

Analysis of a National Biosafety System: Regulatory Policies and Procedures in Argentina

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Virginia Polytechnic Institute and State University
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International Service for National Agricultural Research

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ACRONYMS

| | |
|------------|--|
| ANMAT | National Administration of Food, Drugs and Medical technology (Administración Nacional de Alimentos, Medicamentos y Tecnología Médica) |
| ASA | Argentine Seed Growers Association (Asociación de Semilleros Argentinos) |
| BDV | bovine diarrhea virus |
| BHV | bovine herpes virus |
| CAPROVE | Argentine Chamber of Veterinary Products Manufacturers |
| CASAFE | Argentine Chamber of Plant Health and Fertilizer Products Manufacturers |
| CBI | confidential business information |
| CEFOBI | Center for Photosynthetic and Biochemistry Research (Centro de Estudios Fotosintéticos y Bioquímicos) |
| CIDCA | Food Cryotechnology Research and Development Center (Centro de Investigación y Desarrollo en Criotecnología de Alimentos; Faculty of Exact Sciences, National University of La Plata) |
| CIMMYT | International Maize and Wheat Improvement Center |
| CNAPBA | National Advisory Commission on Policies for Agricultural Biotechnology (Comisión Nacional Asesora de Políticas en Biotecnología) |
| CONABIA | National Advisory Commission on Agricultural Biotechnology (Comisión Nacional Asesora de Biotecnología Agropecuaria) |
| CONASE | National Seed Comisión (Comisión Nacional de Semillas) |
| CONBYSA | National Advisory Committee for Biotechnology and Health |
| CONICET | National Council of Scientific and Technical Research (Consejo Nacional de Investigaciones Científicas y Técnicas) |
| CTNBio | National Commission on Biosafety (Brazil) (Comissão Técnica Nacional de Biossegurança) |
| DMA | Directorate of Agricultural Markets (Dirección de Mercados Agropecuarios) |
| DNMA | National Directorate of Agri-Food Markets (Dirección Nacional de Mercados Agroalimentarios) |
| FAB | Argentina Forum of Biotechnology (Foro Argentino de Biotecnología) |
| FAO | Food and Agriculture Organization (United Nations) |
| FMDV | foot and mouth disease virus |
| GM | genetically modified |
| GMO | genetically modified organism |
| IBR | Cellular and Molecular Research Instituto of Rosario; National University of Rosario (Instituto de Biología Celular y Molecular de Rosario; Universidad Nacional de Rosario). |
| IFEVA | Institute for Physiological and Ecological Agriculture-related Research (Instituto de Investigaciones Fisiológicas y Ecológicas Vinculadas a la Agricultura; Faculty of Agronomy, UBA) |
| IIB-INTECH | Biotechnology Research Institute—Chascomús Institute of Technology (Instituto de Investigaciones Biotecnológicas—Instituto de Tecnología de Chascomús) |
| IICA | Inter-American Institute for Cooperation on Agriculture (Instituto Interamericano de Cooperación para la Agricultura) |
| INASE | National Institute of Seeds (Instituto Nacional de Semillas) |

| | |
|--------|---|
| INGEBI | Institute for Genetic Engineering and Molecular Biology; Faculty of Exact and Natural Sciences, UBA (Instituto de Ingeniería Genética y Biología Molecular, Facultad de Ciencias Exactas y Naturales, Universidad de Buenos Aires) |
| INTA | National Institute of Agricultural Technology (Instituto Nacional de Tecnología Agropecuaria) |
| IRM | insect-resistance management |
| ISAAA | International Service for the Acquisition of Agri-Biotech Applications |
| NGO | nongovernmental organization |
| OECD | Organization for Economic Cooperation and Development |
| PCR | polymerase chain reaction |
| PVX | potato virus X |
| PVY | potato virus Y |
| PLRV | potato leaf roll virus |
| SAGPyA | Secretariat of Agriculture, Livestock, Fisheries, and Food |
| SAGyP | Secretariat of Agriculture, Livestock and Fisheries (predecessor of SAGPyA) |
| SENASA | National Agrifood Health and Quality Service (Servicio Nacional de Sanidad y Calidad Agroalimentaria) |
| SETCIP | National Secretariat for Technology, Science, and Industrial Innovation |
| SPS | Sanitary and Phytosanitary Measures |
| TAC | technical advisory committee: a) SENASA's <i>ad honorem</i> technical advisory committee on the use of genetically modified organisms (Comité Técnico Asesor <i>ad honorem</i> sobre el Uso de Organismos Genéticamente Modificados) b) CONASE's technical advisory committee |
| UBA | University of Buenos Aires |
| UNIDO | United Nations Industrial Development Organization |
| USDA | United States Department of Agriculture |
| US-EPA | United States Environmental Protection Agency |
| WHO | World Health Organization |

EXECUTIVE SUMMARY

Considerable public debate has emerged over the perceived benefits and risks of genetically modified organisms (GMOs), which in many countries is leading to increased government regulation of R&D and trade in GMOs. Under terms of the Convention on Biological Diversity, negotiations began in 1995 to develop a protocol on biosafety. In January 2000, over 130 governments reached agreement on the legally binding Protocol, which will regulate the safe transfer, handling, and use of GMOs. The ultimate goal of the agreement is to ensure an adequate level of protection against potential adverse effects on the conservation and sustainable use of biological diversity.

Biosafety is achieved by assessing and managing environmental and health risks of new technologies, evaluating the potential ecological and health consequences, and weighing these against potential benefits. During the past decade, national biosafety systems have gained importance 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. This country report presents an analysis of the development and present status of the biosafety system in Argentina and its impact on the commercialization of genetically modified organisms. The specific objectives of the report are

1. to assess the efficacy of biosafety policies and procedures associated with the introduction of biotechnology development in Argentina;
2. to develop recommendations for enhancing the operation of Argentina's biosafety system and minimizing potential constraints to technology transfer;
3. to identify areas where ISNAR and other international providers can provide further assistance.

The study focused on the human and organizational aspects of the Argentine biosafety system. Major points of interest were (1) the organization, membership, and operations of the government agencies involved in regulating GMOs; (2) the nature and availability of information on biosafety procedures and requirements; (3) the path of regulatory review and approval leading to commercial release; and (4) the personal experiences of applicants and reviewers in dealing with the biosafety system. Findings and recommendations in the report may serve as the basis for discussions to strengthen and adapt the biosafety system to the changing context for biotechnology products in Argentina. They may also serve to advance efforts in the areas of public acceptance, technology transfer and regulatory harmonization.

Analysis of a National Biosafety System: Regulatory Policies and Procedures in Argentina

I. INTRODUCTION

Many agricultural scientists view techniques of modern biotechnology as a new and promising tool for crop improvement and novel uses of plants, animals, and microorganisms. Concerns about the safety of genetically modified organisms¹ (GMOs) to human health and the environment, however, moderate the rate of GMO product development and deployment. National biosafety systems are intended to 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. Establishing a system for biosafety review has many facets and associated challenges, and requires significant resource investments for designing, implementing, and managing the system.

ISNAR's Biotechnology Service (IBS) and Virginia Polytechnic Institute and State University (Virginia Tech) set up a collaborative research project to assess the efficacy of biosafety systems in selected countries, by reviewing biosafety policies and procedures associated with the introduction and commercial use of GMOs. The project will lead to a set of recommendations addressing identified needs in human, technical, and information resources necessary to strengthen biosafety decision making capacity. The governments of the Netherlands, Switzerland, and the UK provide financial support for the project.

This report presents a review of the biosafety system in Argentina and its function in the commercialization of GMO products. The specific objectives of the report are the following:

1. to assess the efficacy of biosafety policies and procedures associated with the introduction of biotechnology products in Argentina;
2. to develop recommendations for enhancing the operation of Argentina's biosafety system and minimizing potential constraints to technology transfer;
3. to identify areas where ISNAR and other international providers may offer further assistance.

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¹ As used here, a GMO is an organism (plant, animal, microorganism) into the genome of which a segment of nucleic acid has been introduced and stably incorporated, through a deliberate procedure and with the purpose of obtaining a defined phenotype.

Rationale

Agriculture is the most important sector of the economy of Argentina. Over 60% of the nation's exports are grain and oilseed commodity crops and oilseed products, shipped primarily to Europe, Southeast Asia, and Brazil. In 1999, transgenic crops covered 7 million hectares; the total rose to 9 million in 2000 (DNMA 2001). The country is the world's second largest exporter of genetically engineered commodities: virtually the entire production of soybeans—80% or more of which is herbicide tolerant—is destined for export. Insect-resistant maize, presently more than 15% of total maize production, is not segregated, and therefore included in the country's exports.

