with policy

Byerlee and Fisher (2001) present a new study describing policy and institutional options for enhancing biotechnology in developing countries. A second study calls attention to the policy environment that directly affects the likelihood that products will emerge from research, and enter use and commerce (Paarlberg, 2000). Both of these reports stress the importance of the policy environment regarding intellectual property rights, biosafety, trade, food safety, and public research investments. Among these, biosafety is seen to be an especially crucial factor for determining eventual utility of biotechnology products (Paarlberg, 2000). Research priorities, strategies for maximizing public investment, and interactions between research and the various policy elements just mentioned require continuing attention so that biotechnology is integrated with national policy and serves agricultural objectives in their countries.
Ensuring the poor benefit from biotechnology

Benefits expected from biotechnology’s application to food and agricultural needs of developing countries have been presented. Further work is required to ensure that positive impacts regarding incomes and sustainable productivity occur. Escalating, acrimonious debate will do little to ensure that farmers in developing countries benefit from investments in public research and funding expended to meet regulatory and safety requirements.

Not only must the acrimonious debate subside, but it should also be tempered by investment strategies that build capacity within the national and international research community. Such capacity for long-standing collaboration and research can begin to apply new technologies to food and agricultural needs that remain intractable through conventional research and for products that are often outside the reach of market economies and of little interest to commercial agriculture.

Biosafety regulation: restricted budgets and limited human capacity

As noted in sections dealing with the Biosafety Protocol, capacity building will play a central role in the implementation of biotechnology research, policy and regulatory structures. The least advanced countries will be hard-pressed to assemble more than a few qualified professionals with competence in risk-assessment procedures. Studies from Egypt and Argentina noted that both of these countries are functioning near the limits of available expertise, which raises questions as to capacity available for future reviews, and how to circumvent the possibility for conflicts of interest. In addition, regulatory systems need to adequately address risk factors through research and gather or supply relevant data, as recognized by the Biosafety Protocol.

Developing countries with limited funding and investment opportunities face difficulties sustaining adequate research budgets. They use professionals to address regulatory requirements and are not able to compensate them. Such harsh economic realities are not going to change in the immediate future, nor will the needed human capacity become suddenly available to address the policy and scientific challenges that surround biotechnology. Therefore, further consideration by donors, international bodies such as the ICCP for the Biosafety Protocol, and national policy-makers much be given to implementing biosafety guidelines and regulatory systems in the context of developing, not developed, countries. These considerations should draw on opportunities for creating increased efficiencies, economies of scale, regional cooperation, and means by which these countries can economically and scientifically comply with the increased calls for safety and environmental risk assessments.

Increased knowledge of the costs of regulating new product, particularly pest-protected crops, will become essential, as the NRC report (National Research Council, 2000) noted that regulatory testing can be expensive in terms of management time and money (Lichtenberg, 2000). As a result, testing barriers can become barriers to entry for small companies or national agricultural research organizations.
**Biosafety and regulation: policy implications**

There is a particularly strong need to enhance regulatory efficiency and decision making in developing countries while building technical competence in risk assessment procedures. Subsequent review of findings and recommendations from the country studies identified policy matters needed to implement regulatory systems. Key issues include:

1. Ensuring a science-based assessment process for those entrusted with regulatory reviews, separate from activities promoting biotechnology research and development;
2. Ensuring that an effective system of accountability is in place to build confidence in decisions taken, along with policies to maintain and ensure independent technical expertise for environmental review and testing;
3. Providing expertise in benefit assessment, as such information is critical for making comprehensive assessments and balanced decisions, and it is seldom, if ever, available;
4. Developing risk/benefit criteria to be incorporated when setting trade-off levels between agricultural productivity and environmental and human health effects;
5. Building a regulatory culture where transparency and accountability are norms;
6. Devising regulatory procedures that alleviate barrier entry problems while maintaining environmental and human health safeguards, as regulatory testing can be expensive, and can become an effective barrier to entry for small companies or scientists in the national agricultural research systems;
7. Assembling information on regulatory costs in terms of human resources, implementation and provision of adequate information for scientific-based risk assessment.

**Acknowledgements**

The author would like to express his appreciation for the collaboration on this report received from Kate Raworth, Patricia Traynor, John Komen, Muffy Koch, Robert Frederick, Michael Lipton and Cesar Falconi.

**Notes**

1. For the combined academy report, moving towards sustainable agriculture means adopting practices that “do not compromise the health and economic well-being of current and future generations”. The challenge is to increase food production and people’s access to food, which requires local and employment-intensive staples production, without further depleting non-renewable resources and causing environmental damage (National Academy, 2000).
2. These initiatives can be organized by the following five categories: international research programs for plant biotechnology; international research programs for livestock biotechnology; international or regional biotechnology networks for specific crops or regions; special programs initiated and co-ordinated by bilateral or multilateral donor organizations. And organizations providing advisory services on policy and research management issues.
3. Resources are defined to include physical, human and financial.
4. Technical support staff are those that directly assist in designing and conducting agricultural research activities. They include laboratory technicians and biometricians, and usually have a post-secondary professional education.

5. These policy implications follow review of the aforementioned regulatory/biosafety studies, the system studies in Egypt and Argentina, review and consultation with Professor Erik Lichtenberg (personal communication), Department of Agricultural and Resource Economics, University of Maryland, and in reference to articles of the Biosafety Protocol.

References


