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Unlocking Crop Biotechnology in Developing Countries—A Report from the Field

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Summary. — Disputes continue to flare over acceptable safety standards for biotechnology products, and the potential for these technologies to address agricultural needs. Benefits have been documented for a limited number of genetically modified (GM) crops, however, official permission to plant GM seeds in developing countries has not been granted in most countries. Six country studies examined regulatory decision-making, efficiencies, and bottlenecks for GM crops. Building on these, a Conceptual Framework is proposed for implementing biosafety. The paper then highlights political, trade, and market issues external to the Framework, and concludes with recommendations to help unlock GM safety approvals.

Key words — biosafety, regulation, biotechnology, developing countries, Africa, Asia, Latin America

1. INTRODUCTION

Biotechnology applications provide potential contributions to sustainable agricultural productivity and new inputs for poor and/or small-scale farmers in developing countries (Huang, Rozell, Pray, & Wang, 2002; Morris & Hoisington, 2000; OECD, 2003; Thirtle, Beyers, Ismaël, & Piesse, 2003). Recombinant DNA techniques provide plant breeders with abilities to introduce traits into plants not accomplished through traditional plant breeding. These new traits include enhanced resistance to insect pests or diseases responsible for significant yield loss, potential sources of tolerance to drought and soils with high concentration of salt or heavy metals, and improved productivity potential.

Potential adverse environmental and/or human health consequences arising from the introduction of genetically engineered, or transgenic, plants led to the development of specific regulatory regimes to assess safety. Effective national biosafety systems assess safety, but in so doing, can also encourage (*or not*) (a) the growth of domestic biotechnologies, and (b) access to new products and technologies developed elsewhere. Many of these same systems comply with the Cartagena Protocol on Biosafety following its adoption and ratification (Mackenzie, Burhenne-Guilmin, La Vina, & Werksman, 2003). Absence of efficient regulatory frameworks hinders investments in biotechnology from development agencies, and the public and private sectors, and impedes decisions on safety.

Biosafety systems also address information needs of stakeholders. These can include non-governmental organizations (NGOs), members of civil society, and researchers that oppose biotechnology based on the perception that its products are harmful to the environment, human health and to the socioeconomic status of small farmers. Part of the concern and confusion among stakeholders arises as changes

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can occur almost daily regarding biosafety policy and practice, and more specifically, when determining commercialization or release decisions. Lack of public understanding of these changing events, coupled with other external factors, can effectively limit seed choices for farmers.

This paper explores complications and decision-making surrounding the testing and approval of GM crops in developing countries, including crops developed through public sector research. It relates such products and their biosafety review by examining:

(i) *internal factors* including regulatory procedures, capacity, risk assessment, frameworks, and how biosafety systems are implemented, and,

(ii) *external factors* affecting operation of biosafety systems, such as political governance and decision-making, European Union trade implications, and the impact of advocacy groups.

Findings from six country studies are examined, four completed for the International Food Policy Research Institute (IFPRI) and two undertaken by the International Service for National Agricultural Research (ISNAR). While conducted separately, findings are complementary and share common lessons. From these shared lessons, a Conceptual Framework was developed to provide an integrated perspective for biosafety. After describing this Framework, recommendations for action needed internally and externally for biosafety development and implementation are discussed.

2. GM CROP APPROVAL SLOWDOWN AS EVIDENCED IN KENYA, BRAZIL, INDIA, AND CHINA

Studies undertaken for IFPRI revealed that biosafety procedures for GM crops are not yet working well in a number of developing countries (Paarlberg, 2001). Even among states that could be leading GM crop development—such as Kenya, Brazil, India, and China—few GM varieties have been approved. Scientists, agricultural ministries, and private seed companies in these states have worked consistently to help GM crops reach the field, yet even in these leading states the uptake of the technology has been slow.

Kenya's national agricultural research system has been pursuing, with donor support, the development of a locally suitable GM virus-resistant sweet potato since 1991. Brazil's public sector has gone farther by investing its own treasury resources in GM crops. Scientists at EMBRAPA/CENARGEN have developed and patented their own system for crop transformation and have been field tested their own varieties of GM soybeans and potatoes. India's Department of Biotechnology (DBT) also invests state resources in GM research on Bt varieties of rice, cotton, pigeon pea, and mustard.

In China, state efforts to develop GM crops have been considerable. Chinese laboratories have recently applied GM techniques to over 50 different plant species—including rice, corn, and soybeans—and more than 120 different functional genes (Huang *et al.*, 2002). Yet among these four countries, as of 2004, Brazil is the only one to have given official approval to the planting of any GM varieties of food or feed crops.

China and India do grow GM cotton commercially, but neither has yet commercialized GM corn, soybeans, or rice. Kenya has not yet approved the planting of any GM crops, not even cotton. Consider the role that GM crop biosafety approval has played in each of these countries.

(a) *Kenya*

The slow pace of biosafety approvals in Kenya is illustrated by the case of the virus-resistant GM sweet potato. This is a technology first offered to the Kenya Agricultural Research Institute (KARI) in 1991, by the Monsanto Company. Monsanto offered to license the technology on a royalty-free basis to KARI and the rest of the developing world through the offices of USAID's Agricultural Biotechnology Support Project (ABSP). The first step, however, was to be sure that the Government of Kenya had in place adequate biosafety regulations for GM crops. This process took seven years, in part because the drafting process was supported by so many different donors.