Most in-country research is directed towards developing GMOs to address local problems (e.g., *Mal de Río Cuarto* disease of maize caused by a local virus; endemic virus pathogens on potato and garlic, bacterial diseases of sugarcane) or crops of special relevance to the country such as sunflower. In addition, several research groups are engaged in basic research on GMOs. Very few of the products destined for the marketplace come from within the country. Close to 90% of applications for field trials, and all crops that have reached commercial-release status come from overseas-based multinational companies².

Argentina's biosafety system, established in 1991, was one of the earliest to be set up due to a combination of factors. First, agriculture and agroindustry are the country's strongest economic sector and the new technology was seen as a means to increase production and therefore exports. Second, US and transnational seed companies were looking for locations on which local branches or affiliated growers could conduct "off-season" trials, thereby accelerating the development of new varieties. Third, GMO research was well underway at several public-research institutions, so qualified people with expertise in molecular biology and related disciplines were available for the task of developing a workable biosafety system. In the period 1991-2000, 433 applications for release were approved; of these, 55 were for laboratory and/or greenhouse testing. Transgenic maize accounted for 48% of the releases, sunflower 16%, soybean 15%, cotton, 9%, potato 3% and wheat 3%. In more than 80% of the releases, insect resistance and herbicide tolerance were the traits being tested³. In the last two years, an increasing number of field trials involved the development of novel pest resistance and food quality traits.

Having been in operation for nearly a decade, the system's strengths, weaknesses, bottlenecks, gaps, complexities, and virtues should be evident. Some policies and procedures may facilitate sound reviews and decision making so that products follow a clear and timely path into the marketplace. On the other hand, certain aspects of the system may impede the process or undermine the scientific basis of product review, effectively hindering responsible decision making. This examination of the Argentine biosafety system and the elements within it is intended to identify possible impediments to proper and timely biosafety review leading to commercial releases of GMOs and their products.

² SAGPyA data at: www.sagpya.mecon.gov.ar/programas/conabia_ingles/conabia.htm

³ SAGPyA data at: www.sagpya.mecon.gov.ar/programas/conabia_ingles/conabi98.html

Framework for the Study

The review of biosafety policies and procedures in Argentina is structured around four elements of national biosafety systems as described by Traynor (1999). These are (1) written guidelines or regulations for testing and release of GMOs, (2) the people proposing releases or conducting biosafety reviews, (3) the risk-assessment/risk-management review process, and (4) feedback mechanisms to improve the system through experience.

Primary sources of information for the study were personal interviews and official documents pertaining to biosafety (Annex 1). Three groups of people were interviewed (1) members of the national biosafety committees who serve as reviewers and decision makers, (2) applicants from public-research institutes and private companies who are active users of the biosafety system in their pursuit of commercial release, and (3) representatives from consumer and environmental groups and the media (Annex 2). The wide-ranging interviews sought to elicit individual perceptions of and experiences with the biosafety system.

Biosafety reviewers were asked about

- the criteria for decisions on environmental risk,
- how the review process is conducted,
- nature and level of institutional support,
- opportunities for training in risk assessment and risk management,
- sense of farmers' attitudes and public opinion about GMOs, and
- mechanisms for providing information to farmers and the general public.

Applicants were asked about

- their awareness of biosafety issues relevant to their products,
- their knowledge of the biosafety review process,
- their understanding of application, compliance, and follow-on requirements,
- their familiarity with information sources and application forms,
- the status of their products in terms of importation, testing, and commercialization,
- their experiences in working within the biosafety system to secure approvals, and
- their understanding of farmers' attitudes and public opinion.

All interviewees were asked for suggestions on ways to improve any part of the system.

The report is organized into eight sections plus references and appendices. Section I describes the research project and methodology used for the study. Section II outlines the context for biotechnology in Argentina. Included are relevant policies, trade and marketing considerations, efforts to foster regulatory harmonization, current research activities and the status of public awareness and acceptance of biotechnology. Advisory and regulatory agencies having a role in the development, testing and commercial use of GMOs are presented in Section III. Section IV briefly describes a model biosafety system followed by a detailed view of the Argentine system. Interactions between the regulatory and private sectors are given in Section V. A more detailed description of public attitudes is in Section VI. Findings of the study are presented in Section VII, with corresponding recommendations given in Section VIII.

II. CONTEXT FOR BIOTECHNOLOGY

The Role of Agriculture in the National Economy

Argentina's wealth has traditionally come from ranching and grain growing, and agricultural commodities continue to be a mainstay of Argentine exports. In the first part of the 1990s, many agricultural producers saw commodity prices fall while the cost of their inputs rose. They also contended with scarce credit and high export taxes. However later this situation improved fairly dramatically, and the agricultural sector was a bright spot for the economy in 1996 and 1997. Although its direct share of Argentina's gross domestic production (GDP) has fallen to a relatively low level (about 7.3 percent of GDP in 2000⁴)—when ancillary activities such as food processing, transport, and related services are counted—about 30 percent of the economy is still dependent on agriculture. Many Argentine industries are based on the manufacture of products from primary agricultural commodities. In 1999, about 6.2 percent of the workforce was employed in the agricultural sector. Many of Argentina's more than 420,000 farming establishments are small family operations, but the 27,500 large estates—those exceeding 1,000 hectares (2,470 acres) in size—account for an overwhelming share of the production (nearly 40 percent).

The government has targeted the development of new crops and nontraditional products, particularly processed grain, grain sub products, prepared foods, fruit, flowers, and organically grown products.

Government Policy

Agricultural biotechnology plays a key role in the competitiveness of Argentina's farmers. The belief is widely held that as there are no farm subsidy programs, only new technologies and improved varieties can give Argentine farmers a chance to compete in world markets. However, the political atmosphere surrounding biotechnology, and in fact all matters of science and technology (S&T) can be described as indifferent, at best. Considering only expenditures in the public sector, Argentina allocated 0.25 % (in 1999) and 0.22 % (in 2000) of its GDP to science and technology⁵, well below the percentage dedicated in neighboring countries (e.g., Brazil allocates 0.60 % of its GDP and is expected to increase that amount to 1%). Additional factors hindering S&T development in Argentina arise from the standard practice of appointing new officials in most high-level government positions (including S&T officials) after every national election. Following each change in executive positions, the last one occurring in December 1999, new administrators must become familiar with their jobs, which in some cases may take as long as a year. During this period, government actions and decision making can slow down significantly.

For people working in technical and administrative government regulatory positions, the short-to midterm outlook for biotechnology is difficult to predict. At recent public addresses (e.g., the 114th Rural Exhibition on July 29, 2000, a national event focused on agriculture) both the

⁴ Data from US State Department, Bureau of Economic and Business Affairs, 2000.

⁵ Area Presupuesto, Dirección de Información, SETCIP; based on data from the Ministry of Economy.

nation's President and the Secretary of SAGPyA expressed their support for technology in general, and biotechnology in particular, in the agricultural sector. In their view it is a powerful instrument for the country's economic growth. However, members of the biotechnology community express a need for much stronger commitment and support at the highest levels, and assert that this commitment must be reflected in actions.

A long-standing tradition of basic research in biology, biochemistry, and molecular biology has created a favorable environment for the inception and development of many research groups working in a variety of biotechnology areas. The National Secretariat for Technology, Science, and Industrial Innovation (SETCIP) includes biotechnology as one of 17 sectoral priority areas considered for support through research grants, low interest loans, and tax reductions for joint industry-academy projects. Areas such as plant biotechnology and agrifood quality and processing improvement have been deemed of interest within the Biotechnology Program. SETCIP is also the local focal point for the International Center for Genetic Engineering and Biotechnology (ICGEB) sponsored by UNIDO.

The National Council of Scientific and Technical Research (CONICET) supports a wide net of academic institutes throughout the country, several of them having biotechnology-related research. Argentina and Brazil joined efforts in the mid-1980s to establish the Argentine-Brazilian Biotechnology Center (Centro Argentino Brasileño de Biotecnología)⁶, which serves as a coordinating body and operative framework for binational courses and workshops (in which Paraguay and Uruguay also participate) as well as a financial aid agency for joint research projects.

Trade and Marketing

The Argentine economy depends strongly on exports of primary agricultural commodities; consequently, maintaining and protecting markets is a major economic concern. For this reason, GMO commercialization is subject to a strict marketability requirement. GMOs intended for export are approved if and when they are accepted in Argentina's export market, primarily European countries. Otherwise, GMO varieties are not approved for commercialization. When exports are not a significant factor (e.g., in the case of cotton), commercial release can be approved irrespective of the regulatory status elsewhere, since there are no "sensitive" markets for the product.

The possibility of commercial approval of genetically modified (GM) crops not yet approved in sensitive markets would need the GM crop to be segregated. However, commodity segregation is difficult, expensive, and cannot be guaranteed under currently prevailing facility conditions. As currently practiced, segregation of high value flint maize has been calculated to add about 7% (US\$ 8) to the regular cost of US\$ 115 per ton; it has been speculated that similar added costs for GMO segregation would erase the slim profit margin farmers gain from planting transgenic varieties and could operate as a technical barrier to trade⁷. Further, segregation will require an appropriate analytical and quality certification system, most of which is currently being set in place due to import market requirements, and a good system for handling and storing segregated

⁶ www.setcip.gov.ar/cabbio2.htm

⁷ Personal Communication, Alejandra Sarquis, DNMA.

GMO and non-GMO crops, which currently is lacking. Thus, in a departure from regulatory and approval processes elsewhere, Argentina requires a technical statement on the economic impact that commercializing a GMO will have on the country's international trade before granting full approval for commercial release.

The market assessment is based on a current and prospective analysis of the trade and regulatory situation in foreign markets currently importing commodities from Argentina. Applications for commercial production that are not approved due to the marketing requirement may be resubmitted should market conditions change. GMOs intended as nonfood exports and therefore more acceptable to foreign markets (e.g., cotton) may be approved for commercial production within the country.

A soil conservation initiative in the mid-1990s prompted many soybean and maize farmers to switch to direct seeding (no-till), i.e. planting seed in unplowed fields. Varieties engineered to tolerate a particular herbicide are protected when weeds in the field are controlled by the herbicide, rather than by the usual practice of plowing and cultivating. Simple economics was the driving force behind the rapid adoption of herbicide-tolerant soybeans, as farmers could gain US\$ 25–30 per hectare through reduced tillage costs and improved yields⁸.

In maize fields, the no-till method led to significantly worse insect infestations, likely due to survival of pests in field residues. Pest damage caused losses between 5 and 30% depending on the year. The adoption of Bt-maize varieties, engineered for protection against insect infestation, provided economic and health advantages by reducing both the losses due to insect damage and the need for pesticide applications. In addition, Bt maize may be harvested later than conventional varieties, i.e. when the grain is drier, which reduces or eliminates the need for drying and storage facilities⁹.

The rate at which GM varieties have been adopted is remarkable. Of the 8.5 million hectares planted to soybeans in 1999–2000, fully 80% were transgenic (table 1). The proportion of Bt maize in the 2000–01 growing season is projected to be close to 20%, which represents all the available GM seed.

⁸ Personal communication, Juan Kiekebusch, ASA.

⁹ Personal communication, Juan Izquierdo, from Victor Trucco; REDBIO 2001, 8 June 2001, Goiania, Brazil.

Table 1. Area of GM Crops in Argentina

| Crop / Year | Total Area (10⁶ ha) | GMO Area ^(a) (10⁶ ha) | % GMO |
|-------------------------------|---|--|--------------|
| Soybeans^(b) | | | |
| 96/97 | 6.67 | 0.05 | 0.8 |
| 97/98 | 7.18 | 1.4 | 19.5 |
| 98/99 | 8.4 | 6.1 | 73 |
| 99/00 | 8.8 | 6.8 | 77 |
| 00/01 | 10.23 | 8.55 | 84 |
| Maize^(c) | | | |
| 98/99 | 3.27 | 0.03 | 0.9 |
| 99/00 | 3.65 | 0.2 | 5.5 |
| 00/01 | 3.3 | 0.56 | 17 |
| Cotton^(d) | | | |
| 98/99 | 0.75 | .005 | 0.7 |
| 99/00 | 0.34 | .008 | 2.4 |
| 00/01 | 0.47 | 0.03 | 6 |

Source: DMA/ Granos—SAGPyA.

Notes:

a. estimated.

b. herbicide tolerant.

c. Bt, plus small area of herbicide tolerant.

d. Bt.

Regulatory Harmonization

Argentina has participated in several initiatives to achieve regional and international regulatory harmonization. These efforts started as early as 1992 with a regional workshop in Buenos Aires on “Harmonization of Biosafety in the Southern Cone; Oversight of Transgenic Plants” organized by IICA and ISAAA (IICA 1993). In 1995, delegates to the 2nd Latin-American Meeting on Plant Biotechnology agreed on the need to address ways to harmonize national rules for oversight and monitoring of field trials and marketing of transgenic materials. As a result of this agreement, representatives from Argentina, Brazil, Paraguay and Uruguay—with Bolivia and Chile as observers—met later the same year in Buenos Aires to identify “...common actions to harmonize regulations and oversight procedures for development and commercialization of GMOs in the region.” The recommendations made at this meeting were (1) to urgently develop national advisory committees and regulatory frameworks where these were not yet in place; (2) to continue an in-depth examination of the potential for regional harmonization, with a focus on marketing of transgenic plants; and (3) to reach agreement on the profile of a regional database.

In 1996, an Argentina-UK workshop was held in Buenos Aires with the participation of many scientists and regulatory officials, from both countries as well as Brazil, Bolivia, Chile,

Paraguay, and Uruguay. The workshop sought to promote the establishment of common criteria for biosafety oversight in Southern Cone countries (Argentina, Bolivia, Brazil, Chile, Paraguay, and Uruguay). Additionally, the building of a regional database on GMOs and their releases, the development of systems for information exchange, and the designation of focal contact points were discussed. The proceedings of this three-day meeting were published in a bilingual edition (Marquard and Vicien, 1997).

In 1999, in Argentina-US Agrifood Consultative Committee meetings with USDA and US EPA officers, biosafety systems in both countries were examined to identify opportunities for regulatory harmonization. The main objective was to standardize criteria and procedures for authorizing unconfined GMO planting prior to full commercial release (“flexibilization” in Argentina, “nonregulated status” in the US). Granting mutual access to data on post-commercialization monitoring, and other areas of cooperation were also discussed. In particular, biosafety authorities in Argentina are considering the possibility of adopting the Checklist of Molecular Biology Data Requirements currently operating under the Canada-US Bilateral Agreement on Agricultural Biotechnology. The Argentine delegates examined the checklist and suggested a small number of changes that could lead to a similar formal agreement between Argentina and the US.

This bilateral initiative was resumed in September 2000, with the attendance of an Argentine representative at a USDA meeting held in the context of the US-Canada agreement on molecular biology data standardization. The meeting aimed to compare regulatory requirements and set the stage for eventual harmonization of molecular biology data and environmental risk assessment criteria among the three countries, which currently are on a technical, nonbinding basis for Argentina. The documents produced at this meeting (“Molecular Genetic Characterization Data” and “Environmental Risk Assessment Characterization of Transgenic Plants,” both in draft form at the time of writing) are to be discussed within the National Advisory Commission on Agricultural Biotechnology (CONABIA) in 2001 as a basis for further harmonization initiatives with the US and Canada. The short-term outcome of these would be (1) an enhanced information exchange between the respective national agencies, and (2) the probable adoption by Argentina of the Molecular Characterization Data format for release permit requests. Within the region, CONABIA has lent direct assistance on a consultancy basis to Bolivia (2000), Paraguay (since 1997), and Uruguay (since 1996).

The International Biosafety Protocol

The Protocol on Biosafety in Biotechnology¹⁰ (the “Cartagena Protocol”) within the Conference of the Parties on the Convention of Biological Diversity was approved in Montreal in January, 2000 and signed by Argentina in May of the same year. Upon entry into force, it is expected to have a major impact on the export and international trade of GM agricultural commodities.

The agreement imposes upon signatory countries a responsibility for ensuring that activities involving GMOs, including transboundary movement, are conducted so as not to pose a risk to

¹⁰ www.biodiv.org/biosafety/

biodiversity or the environment. The Protocol is intended to increase transparency on the nature of traded goods by stipulating requirements for advanced informed agreement on the part of the importing country, which entails undertaking a scientifically sound risk assessment of the GMO. Accordingly, it calls for the development of regulatory frameworks and a capacity for risk assessment in countries still lacking them. As documented in this report, Argentina is fully prepared and capable of meeting this responsibility. Notably, the Cartagena Protocol incorporates into decision procedures the application of the “precautionary principle” by which a country may refuse the import of a particular GMO even when there is a lack of scientific certainty, due to insufficient scientific information and knowledge, regarding its potential harmfulness. As a leading exporter of GM commodities, Argentina will likely face a significant challenge to balance the adoption of GM varieties against an unpredictable demand for non-GM food commodities as the country is not prepared to segregate them in an efficient way.

As a member of the Intergovernmental Committee for the Cartagena Protocol on Biosafety, Argentina will participate in developing the implementation procedures of the Treaty. Members of CONABIA, are working actively with Foreign Affairs officers to prepare documents to be presented to the Biosafety Clearinghouse as required by the Protocol.