In the lead was the Foreign Ministry of the Netherlands (DGIS), which spent $5 million on biotechnology assistance to Kenya, and subcontracted with a local NGO to turn the process into an extended and highly participatory local priority setting exercise. Also involved were the World Bank (through a National Agricultural Research Project), UNEP and GEF (through a Pilot Biosafety Enabling

Activity Project in Kenya), plus USAID (through ABSP), and also the Monsanto company itself (which trained nine scientists from the Kenyan Agricultural Research Institute (KARI) in the United States and assisted them with two years of mock field trials in four regions of the country). This heavy donor involvement through a variety of competing Kenyan ministries (e.g., Ministry of Environmental Conservation *versus* National Council for Science and Technology, or NCST) pulled the Kenyans in multiple directions.

In 1996 the Kenyans finally formed a National Biosafety Committee (NBC) under NCST, but not until 1998 did this NBC finally have a published set of "Regulations and Guidelines for Biosafety in Biotechnology in Kenya" to work with (NCST, 1998). The multiple local and international drafters of these regulations borrowed heavily from biosafety regulations used in the Netherlands and Sweden. Unfortunately, while the Kenyans had been helped in the writing of strong regulations, they had received much less assistance in the area of scientific and bureaucratic capacity. The 15-member NBC was tasked with screening proposals for the import, field trial, and commercial release of all GM crops, but it scarcely had the capacity to do so. In its first several years of operation the NBC had a full-time professional staff of just one person, little or no Internet access, no independent facilities, and no budget of its own.

Not surprisingly, Kenya's NBC has moved slowly to grant biosafety approvals for GM crops. In 1998 six months after the NBC finally had its regulations in place, KARI made a formal request for permission to bring its GM sweet potato materials into the country from Monsanto in the United States, but it took the NBC a year and a half to say yes to this importation request. Some of the delay was linked to satisfying another government agency—Kenya's Standing Technical Committee on Imports and Exports—but for much of the time KARI's request simply sat with the NBC, which raised more questions about "producer acceptance" of the new GM sweet potato than about actual biosafety. The biosafety issues surrounding this technology should have been relatively easy to resolve, given the low probability of gene flow (sweet potato is propagated vegetatively and hardly flowers, and when it does the pollen is infertile) and the absence of wild relatives anywhere in Africa.

The NBC finally gave its approval for KARI to bring Monsanto's transformed sweet potato materials into the country in January 2000, and approval was then given for small field trials that began later that year at four different KARI locations. The first complete field trial harvests in 2001 were successful in proving the disease resistance qualities of the new GM variety, but more trials were needed for biosafety clearance purposes. A second season of trials began in October 2001, and a total of four seasons of trials (plus final NBC approval) will be required. But field challenge trials concluded in 2003 indicated insufficient levels of protection against the virus complex, thus requiring further research until more resistant material can be delivered to farmers.

(b) *Brazil*

Brazil has also been slow to approve the planting of GM crops. In September 1998 Brazil's National Technical Commission on Biosafety (CTNBio) issued a technical opinion approving five varieties of Monsanto's Roundup Ready soybeans for commercial release, but the release was blocked by an NGO lawsuit and a federal court injunction.

This blockage in Brazil differed from the slow progress in Kenya case, because it did not grow out of weak bureaucratic or technical capacity. Brazil wrote its own national biosafety law in 1995, and when the CTNBio (empowered by that law) began operating in 1996 it was fully capable of handling the task: 25 of the 36 members of the commission were PhD scientists, and the staff included five MA scientists. CTNBio tried to move quickly with a commercial release of GM soybeans, granting its technical approval in September 1998 just 18 months after it first approved field trials. But this attempt to go ahead quickly was immediately blocked by a federal court injunction.

Substantive biosafety worries were not the major problem. Roundup Ready soybeans had been grown widely—and to all appearances safely—in the United States and also Argentina since 1996. By switching to RR soybeans, farmers in these countries could reduce soil-damaging tillage and control weeds with fewer, less toxic, and less persistent herbicides. Gene flow to wild relatives was not an issue in Brazil, since there are no wild relatives of the soybean anywhere in the Western Hemisphere. CTNBio did consider the possibility of adverse weed resistance to herbicide use, and possible harm

to nitrogen-fixing microorganisms in the soil, but its proposal was to limit the planned commercial release to only some parts of the country and called for biosafety monitoring for five years.

Worries about super-weeds were not what animated the NGO lawsuit that initially blocked the release. The central charge in that lawsuit, brought by Brazil's Institute for Consumer Defense (IDEC), was that CTNBio lacked authority to give a final technical opinion on biosafety because the Brazilian Constitution gave environmental impact assessment (EIA) authority to an institute inside the Environment Ministry, the Institute for the Environment and Renewable Natural Resources (IBAMA). When IBAMA itself joined the lawsuit (along with the Brazilian office of Greenpeace) the issue was presented, but did not really focus on specific issues of biosafety.

Both IDEC and Greenpeace have waged their anti-GM campaign in Brazil more on food safety issues than on biosafety issues, and the subtext is often a larger suspicion regarding the role played in Brazil by all foreign-based multinational firms such as the Monsanto company (Paarlberg, 2001). Partisan politics began driving the conflict as well, when a newly elected opposition Workers' Party (PT) governor from the southern state of Rio Grande do Sul decided early in 1999 to challenge the pro-GM views of the more centrist Social Democratic Party that was controlling the federal government in Brasilia at the time.