Current Research

Biotechnology research is being conducted in national research institutes, universities, and some private-sector companies. Academic scientists compete successfully for funding from international sources and collaborate with institutions abroad. There are strong interactions between scientists at the National Institute of Agricultural Technology (INTA) and universities, especially in Buenos Aires. INTA collaborates with CIMMYT on crop-management research and technology transfer. Historically, industry linkages with INTA or academic researchers have been weak. BioSidus, an Argentine company conducting biotechnology research, shows a strong commitment to using the technology for agricultural product development. The company has considerable resources in molecular biology expertise and laboratory infrastructure, and is currently working out a strategy for research. A brief summary of current and projected GMO-research projects in Argentina is presented in table 2.

In addition to the data in table 2, other groups throughout the country are involved in GMO-related research. Scientists in several INTA research stations are trying to transform rice and citrus plants. Other researchers are working to develop a recombinant baculovirus for biological pest control, and several public and private (seed-producer) groups are doing marker-assisted breeding. Practically all of the public and private plant-biotechnology laboratories are members of the FAO-sponsored technical cooperation network on plant biotechnology (REDBIO) founded in 1991. A comprehensive account of biotechnology and GMO-related research in 32 countries of the LAC region, including Argentina, can be found in a user-updated database on the REDBIO Website.¹¹

¹¹ www.rlc.fao.org/redes/redbio/html/home.htm

Table 2. Overview of Current and Projected Research

| Institution | Crops and Traits | Future Research |
|--|--|--|
| Institute for Genetic Engineering and Molecular Biology (INGEBI) | <p>Potato, tobacco: fungal resistance via glucanase or osmotin genes, virus resistance via viral coat or movement protein genes.</p> <p>Garlic: development of transformation techniques.</p> <p>Sugarcane: bacterial resistance.</p> | <p>PVX resistance in potato.</p> <p>Expression of human epidermal growth factor in selected tobacco plant parts or cells.</p> <p>Garlic: virus resistance.</p> |
| National Institute of Agricultural Technology (INTA) | <p>Sunflower: fungal resistance; development of molecular markers for identification, marker-assisted breeding, genomics.</p> <p>Potato: fungal resistance via chitinase, ribosome inactivating proteins, osmotin-like proteins; virus resistance via coat protein or replicase genes (PVX, PVY, PLRV); basic research to screen germplasm for new and better fungal resistance genes.</p> <p>Alfalfa: vaccine for FMD and Newcastle viruses, introduction of antigens to several bovine viral diseases (rotavirus, FMD, BDV).</p> <p>Maize: resistance to Mal de Rio IV virus.</p> <p>Livestock: vaccines and diagnostics for <i>Brucella</i>, <i>Mycobacterium</i>, and <i>Anaplasma</i> via modifications on currently used attenuated vaccine strains.</p> <p>Wheat, barley: fungal resistance; development of molecular markers for identification; marker-assisted breeding, organelle mutational breeding.</p> <p>Tomato: resistance to tomato spotted wilt virus (in Córdoba).</p> <p>Tobacco: model system for research.</p> <p>Chimeric virus vaccines: against FMDV and BHV (types 1 and 5) via insertion of coat protein epitopes into appropriate vectors.</p> | <p>Alfalfa: soluble fructans (for increased digestibility) and fungal resistance genes.</p> <p>New vectors: expression of multiple genes via potyvirus-like mechanism.</p> <p>Maize: cold-tolerance via soluble fructan expression.</p> <p>Soybean: resistance to fungal diseases.</p> <p>Alfalfa: tannins.</p> |
| Bio Sidus | <p>Techniques for animal cell transfection.</p> <p>Recombinant DNA pharmaceutical proteins.</p> | <p>Expression of pharmaceuticals in cow's milk.</p> <p>Tobacco: production of human proteins.</p> |
| Technoplant (Bio Sidus) | <p>Potato: resistance to 2 local strains of PVY; herbicide tolerance; resistance to lettuce mosaic virus and potato leaf roll virus.</p> <p>Sugarcane, alfalfa: resistance to insects, fungal diseases, herbicide tolerance.</p> | <p>Improved varieties of yerba mate, berries, garlic, ornamentals, sugar cane, grapes.</p> |
| Advanta | <p>Sunflower: gene mapping of factors controlling fungal resistance, virus resistance, and other qualitative and quantitative traits of agronomical value; marker-assisted selection for international breeding programs.</p> | <p>Sunflower: <i>Sclerotinia</i> resistance (OxOx gene); herbicide tolerance.</p> |
| IFEVA | <p>Oat, Arabidopsis, potato: effects of levels of phytochrome expression in transgenic plants.</p> | |

Table 2. Overview of Current and Projected Research (continued)

| Institution | Crops and Traits | Future Research |
|---|---|---|
| INSIBIO-Universidad Nacional de Tucumán | Strawberry: resistance to fungal diseases. Tobacco: model system for research | |
| Facultad de Ciencias Agrarias, Universidad Nacional de Cuyo | Grape: resistance to fungal diseases. | |
| Facultad de Ciencias Agrarias, Universidad Nacional de Río Cuarto | Tomato: peroxidases. | |
| Universidad Nacional del Sur, Facultad de Ciencias Agrarias | Pasture grasses (<i>Festuca</i> , <i>Lolium</i>): resistance to fungal diseases. Onion: resistance to fungal diseases. | |
| CEFOBI | Wheat and maize: herbicide resistance. | |
| IBR | Tobacco, Arabidopsis and tomato: basic research on plant physiology. Tobacco: resistance to abiotic stresses. | |
| Facultad de Química, Universidad Nacional de Córdoba | Basic research (Arabidopsis): plant defense mechanisms. | |
| Facultad de Ciencias Agrarias, Universidad Nacional del Noreste | | Characterization of <i>Paspalum</i> apomixis genes. |
| Universidad de Santa Fé | | Characterization of sunflower homoeotic genes. |
| IIB-Fundación Campomar—IFEVA (Facultad Agronomía—UBA) | Arabidopsis, tobacco: basic research on phytochromes. | |
| IIB-INTECH | Tobacco: basic research on mitochondrial genes. | |
| CIDCA Universidad Nacional de La Plata | Basic research (tobacco): gene expression in transgenic plants: mouse antibody chains; rice transcription factors. | |

III. ADVISORY AND REGULATORY AGENCIES

Agencies within the Agricultural Directorate of the Secretariat of Agriculture, Livestock, Fisheries, and Food regulate the use of biotechnology and its products. The major entities are CONABIA, the National Institute of Seeds (INASE), and the National Agrifood Health and Quality Service (SENASA). In addition, the National Directorate of Agrifood Markets (DNMA) plays a role in the commercialization of GMOs. A summary of the relevant Laws, Resolutions, and Decrees is given in table 3.

Table 3. The Legal Basis for Regulation of GMOs

| SAGPyA Law, Resolution, or Decree | Description |
|--|--|
| Resolution No. 124/91 | Establishes CONABIA |
| Resolution Nos. 656/92, 837/93, 289/97 | Describes CONABIA's jurisdiction and procedures |
| Resolution 328/97 | Describes CONABIA membership |
| Law 18284 | Argentine Food Codex |
| Decree 1585/96 | Creation and jurisdiction of SENASA |
| Decree 4238 | Meat Inspection |
| Decree 815/99 | Food Control System |
| Resolution 289/97 | Establishes SENASA's jurisdiction over GM foods |
| Resolution 511/98 and Annexes | Establishes food-safety review criteria (under review) |
| Resolution 1265/99 | Establishes SENASA's technical advisory committee |
| Resolution 289/97 | Requires DNMA review prior to commercialization |
| Resolution SAGPyA No.131/98 | Authorizes flexibilized conditions |

CONABIA

The National Advisory Commission on Agricultural Biotechnology (CONABIA)¹² is a multidisciplinary interinstitutional advisory group responsible for evaluating scientific and technical issues associated with the potential environmental impacts of GMOs. It reviews requests for environmental releases and prepares recommendations for the Secretary of Agriculture to issue corresponding permits. The Commission was created in 1991 by virtue of Resolution No. 124/91 of the then Secretariat of Agriculture, Livestock, and Fisheries (SAGyP). Its jurisdiction and procedures were formalized by successive resolutions: Nos. 656/92, 837/93, 289/97 (currently in force) and 328/97 on membership. Until 2000, the head of the Directorate of Agriculture within SAGPyA coordinated all activities of the Commission. Currently an *ad hoc* coordinator is in charge.

As its main activity, CONABIA handles applications for laboratory and greenhouse testing, field trials, and flexibilization of conditions for release (unconfined release, usually large-scale, for regulatory purposes or off-season seed multiplication) of genetically modified plants. Additionally, the Commission recommends Secretarial decisions on requests for experimentation and/or environmental release of genetically modified microorganisms and

¹² www.sagpya.mecon.gov.ar/0-0/index/programas/conabia/index_conabia.htm

GMO-derived or GMO-containing products. CONABIA does not regulate recombinant products of fermentation technology, such as industrial enzymes or microbial inoculants.