Commercial uncertainties also played a role. Export-oriented agricultural and trade officials in Brazil were initially enthusiastic about GM crops, but they began to reconsider when consumers in big importing regions such as the EU and Japan started showing a clear preference for non-GM soybeans and corn. Following the 2000 StarLink GM corn scare, some importers in Spain and Japan turned away from the United States and Argentina (both of which had planted GM corn) and began buying from Brazil (which had not officially released GM corn) at a \$6–\$7 per ton premium. [1] It was not as easy for Brazil to market itself in Europe and Japan as a GM-free supplier of soybeans, given that Roundup Ready soybeans had been planted illegally for several years over wide areas. But even so, the growing international market resistance to GM foods and feeds gave Brazilian officials pause, and helped to keep in place the court-led blockage against official releases of RR soybeans.

The top leadership of the Brazilian federal government struggled to overcome the court injunction against planting RR soybeans. In July 2000, President Fernando Henrique Cardoso persuaded six senior cabinet members—including even the Environment and Health ministers—to sign a "manifesto" supporting GM crops and the lead role of CTNBio. Then late in December 2000, President Cardoso signed a provisional law (something he can do on his own authority under the Brazilian Constitution) intended to delineate further CTNBio's jurisdiction over the matter. But political opposition to GM crops has remained intense as well. Late in March 2002, a special commission on GM foods approved a positive report designed to provide momentum for a bill being considered by the Chamber of Deputies favoring of planting GM crops, but environmentalists and MST representatives on three occasions occupied committee rooms in hopes of blocking or at least postponing a favorable vote (www.checkbiotech.org, ref. 2957, April 20, 2002). Finally in 2003, faced with a continued spread of illicit seeds, the government of Brazil issued a temporary decree to make the planting of GM soybeans legal, but local and international NGOs promised to challenge this step in the courts as well.

(c) *India*

A long absence of any GM crop biosafety approvals in India was finally broken in March 2002, when the Genetic Engineering Approval Committee (GEAC) gave permission to an Indian seed company, Mahyco, to begin commercial production and sale of three varieties of Monsanto's Bt cotton seeds, thus offering Indian farmers a new strategy for protection against bollworm. This regulatory breakthrough was hailed as opening the door for a wider GM crop revolution in India, yet the scope and speed of that revolution remains in doubt, owing to the highly politicized nature of India's biosafety approval process.

The Indian government began issuing biosafety guidelines for handling GM organisms in December 1989 (DBT, 1990). These guidelines were drafted before GM crops became an ideological battleground, so they do not explicitly embrace a "precautionary principle." They specify screening only for risks that can be scientifically demonstrated. Furthermore, these guidelines are applied at the GM research stage by a Review Committee on Genetic

Manipulation (RCGM) that is constituted by the Department of Biotechnology (DBT) and friendly to the technology. Beyond the early research stage, however, biosafety approvals in India are now subject to strong political challenge. All large scale research activities involving GM crops in India, as well as environmental release and final permission for industrial use, must be approved by the GEAC, which is chaired by the Ministry of Environment and Forests (MoEF), and at this stage in the approval process a variety of concerns about GM crops not necessarily linked to biosafety can come to be expressed.

In the case of Bt cotton, Mahyco began its quest for biosafety approval in 1997. RCGM approved small-scale field trials in 1998, but anti-GM activists in India responded immediately by filing lawsuits against DBT and by staging direct actions against the trials, invading the test plots and burning the cotton. These protests were not motivated by any particular biosafety concern. The ''Bollgard'' Bt cottonseeds that Mahyco was testing were not an experimental technology; they were a Monsanto product that had been grown widely and successfully in the United States since 1996, and also in Australia, South Africa, Mexico, Argentina, and China. An environmental benefit from planting these seeds was a dramatic reduction in the number of insecticide sprayings needed to control bollworms. The environmental risks seemed few; there are no identified noncotton plants that are sexually compatible with cultivated cotton. Outcrossing to wild species is a possibility, yet commercial cotton production in India generally does not take place in the same geographical locations as these varieties.

The NGO protests against Bt cotton in India were primarily an outgrowth of earlier campaigns in the country against international corporate control of the country's seed and farm sector. The NGO invasions of Mahyco's field trials were specifically driven by an erroneous charge that the seeds contained the Monsanto company's so-called terminator gene, and were part of a plot to force Indian farmers to buy corporate seeds every year rather than saving and replanting their own. [2] In 1998, a Parliamentary uproar over this ''imagined threat'' led to ministerial promises that the terminator gene would not be allowed in India.

It was under the intimidating threat of these anti-corporate NGO protests, rather than because of any specific biosafety concern, that India's GEAC took so long to approve Bt cotton. GEAC finally did approve large-scale field trials for Bt cotton in July 2000, but in the following June GEAC demanded yet another year of large-scale trials before it would consider the approval of Bt cotton for commercial use. The reason given for the extra year of trials was political and procedural rather than substantive; GEAC wanted the extra year of trials monitored by the Indian Council of Agricultural Research (ICAR), as a reassurance of firm public sector control. GEAC's final approval of Bt cotton in March 2002 was also shaped by a political context.

In September 2001, approximately 500 farmers in Gujarat were found to have been planting Bt cotton seeds illegally; having purchased them from a local seed company that had sought to conceal their GM nature. This law-breaking practice was exposed when a major bollworm infestation left many fields planted to conventional cotton devastated, while the Bt fields continued to thrive. Farmers were understandably angered when the government told them they had to burn their standing crops. At this point it became more difficult for government officials to continue denying to Indian farmers this technology so well suited to their pest control needs and so widely in use elsewhere.