CONABIA meetings are scheduled on an as-needed basis, averaging once every two weeks, more often during the planting season. Most members are concerned with plant GMOs, while a few individuals focus on products for veterinary use. However all are entitled to participate in all discussions according to their expertise or field of professional activities.

After applications are reviewed by the Commission, the Coordination staff communicates with applicants about field trial permits on matters regarding (1) any deficiencies detected by the Commission in reviewing the authorization request, or (2) any specific trial conditions which CONABIA has decided the applicant should meet for the test to be carried out, based on biosafety considerations. INASE (see below) receives from the applicant a notification answering the missing points and accepting the trials conditions, if any, before going forward with the trial.

The Commission recently drafted regulations regarding transgenic animals, as some R&D activity in this field has already started in both public and private sectors. Projects underway seek to develop transgenic goats and cows that will express valuable human therapeutic proteins in their milk. The draft regulations were expected to be submitted to the Secretary of SAGPyA for approval and promulgation in early 2002.

Although its regulatory mandate is environmental risk assessment, CONABIA acknowledges that human health effects must be assessed prior to field-testing, as unauthorized consumption of GMOs cannot be completely ruled out. Therefore, applicants for field trials are required to answer questions about “known toxic or harmful effects for human or animal health...which may arise from the genetic modification,” or to “provide a description of...the (plant) tissue specificity of expression and on the production of secondary metabolites, in order to evaluate compounds which might eventually enter the food chain.”

The resolutions defining CONABIA’s mandate do not comment on activities other than those involving plant GMOs and biotechnology products intended for veterinary use. CONABIA, however, is recognized by the scientific and industrial community as a reference institution for dealing with any kind of GMO, including small GM laboratory animals for basic research under full containment, or whenever an environmental release of a novel organism is proposed. Preliminary dossiers of some nontransgenic GMOs, such as food lactic acid bacteria with engineered deletions or overexpressed gene sequences, have been brought to CONABIA in advance of a formal request for product approval. In these cases, the Commission informally discusses the matter and advises the applicant on salient points. Non-GMO products, such as microbial formulations for bioremediation of contaminated soils, are not regulated by CONABIA, however some developers have occasionally approached the Commission for technical advice due to their product’s novelty, intended extensive release, or expected increased use.

Given private-sector participation in the Commission, there is always a potential for conflicts of interest within CONABIA. Strict adherence to internal rules helps to ensure transparency and fairness in decision making. Any business interests, affiliations, and relationships that members may have with the private sector or other research groups are made known to the full Commission prior to appointment. Involved members are not allowed to take part in decisions pertaining to GMOs associated with their personal or professional interests.

CONABIA meets with environmental nongovernmental organizations (NGOs) and other opinion groups both formally, at meetings organized by third parties, and informally. Statements and documents coming from these public organizations are distributed to all Commission members and discussed at regular meetings; in all cases, a letter of response is sent. CONABIA also advises Congress Representatives and Senators on GMO-related projects and answers questions raised by national, provincial, municipal and public sector organizations.

SENASA

The National Agrifood Health and Quality Service (SENASA) is the agency within SAGPyA entrusted with the mandate to regulate food safety and quality, animal-health products (e.g., vaccines), and pesticides. Regulatory authority is granted under Law 18284 on Argentine Food Codex, Decree 1585/96 on the creation and jurisdiction of SENASA, Decree 4238 on meat inspection, and Decree 815/99 on the food-control system. The agency has the authority to propose regulations and is empowered to do so within their own regulatory framework. SENASA can also develop rules applicable to outside institutions, e.g., grocery stores.

Biosafety review of GMO-derived foods is regulated under two resolutions by the Secretariat of SAGPyA: Resolution 289/97, which establishes the jurisdiction of SENASA in the oversight of GMO-derived food, and Resolution 511/98 including Annexes (SAGPyA 1998), which establishes the food-safety review criteria. The latter is based on FAO and WHO documents, as well as on relevant regulations from Australia, Canada, the EU, Japan, and the US.

A supporting technical advisory committee (TAC) on the use of GMOs was created under Resolution 1265/99. The agency selected institutions to be represented, which in turn designated their delegates. The main purpose of this TAC is to provide SENASA with an external, multidisciplinary advisory body that will give a broader base to its regulatory decisions. Consequently, the activities of the TAC have started with a thorough review of Resolution 511/98, aimed at improving the entire food-safety review process. Main topics for examination include a stricter and thorough definition of terms, a review of the substantial equivalence concept (a topic currently under lively discussion in many fora). The TAC had finished reviewing Resolution 511/98 by October, 2001, and a new text is now ready to be submitted to the President of SENASA for promulgation. Implementation of the TAC has broadened the expertise available for assessments and speeded up the food-safety review process, which, in previous cases, had taken far longer than most applicants' expectations.

SENASA also administers plant- and animal-quarantine regulations and phytosanitary requirements. Newly adopted forms needed to import plants, plant parts, and animals intended for research now include a checkbox in which the importer must declare whether or not the material entering Argentina is genetically modified. If marked "yes," the import application is referred to CONABIA and the applicant must provide the Commission with a detailed description of the GMO, the nature of the work, and the kind of facilities in which the research is to be performed. CONABIA's technical staff then conducts a safety assessment and writes a letter acknowledging the review and approval; the letter is a prerequisite for importation. Until authorization for importation is granted, SENASA provides temporary storage of the GMO in a secure place.

INASE

The National Institute of Seeds (INASE) is the SAGPyA agency in charge of registering and controlling commercially marketed seeds. Depending on the species, registration of new varieties requires two or three years of comparative field trials carried out at different locations. Transgenic varieties are treated similarly to new hybrids: they are submitted to the same performance tests (in which their performance is compared with that of the conventionally derived parent variety) as non-GMOs. Field trials with GMOs, made under conditions indicated by CONABIA after an environmental safety assessment, may double as performance trials for registration purposes. A technical advisory committee (TAC) of the National Seed Commission CONASE reviews the test results and decides if the material qualifies as a new variety. Variety registration may then be undertaken after a commercialization permit has been granted.

INASE also plays a role in the biosafety system by receiving and logging applications for GMO field trials. Applications containing confidential business information are kept secure at INASE's offices. Agency personnel perform field test site inspections, checking for compliance with the biosafety requirements set by CONABIA.

Plants cannot be patented in Argentina but they can be granted plant-variety protection. Currently, those seeking protection for a new GMO cultivar need only provide general information on the DNA construct. However INASE is moving towards requiring applicants to submit certain nucleotide-sequence data. An initiative currently under consideration (and viewed favorably by most CONABIA members) would have holders of permits for flexibilized release (unconfined planting, see Section IV) deposit a set of DNA primers with INASE, as well as a protocol for straightforward identification of the event by molecular techniques. This will allow (1) straightforward monitoring for gene flow, (2) analysis for GMO content certification (when needed), and (3) future development of segregation or identity-preservation practices. A bank of such primers would also be useful in cases of intellectual property claims. INASE has a lab that can perform PCR analysis for variety identification and INTA can perform both identification and analysis of GMO content.

At the end of 2000, the structure of INASE was changed. It is no longer a "national institute," but its mandate and functions are conserved and continue to be performed by the same personnel. At the time of this report, the definitive structure and status of the former INASE (referred to as ex-INASE) have not been established.

DNMA

Resolution 289/97 establishes that a further requirement for commercialization of GMOs comes under the National Directorate of Agrifood Markets (DNMA). The agency's review consists of an assessment of the possible impact commercialization of the GMO may have on Argentina's international trade. DNMA has two divisions, the Directorate of Markets and the Directorate of International Affairs. The former is in charge of the market-oriented review, which comes after the environmental biosafety approval by CONABIA and food biosafety approval by SENASA.

CONBYSA

Pharmaceuticals and other human health-related products obtained through biotechnology

methods (e.g. clinical diagnostic products, recombinant therapeutic proteins, gene-therapy agents) are regulated by the National Administration of Drugs, Food and Medical Technologies (ANMAT), an agency within the Ministry of Health. ANMAT is supported by a National Advisory Committee for Biotechnology and Health (CONBYSA).

CONBYSA's mandate was established by government Resolution 413/93 from the Secretariat of Health. The Committee's twelve members are chemists, biochemists, and biologists by profession, and they represent both the public and the private sector. Four members are from the Ministry of Health, four are from an industry group, the Argentina Forum on Biotechnology. CONBYSA has produced documents with recommendations regarding the regulatory framework for biopharmaceuticals and for *in vivo* diagnostics produced by biotechnological techniques.

IV. ANALYSIS OF ARGENTINA'S BIOSAFETY SYSTEM

Biosafety is a principle that tempers the adoption of new technologies with careful consideration of their potential effects on human health and the environment. Judicious use of agricultural biotechnology and its products is achieved by assessing and managing environmental risks, evaluating food and feed safety, and weighing these against potential benefits. A relatively new concept in agricultural research, biosafety is associated with the introduction of nonindigenous species that may have adverse effects on biological diversity; more particularly it is associated with the use made of GMOs to address constraints to agricultural production.

Accordingly, developed and developing countries alike have instituted biosafety policies and procedures to ensure the safe use of GMOs. These protective measures are implemented through the establishment of a biosafety system, which provides a mechanism for making informed decisions.

Model Framework with Four Elements

Biosafety systems can be viewed as consisting of four common elements—guidelines or regulations, applicants and reviewers, a review process, and mechanisms for feedback—that work together in an interdependent manner. This view of biosafety systems is presented briefly here; a more detailed discussion has been published previously (Traynor 1999).

Guidelines

Biosafety guidelines or regulations may be developed as new documents or adaptations of existing regulations. They typically authorize the formation of national and institutional biosafety review committees, specify their respective duties and membership, and describe application and review procedures for environmental releases of GMOs.

People

Applicants seeking to conduct field tests of GMOs and members of review committees making decisions on proposed releases are equal partners in ensuring the safe use of biotechnology products. Both need to be familiar with the environmental risk/benefit issues associated with biotechnology and to have a working knowledge of the review process.

The Review Process

A biosafety review is a systematic evaluation of the GMO, the site on which it will be released, and the conditions under which the release will be conducted. If a potential risk is identified, appropriate management procedures are built into the release plan to reduce the risk to an acceptable level. Although the emphasis of most biosafety reviews is on potential risk, applicants and reviewers need also to consider the potential benefits of a test that may lead to eventual use of the GMO, and recognize that *not* proceeding may carry risks as well.

Mechanisms for Feedback

Effective biosafety systems include mechanisms through which new information and accumulated experience are incorporated. Reporting and record keeping requirements are commonly a condition of approval. Additionally, technical information and scientific data gathered from previously approved releases, and information and assessments from other countries can be factored into review and decision making. A periodic reevaluation of guidelines and implementation procedures gives applicants, reviewers, administrators, regulators, and the public an opportunity to assess how well the system is working.

Establishing and maintaining a functional, effective biosafety system presents challenges at every step. It requires adequate and dependable funding. It entails education and coordination across government ministries, universities and research institutes, private-sector interests, individual scientists, and the public. Significant investments may be needed in training and in human-resource development, information and communications systems, facilities, and follow-up activities. The elements in a biosafety system are interrelated and interdependent. Efforts to strengthen any one part will ultimately strengthen the entire system and the decisions coming from it.

The Argentine Biosafety System

Oversight of biotechnology activities and products is handled within the Secretariat of Agriculture, Livestock, Fisheries and Food (SAGPyA), its departments and institutes. The Agricultural Directorate within the SAGPyA regulates the use of GMOs in field tests, unconfined releases, and commercial applications. This Directorate encompasses CONABIA, which serves as a biosafety advisory body, INASE, which oversees the commercial seed market; and SENASA, which regulates food safety and quality, animal health products (e.g., vaccines), and pesticides. DNMA imposes a further requirement for market analysis prior to commercialization of GMOs.

Guidelines

The Argentine biosafety system encompasses four sets of guidelines that apply to the development and use of GMOs and their products: greenhouse research with transgenic plants, environmental release of plants and microbes for field tests and unconfined (usually large-scale) plantings, food safety, and the handling and confined release of transgenic animals. The guidelines, in the form of nonlegislative resolutions, are part of the broader regulatory system governing the agricultural sector, in particular laws related to the protection of plant and animal health and seed registration.

Greenhouse Research

Formal authorization for greenhouse research involving GMOs derived from *basic research* is not mandatory. It is at the applicant's discretion whether to look for specific clearance from CONABIA for such studies. Although not mandatory, most researchers submit permit requests to CONABIA for releases at the greenhouse level, even those involving basic research. Growing transgenic organisms derived from applied or commercially oriented research, however, is considered a confined release and subject to review and approval by CONABIA. Applicants are requested to provide information about the structural characteristics of the facility, on how pollen escape and rodent, bird, or insect entry are prevented, what the personnel-access rules and the isolation and contingency measures are, etc. Customarily, companies and most public-research institutes submit greenhouse applications that are reviewed by CONABIA and included in official statistics.

The question whether greenhouse research should be reviewed by CONABIA is currently under discussion. The issue is not simple, as the distinction between basic and applied or commercially oriented research often is difficult to establish. Moreover, some studies sponsored by companies and carried out in public institutions have a strong component of basic research and no certainty regarding commercial potential. Accordingly, CONABIA is considering a proposal to implement a system for approval of greenhouse research based on notification. The proposed system involves a form of facility certification, in which greenhouse facilities would be inspected for compliance with established biosafety standards pertaining to structural features and practices. Once approved, researchers using the facility would only need to notify CONABIA as to the kind of experiments being conducted. CONABIA would intervene only if the commission perceived a breach of biosafety standards. The nature of the intervention would depend on the magnitude of the breach. Such a certification system would be similar to the one implemented in Brazil by the National Commission on Biosafety (CTNBio).

Environmental Release

Argentine biosafety guidelines for release of genetically modified plants (SAGPyA 1997) and microorganisms (SAGPyA 1992) are detailed in SAGPyA resolutions No. 656/92, No. 837/93, and No. 289/97. They are based on the regulations and experience of the US and UK, adapted to local needs. CONABIA is the advisory body charged with proposing and applying environmental release guidelines.

The full text of the environmental release guidelines is available on the Internet¹³. The main points are as follows:

1. The guidelines apply to GMOs obtained through use of recombinant DNA methods.
2. They pertain to (a) plant GMOs in greenhouses and field trials where they are released into the environment; (b) flexibilization of release requirements to allow unconfined release, including large, commercial-scale multiplication (e.g., seed increase for export or stock build up in preparation for prospective sales, but not for commercial release in the country), and (c) recombinant DNA products intended for animal health, primarily recombinant vaccines.
3. The focal activity of CONABIA is a technical, science-based environmental risk assessment of the action proposed by the applicant, made on a case-by case basis.
4. Three types of information are required from the applicant: (a) a short summary, (b) a

¹³ www.sagpya.mecon.gov.ar/0-0/index/programas/conabia/reglamentaciones.htm

form to be filled out with the data needed for the assessment, including full biosafety measures proposed, and (c) a set of complementary information, including a more detailed account of agronomic and molecular biology data. The applicant must also submit a final report to CONABIA at the end of the trial.

5. CONABIA is to prescribe what biosafety measures should be taken in addition to those proposed by the applicant.
6. While the focus is on environmental safety, the guidelines provide for the assessment of certain aspects of safe handling and transport, and for some aspects of GMO food safety.
7. Guidelines for flexibilization address a more in-depth risk assessment of unconfined, usually larger-scale environmental release and some aspects of the GMO as a food or feed source.

Food and Feed Safety

Current guidelines for food-safety approval are set forth in Resolution 511/98 and its two Annexes (SAGPyA 1998). They are based on the concept of substantial equivalence per 1996 FAO and WHO documents, and on relevant regulations from developed countries and OECD reports. They refer to requirements and criteria for biosafety review, and address the characterization of the GMO-derived food with regard to fitness for human and animal consumption. The following main elements are considered:

- the content of natural toxic compounds in the GMO-derived food, as compared with data of the traditional, non-GMO source;
- studies that address changes in nutritional properties as compared with the non-GMO food, changes which can affect processing, and modifications on bioavailability of major and/or micronutrients;
- required studies on newly expressed proteins;
- toxicology tests that include all clinical parameters and observations from feeding studies;
- allergenicity, carcinogenic and teratogenic tests, both short and medium term;
- absorption, distribution, and metabolic products;
- regulatory toxicology, including standardized tests that resemble those required to assess the safety of drugs, food additives, and the like, which are not observed in typical feed trials;
- protein sequence homology with known protein toxins and allergens.

Other features of the food-safety guidelines specify touch on the following points:

- If the applicant considers unnecessary any of the data requirements, a scientifically based explanation must be provided (this observation is likely to be removed under the current revision, as the future list will have a wholly inclusive feature).
- Pertinent documents (studies, approvals) from other countries may be submitted as supporting data, but they must fit with the requirements and review criteria of the Resolution.
- When needed, qualified scientific institutions may be consulted on the toxicological risks and/or on other issues related to the safety of the product.
- After commercialization approval is granted, the applicant is still responsible for the safety of the GMO-derived food, under the terms of its approval (under the current revision, this will include monitoring the constancy of the properties of the GMO).
- The authorized GMO-derived food is to be reassessed periodically.