India's approval of Bt cotton does not necessarily presage a quick approval for other GM crops (other than India's own indigeniously developed Bt cotton varieties, which are still several years away from being ready). Cotton is an industrial crop critical to an important export industry, and largely free from the consumer food safety concerns that tend to arise in commodity export markets. For food and feed crops that might enter export markets, Indian regulators could take a more cautious approach.

While cotton was finally approved by India, a GM food crop—a transgenic hybrid mustard variety—has been undergoing field trials in India since 1995 and has still not been released for commercial use. Indian regulators have held this product back by continuously demanding from the applicant company (Pro-Agro-PGS) new information on an increasing number of increasingly hypothetical biosafety risks (e.g., effects on soil micronutrients). This regulatory pattern of saying yes to GM industrial crops, but holding back on food or feed crops, is even more plainly visible in the case of China.

(d) *China*

China had an early history of moving ahead aggressively with GM crops, while paying only token attention to biosafety. China planted GM tobacco over a wide area in the early 1990s before its Ministry of Science and Technology had even promulgated an official biosafety regulation for GMOs. Not until China's Agriculture Ministry finally issued its Implementation Regulation on Agricultural Biological Genetic Engineering in July 1996 did China have a detailed set of standards in place for the biosafety screening GM crops (Ministry of Agriculture, 1996). This regulation gave institutional authority over biosafety screening directly to a Committee on Safety of Agricultural Biological Genetic Engineering within the Ministry of Agriculture.

The 33 members of the Committee on Safety represent the full range of China's larger scientific establishment (including the Chinese Academy of Science, the Ministry of Science and Technology, the Ministry of Education, and the Chinese Society of Agro-Biotechnology), but roughly one-third of the members come from the agriculture ministry itself. China's biosafety screening committee is thus more sensitive to agricultural production imperatives than either the Kenyan or Brazilian committees (which are located under ministries of science and technology) or the Indian committee (which is chaired by the environment ministry).

Initially this Chinese system produced a steady stream of biosafety approvals for GM crop field trials, environmental release, and commercial release. During 1996–2000 the Committee on Safety approved 45 GM plant applications for field trials, 65 for environmental release and 31 for commercialization (Huang *et al.*, 2002). The only major GM field crop approved for commercial production was cotton, but a number of minor food and horticultural crops (green peppers, tomato, petunia, and an herbicide-resistant rice hybrid potentially useful for hybrid seed production) were also given final approval (Paarlberg, 2001). It appeared at this point that while other developing countries were holding back, China was going boldly ahead.

But then in 2000, the approval process in China suddenly slowed. By September 2000, according to one official on the Committee, there was a backlog of nearly 200 products for various kinds of release that had not yet been approved (He, 2000). Field trials for GM corn had been underway since 1998, but approval for commercial release has not been given. Initially this slowdown seemed to have some legitimate biosafety foundations; applicants were told that more information would be needed on pest population resistance problems, since some of the insects that would attack Bt corn in northeast China would also attack Bt cotton. But following the 2000–01 StarLink corn crisis, which turned importers in Japan and South Korea away from GM corn, China discovered another motive to go slow. As an exporter of corn to Korea and other Asian markets, China saw a possible new advantage to remaining GM-free. In April 2001, Chinese officials signaled informally that new commercial releases, especially GM food or feed crops, would be put under at least a temporary freeze, and they cited international consumer resistance to GM foods as one reason for the freeze (Paarlberg, 2001).

Chinese officials have also been moved by commercial considerations toward adopting a GM-free posture toward soybeans. Even before the StarLink scare in corn, a shipment of soy sauce produced in Shanghai from US-grown GM soybeans was turned back by skittish EU importers, causing the Chinese to begin placing tighter labeling restrictions on imports of US soybeans. Then late in 2001, Korea purchased 300,000 tons of Chinese soybeans for food use as an alternative to GM-contaminated US, Argentine, or Brazilian beans.[3] With such international commercial incentives to remain GM-free, it is unlikely that herbicide-resistant GM soybeans will be released for commercial use in China any time soon.

China has thus moved, since 2000, from an originally permissive screening posture for GM crops toward a highly restrictive posture (see Jia & Peng, 2002, for update on China's approval decisions). In China's case the explanation is not a lack of bureaucratic capacity, or confusion caused by divergent donor pressures, or direct action campaigns by NGOs, or opposition party resistance, or lawsuits and court injunctions, or consumer fears brought on by adverse media publicity, or jurisdictional competition between ministries. The Chinese political system is substantially immune to all of these things. The most probable explanation is growing skepticism toward GM foods and feeds in international commodity markets. China is a substantial exporter and wants to hold onto its GM-free status for major field

crops (all except cotton) until importer policy and consumer preference trends in world markets have been clarified.

3. GM CROP APPROVAL STUDIES IN ARGENTINA AND EGYPT

The next two studies describe regulatory procedures and regulations in Argentina and Egypt. These research studies were initiated to review policies and procedures associated with the introduction of GM crops. The specific objectives of the studies were to:

—assess the efficacy of biosafety policies and procedures associated with the introduction of biotechnology products;

—develop recommendations for enhancing the operation of each country's biosafety system and minimizing potential constraints to technology transfer.

These studies, (Burachik & Traynor, 2002; Madkour, El Nawawy, & Traynor, 2000), examined four common elements of biosafety systems: guidelines, people, the review process and mechanisms for feedback (Traynor, 1999). This original methodology has been revised, taking into the Conceptual Framework described below. This Framework serves as the basis for a more recent study undertaken for Kenya (Traynor & Macharia, 2003) and one planned for Uganda in 2004.

Information is collected regarding: organization, membership, and operations of national biosafety committees; the nature and availability of information on biosafety procedures and requirements; regulatory review paths and approvals leading to commercial release; the extent of public involvement in biosafety matters; and, personal experiences of applicants and reviewers in dealing with the biosafety system. Additional data are now collected for the five elements of the Conceptual Framework.

(a) *Egypt*

In Egypt, regulatory decisions for commercializing GM crops were affected by many factors. Much of this work is undertaken through The Agricultural Genetic Engineering Research Institute (AGERI), which conducts research in genetic engineering and agricultural biotechnology. This research develops GMOs tailored for local conditions and consumer preferences. In addition to this work, multinational companies sought permission to import GMO crops for testing in Egypt since 1995. But, while extensive confined field tests have been approved and conducted, no commercial releases have been approved.

Procedures for commercializing GM crops were set up in 1998, through a Ministerial Decree (Madkour *et al.*, 2000). There is a four-step process for varieties developed through Egyptian research, while for commercial providers outside of Egypt, a fifth step is added. The applicant must first obtain a permit for importing the seed from the Supreme Committee for Food Safety, Ministry of Health. In addition, Egypt made a strategic decision to first try to commercialize crops of local importance, produced through its own research, before approving an imported product. In this way, the public would be introduced to GM crops through products developed in-country, for the benefit of Egyptian farmers, consumers and growers.

This decision and the work of AGERI were well received, and optimism was expressed regarding commercial use. In the latter part of 1998, however, an abrupt turnaround in public opinion occurred. Highly negative articles began to appear in newspapers, magazines, and on TV. Their inflammatory messages duplicated the more radical arguments seen and heard in Europe, India, and elsewhere. Lack of understanding in the media confused the public; many people came to believe that plots and corruption taint biotechnology products.

The timing and strength of this anti-biotech media campaign caught the biotechnology community unprepared. Months passed before biotechnology proponents began to mount a public response. While the response was limited to newspaper and television interviews and publication of general articles, there is general agreement that not enough information is being distributed to counteract the misinformation. Researchers requested that the government should use the media to inform the public from a neutral position. Presently, the situation is calmer. Negative comments and articles no longer appear in local publications, however the public hears anti-biotechnology messages from national and international media. Biotechnology research progresses, but without commercialization.

In December 2000, Egypt signed the Cartagena Protocol on Biosafety (CPB, 2000). This meant that in addition to the regulatory rules and procedures established, the articles and guidance provided by the Protocol would also

have to be integrated with regulatory decision-making. This includes the concepts of Advanced Informed Agreement, and the Precautionary Principle.

Since 1995, there have been products from public collaborative research suggested for commercial release: potatoes engineered to resist virus infestation and squash plants resistant to viral pathogens (Atanassov *et al.*, 2004). But, despite scientific success and progress (Madkour, 1998), other difficulties have been encountered. One of which requires that AGERI find funding from commercial partners to fully develop and complete regulatory requirements for GM products of its research. To date, this has not been possible, in addition, for GM potatoes there is concern with acceptance in international markets.

There have also been commercial products submitted for approval from commercial providers of yellow and white maize modified for insect resistance. As described above, however, these applications have not yet been approved as Egypt initially expected its own products to be approved and used before commercial imports.

The recent politically motivated opposition campaign in the media unquestionably raised public awareness about biotechnology with an intended negative effect on public opinion. Lack of preparedness for the unexpected attack was evident in the slow and limited response from the biotechnology community. This has heightened awareness among researchers for a program that disseminates fair and accurate information. Current low levels of NGO activity in Egypt cannot be assumed to continue in coming years. Public concerns, as expressed in Europe and the United States, are affecting agricultural markets around the world, and countries need to prepare public information materials accordingly.

A combination of issues, many falling outside the regulatory system *per se*, have led to "regulatory uncertainty" for applicants seeking commercial approval in Egypt. These issues include the fact that, in the first case, the Ministry of Agriculture made a strategic decision to approve commercial release of products from its own research prior to granting approvals to commercial or external providers. Second, the emergence of NGO campaigns made itself apparent, and lobbied extensively to slow down research and regulatory decisions. Third, Egypt's research on GM food crops with export market potential, such as potatoes, was halted do to trade restrictions imposed by potential importers. Research supported by the Ministry of Agriculture and AGERI must seek commercial support and funding to gain regulatory approval and gain commercial release. So far such partners and funding have not been found. A combination of regulatory uncertainty, lack of funds for public-private partnerships, and growing effects of NGOs has effectively put commercial release and scale-up decisions on hold.

(b) *Argentina*

In the case of Argentina, a well-established regulatory structure had been in place for many years. Despite many commercial approvals, however, it too has been subject to delays and pressures from trade concerns, environmental NGOs, and at the top level of political leadership. These pressures combined to create an unofficial moratorium on the approval of GM crops lasting three years. This moratorium, beginning in 1998, held up final approvals for commercial use and ended when Monsanto's Roundup Ready cotton was approved in April 1991, making six varieties approved for commercial use.

Two important advisory bodies, established to secure regulatory evaluation of proposed GM crop releases, work together on the approval process (Burachik & Traynor, 2002). The first is the National Advisory Commission on Agricultural Biotechnology (CONABIA). Its purpose is to evaluate the scientific and technical issues associated with the potential environmental impacts of GMOs. The second is the National Service for Agrifood Safety and Quality (SENASA) has the mandate to regulate food safety and quality, animal health products and pesticides. It has created a Technical Advisory Committee to advise SENASA on food safety issues, and to speed up the food safety review, which has run beyond most applicants' expectations.