SENASA's TAC reviewed Resolution 511/98 and its Annexes with the goal of making food-safety review more focused and straightforward. The review was concluded recently, and a new text is ready to be submitted to the President of SENASA for promulgation. The new document reflects the draft International Standards currently under development by the Codex Committee on Food Biotechnology.¹⁴

GM Animals

Draft guidelines for the handling and controlled release of GM animals are expected to become official in early 2002. According to the final draft document, importation of GM animals, gametes, or embryos, and testing animals under contained or controlled conditions, are to be conducted under permit. Applications are submitted to SENASA (serving as the entry office for animal applications, as INASE does for plants) and forwarded to CONABIA. For laboratory or animal facility studies, CONABIA first reviews a short description of the intended work to determine whether a complete application needs to be submitted.

Where a full biosafety review is indicated, the application form calls for extensive information. Data obtained from experiments done in other countries is acceptable. CONABIA's review leads to a recommendation to the Secretary of SAGPyA indicating approval or denial of the request. At the end of the experiment or release the applicant must submit a final report, which will describe the research and its results, tests performed on the animal or on parts of animals, and final disposal methods; the report will record compliance with biosafety measures through the end of operations, and include comments. Failure to file a final report will result in denial of the applicant's future permit requests.

People

Argentina's biosafety system includes people from government agencies, the private sector, professional societies, and academic institutions. CONABIA is constituted with members from each of these sectors (table 4). A representative of the Secretariat of Natural Resources and Environmental Policy joined in 2000. While the Ministry of Health has been invited to nominate a representative to serve on CONABIA, stable membership has not yet been achieved. The new authorities at SAGPyA appear determined to secure representation of this Ministry within CONABIA. The Commission does not have members representing individual companies; the Argentine Biotechnology Forum (FAB) is a nonprofit biotechnology entrepreneurial association that works to promote Argentine biotechnology both in Argentina and abroad. FAB is actively involved in promoting better policies, public awareness, and capacity building in Argentina.

¹⁴ <http://www.fao.org/waicent/faoinfo/economic/esn/codex/>

Table 4. Institutions Represented on CONABIA

| Public Sector | Private Sector |
|--|--|
| <ul style="list-style-type: none"> • Directorate of Agriculture of the Secretariat of Agriculture, Livestock, Fisheries and Food (SAGPyA) • National Agrifood Health and Quality Service (SENASA) • National Institute of Agricultural Technology (INTA) • National Seeds Institute (INASE) • National Science and Technology Research Council (CONICET) • Argentine Ecology Society • University of Buenos Aires | <ul style="list-style-type: none"> • Argentine Seed Growers Association (ASA) • Argentine Chamber of Veterinary Products Manufacturers (CAPROVE). • Argentine Chamber of Plant Health and Fertilizer Products Manufacturers (CASAFE) • Argentine Biotechnology Forum (FAB) |

Collectively, the membership of CONABIA has expertise in the professional fields necessary to perform a thorough environmental risk assessment. Members have formal academic qualifications in agronomy, molecular biology, ecology, plant pathology, biochemistry, biology, veterinary medicine, and virology. Additionally, some members have received biosafety training abroad. The major consideration for membership is the candidate's qualifications in the desired area of expertise. Institutions chosen to be represented on the Commission submit the *curricula* of three candidates, two of whom are selected for consideration and eventual approval by the Secretariat of Agriculture. Public-sector entities are invited by the Secretariat to send their representatives. Outside interests of nominated members, such as research agreements with companies or other institutions, or involvement in matters related to the Commission's mandate which may lead to conflicts of interest, must be fully disclosed prior to appointment.

It has been argued that consumers and environmental NGOs should be represented on CONABIA to supposedly bring greater transparency to the decision making process. Members of the Commission maintain that CONABIA is a technical advisory group, and the quality of reviews and decisions based on scientific grounds depends on the members' scientific training and experience. Further, they assert that taking only technical considerations into account ensures transparency, as both biosafety reviews and decisions must be consistent with available scientific information.

SENASA constituted in 1999 an *ad honorem* technical advisory committee on the use of genetically modified organisms (TAC for short) to evaluate food-safety issues in GMO foods and feeds. Similar to CONABIA, the TAC has representatives of public and private-sector research institutions, government agencies, industry organizations, a consumers group, and farmers associations (table 5). Outside experts may be called on an *ad hoc* basis if needed.

Table 5. Institutions Represented on the TAC of SENASA

| Public sector | Private sector |
|---|--|
| <ul style="list-style-type: none"> • Agrifood Quality Directorate of SENASA • SAGPyA Directorates of Food and Agriculture • Faculty of Agronomy, University of Buenos Aires • Faculty of Pharmacy and Biochemistry, University of Buenos Aires • National Institute of Foods • National Science and Technology Research Council • National Institute of Drugs • National Directorate on Foods | <ul style="list-style-type: none"> • Argentine Seed Growers Association (ASA) • Argentine Agrarian Federation (small scale farmers) • Coordination of the Food Products Industry • Argentine Rural Confederation • Intercooperative Agrarian Confederation (medium scale farmers) • Argentine Rural Society (large scale farmers) • Consumers Action League • Argentine Chamber of the (Edible) Oil Industry |

The TAC will review food-safety data provided by the applicant. In most cases this data will be in the packet prepared by the parent company for approval in the US and EU; however, the Committee will request additional data if deemed necessary. Company officials, often regulatory managers or scientists from local branches of transnational concerns, meet occasionally with members of CONABIA, INASE, or SENASA. In these meetings, visitors may present the Company’s research or marketing goals for the following several years, or ask for opinions on current regulatory issues on an informal basis. However, these meetings are not to be taken as opportunities for promotion or discussion of specific applications.

Institutional Biosafety Committees

Only few basic research institutes have an “institutional biosafety committee” (IBC), a written set of biosafety rules, a mechanism for project approval with regard to specific biosafety procedures, a record of incidents, or a formal training program for researchers, technicians and other workers. INTA has an IBC that is responsible for all areas of safety—radiation, hazardous chemicals, infectious organisms, and biotechnology. The committee seldom is active. Several university groups are performing basic and applied GMO research under confined laboratory conditions and up to greenhouse level without having an institutional biosafety committee and without seeking clearance through the officially established biosafety system. In the past CONABIA has, without success, made repeated proposals for the implementation of such rules, based on guidelines and biosafety recommendations formulated by US agencies. A new approach to address this gap is the recent preparation of a code of conduct by the SETCIP. The code, approved and now in press, is to be enforced at public-research institutions by conditioning grant approval on compliance with the biosafety rules¹⁵.

Review and Approval Process

The process leading to commercial release of a genetically modified food crop entails three kinds of regulatory review: (1) an environmental risk assessment conducted by CONABIA, (2) a food-safety evaluation conducted by SENASA, and (3) a market analysis conducted by DNMA. Other regulations, which are common to non-GMO counterparts, such as pesticide registration and new seed variety registration, apply as well.

¹⁵ To be available at www.setcip.gov.ar

Environmental Review

Field-test applications are received by INASE and passed to CONABIA, where they are first reviewed for completeness. If on the application form, requested information is missing, inadequate (e.g., test location not clearly identified, molecular biology data incomplete), or inconsistent (e.g., one section states that plants will not be allowed to flower while a later section refers to collecting seed), the applicant will be prompted to complete and correct the information. Once complete, the application is submitted to the full commission. Members who have particular concerns may actively seek outside confirmation of points they question or believe are not based on sufficiently solid grounds. Reviews are conducted on a case-by-case basis. A case is defined as involving a specific applicant organization and a well-defined transformation event in a given crop; changing either one of these constitutes a new case. Although a previously approved small-scale release can be scaled up without being considered a “new application,” the bigger-scale release will call for a special environmental assessment, for biosafety reasons. Applicants wishing to renew their trial permits are not obliged to resubmit the detailed complementary information, but the Commission is entitled to ask for it if deemed necessary. Renewals are reviewed and granted only if a final report of the previous trial has been submitted within the time limit agreed.

When all CONABIA members are satisfied that they have sufficient knowledge of the application, a decision to recommend approval or denial is taken. Although the Resolution that created CONABIA stipulates that a simple majority of votes is needed for approval, the Commission adopted a rule that all decisions are taken by consensus. Should unanimous agreement not be reached after initial deliberations, the issue remains pending. Lack of consensus is interpreted as a lack of information somewhere in the analysis or discussion process. The discussion then shifts to define what information is needed and how to obtain it. Once resolved, the Commission resumes discussion and, eventually, reaches consensus on its recommendation.

CONABIA in Action

CASE 1: HERBICIDE-TOLERANT CANOLA

Canola is a minor crop in Argentina, but the country is the center of origin of one *Brassica* species and has many cruciferous weeds sexually compatible with canola. A canola variety was engineered to be tolerant to glyphosate, a widely used low-cost, broad-spectrum herbicide with low toxicity to humans. In 1996, small field tests of the canola were authorized by CONABIA under very stringent containment and isolation conditions. When the applicant requested authorization for a large planting (two 250–hectare lots) in 1997, the review was more intensive and a long debate preceded a final decision to deny the request.