Delays occurred after both CONABIA and SENASA recommended approval of products, including the Roundup Ready cotton, to the Secretary of Agriculture, Livestock, Fisheries and Food. Delays occurred at the level of the Secretary and his main advisors, who had adopted a hesitant attitude towards approval. This delayed the cotton approval. This former Secretary also halted field test approvals, which prevented many developments from advancement, in part influenced by environmental groups that were anti science and technology.

In order to advance regulatory decision-making, the ISNAR study recommended the government to further clarify and strengthen national and institutional policies regarding the context for and the application of regulatory decision-making. This will help clarify the roles of CONABIA and SENASE, as well as build deeper understanding of the regulatory process. In addition, the need was recognized to modify biosafety regulations to enhance timeliness and transparency. This was supported by the final recommendation, to design a program to address public awareness and acceptance.

Despite its long record of approvals for testing and export of GM crops, the Argentine regulatory system was held under a *de facto* three-year moratorium by a number of factors. These include those that placed the Secretary under political and environmental pressure to no longer approve GM crops. Only a change at the political level of the Secretary helped end the moratorium, and gain approval for GM cotton.

4. SYNTHESIS: LESSONS FROM THE FIELD

This evidence from the field provides an analytical basis for strengthening regulatory systems and capacity, stimulating scientific risk assessment, and advancing efforts in the areas of public acceptance, technology transfer and regulatory harmonization. The seven actions below, as summarized from the studies, focus on improving biosafety system efficiencies, capacity, and transparency.

—*Emphasizing the central role of capacity*: provide resources to stimulate the development of qualified individuals to enhance the knowledge and skills base available for regulatory review and decision-making.

—*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. Such work is supported through the UNEP/GEF project for developing biosafety framework and guidelines for signatories to the Cartagena Protocol on Biosafety (Briggs, 2001).

—*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 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 stakeholders; distribute responsibility for review of confidential business information between at least two biosafety officials; and organize ''customer service'' meetings.

5. WORKING INTERNALLY AND EXTERNALLY

The controversial nature of GM crops continues, especially as regards their role in agricultural development and as a source of food aid (Nuffield Council on Bioethics, 2004). Developing countries are reacting in a precautionary manner, and justifying this approach by referring to the options articulated in the Convention for Biological Diversity, and the Cartagena Protocol on Biosafety. While significant progress has been made in building regulatory capacity, and sorting out guidelines, decision-making is still complicated, which is of great concern regarding the review of GM crops for public use.

This paper mentions several such GM crops in various stages of research and development. The magnitude of this research is important, with recent data collected from 16 countries, identifying over 200 independent genetic transformation events in 45 crops (Atanassov *et al.*, 2004). These numbers include many of the research products discussed earlier in this paper. The study showed that 44 events were in confined field testing, indicating the need for regulatory advancement and approval for these crops to reach farmers. For this to occur, however, these crops require clear regulatory frameworks and policies. Delays and complications, as encountered in the proceeding

examples, limit opportunity for GM crops to reach those intended.

To review public GM crops efficiently, it is necessary to first analyze and then strengthen regulatory decision-making. This necessitates actions internal and external to the system itself. Actions, as summarized in the previous section, address internal needs and efficiencies. But, these efficiencies, absolutely essential for application review, can be neutralized by a combination of external factors, including political, trade and activist positions, and especially difficulties when encountering European markets that are essentially closed to GM imports or use.

It is more complex to develop actions that will have an impact on voices external to the regulatory system. No uniform roadmap is available for working externally, facing political, trade, environmental concerns, anti-GM lobbies, moratoriums, and nongovernmental or activist influence. Informed discussion regarding biotechnology's benefits and potential risks is needed, but in a context of specific GM crop examples, political governance and advocacy concerns, and including farmer perspectives.

In the next section, a Conceptual Framework is presented that can guide internal work. Its policy component calls for integration of regulatory policies with broader recommendations for each country, e.g., development goals and environmental objectives. The policy component connects the internal and external needs of the system side by creating an agenda for discussion among diverse stakeholder perspectives. Using the Conceptual Framework itself cannot ensure timely, efficient decision-making and safe use of GM crops. Equal emphasis is needed on the political, policy, and advocate front.

Addressing the seven items above, identified from our analysis in the field, provides starting points for working internally. The Conceptual Framework is available to guide and ensure integration of the seven actions previously identified.

6. WORKING INTERNALLY: BIOSAFETY FROM A SYSTEM'S PERSPECTIVE

(a) *Conceptual framework for implementing biosafety*

Over the past two decades, developing countries have attempted to develop national biosafety frameworks and guidelines. These have often been implemented in a fragmented or *ad hoc* manner due to particular needs and urgent pressures. Our studies, findings and actions illustrate how difficult a task this is, as the design and implementation of a national biosafety system attempts to balance or align public policy goals, perceptions of safety and risk, and economic, political, and technical realities.

Ideally, developing countries would benefit by working with a comprehensive plan to help with policy development and regulatory implementation. There is no single "best approach," however, that can reflect each country's environmental, political, financial and scientific differences. Consequently, a comprehensive, conceptual framework for biosafety implementation has often been lacking. For this reason, an international expert consultation [4] was convened to explore how such a framework could be constructed.

The consultation reviewed prior studies, and concepts and lessons derived from other national, regional and international experiences. The Conceptual Framework produced was developed with developing country partners, regulatory specialists from developed and developing countries, international agricultural research scientists, donor agencies, and capacity building providers. It can systematically guide regulatory implementation and capacity building, and addresses concerns arising from the country studies.

The conceptual framework identifies and discusses five elements fundamental to the development and implementation of national biosafety systems, as well as three crosscutting topics: transparency, public participation and resources (McLean, Frederick, Traynor, & Cohen, 2002). The first two elements describe national policies, strategies and research agendas regarding biotechnology and biosafety, and suggestions as to the use of national inventories and evaluation. These two elements provide the foundation for implementation, described in the next three elements.

Requisite knowledge, skills and capacity base is the third element, and describes the resource base within which the final two elements occur: development of regulations and implementation of regulations. Taken together, these elements build an integrated system, one which can avoid the difficulties encountered in the earlier *ad hoc* approaches, where elements and pieces were assembled on an as needed basis,

only then to be revisited each time that systems were advanced.

(b) *Implications of the conceptual framework*

Here, we emphasize two elements of the framework, policies and capacity.

(i) *National policies and strategies*

Biosafety policy should articulate a national approach for implementing regulatory guidelines or frameworks. This policy element serves to integrate political, social, ethical, health, economic, and environmental considerations into decisions regarding the safe use of biotechnology methods and products. These discussions are taken up in a national strategy that provides direction on many of the fundamental issues and public policy decisions considered during regulatory development.

Paying explicit attention to this policy element helps ensure that links between biosafety and national food, sustainability, and environmental objectives are explored. This process and consultation helps define a biosafety system's goals and objectives, and provides a place for this effort and dialogue to occur. In so doing, the Conceptual Framework anticipates a policy forum for discussing major issues affecting the goal and policies for biosafety, as these issues remain outside the sphere of implementing regulation, decision-making, and determinations of biological safety.

(ii) *Scientific knowledge, skills and capacity base*

Building a strong base of scientific knowledge and development of core competencies in biotechnology product evaluation, are fundamental to any national biosafety system. These activities allow an improved scientific basis for assessments of potential risks and/or benefits, and they strengthen the scientific capabilities for risk management, inspection, and monitoring. A deep and broad knowledge, skills and capacity base tends to foster more latitude in regulatory development and more flexibility in regulatory implementation.

Special attention to this matter is necessary, despite the work done in training and human development thus far. Many skills are involved, and require competency in the disciplines of biological science; expertise in information acquisition, communications, and management; and, experience in critical thinking, analysis, and decision-making. Where these skills are found, they reside in very few people, and thus scientific safety review committees are strained, and competent staff are lacking to staff the official regulatory office.

The expert consultation identified key decision points and subsequent policy options for building scientific knowledge, skills and capacity. The two key decision points are:

—providing a coordinated approach to incorporating scientific advice into biosafety decision-making, and,

—locating the science evaluation function within the regulatory system.

These two decision points and their subsequent policy options are summarized below.

(iii) *Key decision point one: coordinating scientific expertise*

As the science involved in the creation of GM crops advances, and the products themselves become more complex, there is an increasing need to strengthen the science base supporting risk assessment and regulation. Developing skills required for biotechnology product evaluation and maintaining parity between risk assessors and their counterparts involved in developing new products is of fundamental importance. It requires ongoing training about new scientific advances, without which a regulator's knowledge base has a limited life expectancy.

The first policy option regarding coordination determines whether development of national capacity for scientific risk assessment should be given exclusive priority or whether it is possible to coordinate risk assessment at a regional or subregional level. The second policy option is to determine if a country will rely on international experts *versus* domestic self-sufficiency and capability. Each of these policy options is being explored in various ways by developing countries, and in relation to expectations for adequate risk assessment of GM crops in relation to the Cartagena Protocol on Biosafety.

(iv) *Key decision point two: locating the science evaluation function*

Maintaining access to scientific expertise is an issue for developed as well as developing countries. Structurally, different approaches to locating and securing scientific advice within the regulatory structure can be taken. In considering the risk assessment of biotechnology products, some countries have implemented a system of expert advisory committees, while

others have relied primarily on scientists and professionals working within government agencies. In the latter approach, the mandate for risk assessment may be vested within a single agency exclusively tasked with regulating products of biotechnology (e.g., a gene technology regulator) or it may be distributed between agencies in accordance with their existing responsibilities (e.g., departments of health, agriculture and/or environment).

The first policy option identified, as related to location of scientific expertise, is the development of core competence for risk assessment within government departments and agencies, *versus* a combination of both in-house and external scientific expertise. The second policy issue discussed was whether a country concentrates the risk assessment function within a single indefinable body, *versus* distributing this function among different government departments and ministries.

(v) *Summary*

Implementing a comprehensive biosafety system, responsive to national regulatory needs and to various articles of the Cartagena Biosafety Protocol, is a complex, resource-intensive undertaking (Lichtenberg, 2000). The Conceptual Framework clarifies five system elements and critical decision points reached during its design and implementation. It examines choices among various policy options; and delineates scientific and social dimensions of these options (McLean *et al.*, 2002). It is a tool to guide capacity building as biosafety systems are developed or re-evaluated.

7. WORKING EXTERNALLY—WHAT CAN HELP?

The case studies highlight some of the difficulties, challenges, and policies that affect biosafety systems in the developing world. Coming into force of the Cartagena Protocol on Biosafety (CBD, 2004), together with the UNEP/GEF program, has given renewed attention to frameworks, legislation, policies, and trade related measures regarding GM crops, or LMOs (living modified organisms). It is clear that decisions and actions outside the formal regulatory system, or those taken by individuals responding to external pressures, environmental advocacy, or judicial appeals, have caused serious delays and shifts in policy for approving GM crops.

Three actions are discussed below to help countries understand and evaluate factors external to regulatory decision-making. First, it is essential that all those concerned are focusing on the key problem, and this is one of regulation (Cohen & Paarlberg, 2002). Second, addressing areas of regulatory conflict is best done through specific GM crop by trait examples that build understanding as to *actual* trade, or other, impacts. Finally, ensuring the farmers voice is heard is instrumental for understanding potential benefits and demand from a farm perspective so that regulators are aware of such information, especially when commercial or open use decisions are made.

(a) *Getting the problem right*

We start with regulatory decision-making, including regulatory procedures, policies, and their implementation, as the key focus of attention to unlock further testing and deployment of GM crops. This is our recommendation, while keeping in mind that much has been written regarding intellectual property right systems and their need for revision (Victor & Ford Runge, 2002), and studies as to how IPR poses restrictions on the movement, testing and commercial use of GM crops in developing countries (Glover & Yamin, 2003). There are, however, a growing number of cases where IPR agreements have been reached, thus creating platforms for technology and skill transfer.

Placing emphasis on biosafety decision-making calls attention to the responsibilities developing countries face for the Cartagena Protocol on Biosafety, preparation for guideline and framework development with UNEP/GEF, and broader considerations as to how regulation takes into account development, trade and environmental objectives. Indeed, biosafety now commands a multiplicity of actors and ministries. Consequently, diverse agendas find their way into regulatory and safety decision-making and can cause regulators to vacillate or safety decisions to stand still.

This indicates how difficult it is to manage regulatory systems in developing countries. Focusing attention on regulation is one way to help policy-makers and politicians understand this issue. Obviously, regulation is not the only consideration in setting a biotechnology strat-

egy. But, it is the National Biosafety Committee that will evaluate GM crops, such as banana for Uganda (Smale & De Groote, 2003). and cassava for Kenya, to determine whether or not they are safe.

(b) *Policy, trade and advocacy positions complicating safety approvals*

Difficulties in making regulatory decisions occur primarily at three points: approvals for confined trials; approval for scale-up, or multiple and larger location trials; and finally; approval for commercial use or release.

For each step beyond the laboratory, there are specific criteria, which can vary from country to country, that are required for biosafety approval. As GM crops approach commercialization, broader decisions come into play. These often go beyond decisions regarding biological safety and reside external to the official purview of regulators. Final decisions are then made by senior officials or ministers and then signed personally.

The ability to affect this individual's judgment, or suspend decision-making, have resulted in serious delays, unofficial moratoriums, and in some cases, overruling of regulatory council and scientific review committees. Commercial release decisions can also be affected by broader trade considerations, especially as regards differences between Europe and United States, given that current European markets are closed to GM products (Vogel, 2001), whether or not a country wishes to remain or become GM free, or if GM crops will be acceptable for international export or trade (Victor & Ford Runge, 2002). These broader questions of policy and agricultural strategies go far beyond the responsibility of those performing regulatory, safety and environmental reviews.

Countries can use the interrelation of elements in the Conceptual Framework to establish clear relations between policy goals and objectives, and the functions of a national biosafety regulatory system. When specific attention is needed as per trade, food aid shipments, acceptance, or advocacy positions affecting regulatory approval, then specific GM crop by trait combinations and their potential impact, should be examined. Given the global debate regarding GM crops, while discussion and resolution can be sought on specific issues, reaching consensus among all parties may not be achievable.

(c) *Ensuring the farmer's voice is heard*

The voice and perspective of farmers is often missing during regulatory review and national debate on GM crop approvals and their utility. Why is this a concern? Because it is the farmers in many countries who are at the vanguard of using GM crops in smallholder settings and now covering thousands of hectares (Huang *et al.*, 2002).

While regular communication channels exist for advocacy groups, trade negotiators and civil society, regulatory systems lack a parallel process to ensure that farmer's perceptions or needs are part of the regulatory review equation.

As shown in the studies of Egypt and Argentina, biosafety regulatory review focuses on risk analysis of perceived or hypothetical risks. There is, however, little opportunity for such assessments to consider the benefits from a new GM crop that could counterbalance any severe concerns identified in the risk analysis. If this voice is lacking, then regulators may not fully understand the demand or need for such technologies.

Obviously, one would turn to the Ministry of Agriculture as the logical conduit for bringing the voice of farmers to regulatory decision makers. Such structures would enhance the accountability, stakeholder relations, and transparency of the regulatory system, as found to be needed for Argentina and Egypt.

NOTES

1. See "Brazil GM-Free Corn Exports Seen At Record," Reese Ewing, Reuters News Service via *AGBIOS*, December 20, 2001. Brazilian soybean exporters cannot capture the same premiums because of illicit planting of GM soybeans.

2. The "terminator gene" was a patented gene use restriction technology that had not yet been incorporated by Monsanto into GM crops anywhere, let alone the Bt cotton being tested in India.

3. Despite its failure since 1998 to give formal approval to planting GM soybeans, Brazil is not considered a GM-free source of supply by the private trade. As noted, GM soybean seeds smuggled in from neighboring Argentina have been planted widely by farmers in the southern Brazilian state of Rio Grande do Sul.

4. *A Framework for Biosafety Implementation—A Tool for Capacity Building*, an international expert consultation, organized by ISNAR and Virginia Polytechnic and State University (Virginia Tech), Washington, DC, July 23–26, 2001.

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