The decision not to allow planting on 500 hectares was based on (i) the applicant's apparent intention to move towards off-season seed increase for export and/or eventual commercialization in Argentina; (ii) the inevitability of outcrossing to compatible weeds, estimated at 20%; and (iii) recognition of the fact that extensive use of glyphosate by canola growers would exert a selection pressure favoring growth of glyphosate-tolerant crop-weed hybrids, which could be controlled only by less environmentally acceptable herbicides. Therefore, appearance of these glyphosate-tolerant weeds would likely result in farmers having to remove a relatively benign herbicide from their weed control options. In this case, CONABIA made a decision based on scientific and agronomic grounds; at the same time, socio-economic reasons—farmers having to switch to more expensive inputs—were also taken into account. Since then, neither the original applicant nor other seed companies have submitted applications to CONABIA for release of herbicide tolerant canola.

Once the review process passes the approval by the full Commission, a letter is sent to the applicant, usually stating any additional requirements, which are needed to ensure biosafety and/or for completing the information on the release. The applicant must acknowledge and respond to this letter for the process to follow its course.

CONABIA sends the application file with a letter of recommendation to the Secretary of SAGPyA for approval. The letter states that CONABIA has reached the conclusion that there is no environmental risk involved in the release, and includes a comment on whether additional information was requested from the applicant in order to complete the review process. Before the recommendation for approval is sent to the Secretary, the applicant must provide a written notification of agreement to the conditions set forth by CONABIA in a separate communication, as indicated above. Until an official procedure is in place for applications pertaining to transgenic animals, applicants submit to the animal-health section of SENASA a full dossier concerning the project. The material is then passed to CONABIA, who reviews the proposal, formulates a set of recommendations on how the experiments should be conducted, and indicates any inspections deemed necessary. At the time of writing, under the new administration (i.e., the second Secretary of SAGPyA under the current presidential period), the full review process up to the Secretary's approval takes around 35 days to complete. Before that, the process (as well as other regulatory decisions on GMOs) took much longer, which led some to qualify that period as a virtual moratorium.

Flexibilization

Once a plant GMO has been sufficiently field tested, the applicant may request that the crop be “flexibilized,” that is, be approved for unconfined (usually large-scale) planting for certain specified uses. These are (1) for regulatory purposes—to provide material for analytical, toxicological and other required tests; (2) for export; (3) for off-season seed multiplication—not to be sold in the country; (4) for tests to be presented at a later stage (after approval for commercialization has been granted) in support of new variety registration; or (5) for pre-commercial multiplication pending variety registration. Flexibilization is authorized under Resolution SAGPyA No.131/98, “Request for Flexibilized Conditions for Release into the Environment of Genetically Modified Plants for Field Trials” (Annex 3). Flexibilization does not constitute approval for commercial release within Argentina; it only entails unconfined, usually large-scale, planting for the purposes indicated here.

CONABIA's risk assessment for flexibilization evaluates the GMO's

- weediness potential or its capacity to survive, become established and disseminate,
- outcrossing potential,
- potential for horizontal transfer or gene exchange with other organisms,
- nature of products of introduced sequences,
- phenotypic expression and genotypic stability,
- pathogenicity to other organisms,
- potential to produce hazards in the environment,
- potential harmful effects on humans including allergenicity, and
- potential effect on rate of resistance development in pest populations.

Under current CONABIA practices, applicants must address the following food-related issues when requesting flexibilization:

1. *Equivalence*. Comparison of data from analyses of the GMO and non-GMO counterparts for major components (the "proximate composition") and micronutrients; effects of the genetic modification on processing into food, food products, and by-products; nutritional equivalence and bioavailability.
2. *Safety*. Comparison of toxic, pathogenic, antinutritional, or allergenic characteristics in GMO vs. non-GMO, to include newly expressed proteins as well as their derivatives and metabolic products; evaluation of gene-donor organisms with regard to characteristics that can be harmful to humans or animals; potential for biochemical transformations due to processing; interactions with usual components in the human diet.
3. *Composition*. Level of expression of new proteins expected or found in food products, by-products, and residual materials, in support of the "substantial equivalence" qualification.
4. *Food characteristics*. Quantity of new proteins in foods; digestibility in simulated gastric juice; maximum daily intake (considering a standard dietary contribution); no-effect level (as determined in animal feeding tests), etc.

Comments on these topics are annexed to CONABIA's environmental risk-assessment decision documents. They are submitted to SENASA as a nonbinding, preliminary review, as SENASA is the regulatory agency responsible for conducting the full food-safety review.

CONABIA in Action

CASE 2: BT ENDOTOXIN CRY 9C

In 1998, CONABIA received an application requesting flexibilization of a maize variety expressing a new Bt gene, *Cry9C*, from *Bacillus thuringiensis* subsp. *tolworthi*. Review of the dossier triggered thirty questions on data from several studies conducted per application requirements. Two of these concerned data showing that the Cry9C protein exhibited remarkable resistance to hydrolysis under simulated gastric fluid conditions, an unusual finding and certainly not like other Bt proteins already in use. The applicant responded with data that supported the safety of the protein in terms of toxicity and allergenicity, including mouse studies by oral acute toxicity, intravenous injection, or subacute gavage.

Not satisfied with the data from simulated gastric digestion studies, the Commission consulted with a physician and two biochemists having research and clinical experience in digestive physiology from the Faculty of Pharmacy and Biochemistry, University of Buenos Aires. After two meetings with the experts, CONABIA considered that a food-safety issue remained. Unanswered questions concerned the permeability of the intestinal epithelium to Cry9C and the effects of the undigested protein on the colonic microbial population, both extremely important physiological factors. As a result, the applicant was informed that a final decision on the application would be made only after these questions were properly addressed.

This case illustrates two points about CONABIA: first, its review anticipates issues that, although not part of environmental safety, are relevant and deserve further examination, and second, the Commission is willing to seek outside consultancy when necessary.

Once the crop has passed environmental and food-safety reviews and been granted flexibilized status, isolation distances or other means of confinement are no longer required. Prior to planting, the applicant must provide to CONABIA only the site of the release, size of area to be sown, date of sowing, date of harvest, and residue disposal methods, all of which is monitored by inspectors.

At the time of writing, two soybean varieties, two cotton varieties, and five maize varieties have been flexibilized. Of these nine varieties, seven have been approved for commercial release: the two cotton varieties, one soybean, and four maize varieties. Applications for two additional maize lines, one herbicide-tolerant and one Lepidopteran-resistant, were withdrawn by the respective companies in late 1999 for commercial reasons. No commercial approvals were granted from July 1998 to April 2001. At that time, five crops were approved for commercial release. After this virtual moratorium, two additional crops (a Lepidopteran-resistant maize and a herbicide-tolerant cotton) were added to the list of approved commercial releases. Two more herbicide-tolerant soybean varieties are expected to be approved for commercialization soon. One herbicide-tolerant maize variety has been approved by CONABIA (environmental safety) and SENASA (food safety), but approval is in anticipation of changes in its regulatory status in the European Union.

In 1999, a standardized decision document for flexibilization was designed, replacing the *ad hoc* statements written previously. At the time of writing, CONABIA is considering to use their Website to disseminate public information about actions to flexibilize GMOs, by posting a nontechnical summary of the decision document.

Food-safety Review

SENASA's current food-safety guidelines (Annex 2 of Resolution 511/98,) call for the assessment of the modified food for

- natural toxins,
- new forms of toxins,
- sequence homology of the newly expressed proteins with known allergens and toxic proteins,
- nutritional changes resulting of the genetic modification,
- nutritional changes and nutritional characterization resulting from processing methods,
- modifications in micronutrients and/or bioavailability of micronutrients, and
- characterization with regard to safety for human and animal health.

Revisions to the guidelines are expected to follow the conclusion of the current Codex Alimentarius meetings on the Safety of Foods Derived from Biotechnology, which are being attended by a member of SENASA. Anticipated changes will provide much greater detail on the specific tests to be done, methodologies, and data requirements.

At present, the technical advisory committee has completed three reviews (a Lepidopteran-resistant maize, a herbicide-tolerant maize and an herbicide-tolerant cotton) and is conducting a fourth on another herbicide-tolerant soybean (two varieties transformed with the same construct). The application is discussed in plenary meetings, although technical members take the lead, giving nontechnical members an opportunity to verify that the evaluation is being done properly and consumer concerns are being taken into account. The TAC then sends its position on the commercial release of the product to the President of SENASA. Since its inception in 1999, the TAC has slowly shifted from a heterogeneous technical and nontechnical attendance to a more technical one, currently reaching a good level of efficiency in its review work.

Market Analysis

The Directorate of Agri-Food Marketing (DNMA) conducts the third type of review, which is based on market potential. The agency assesses the impact of the GMO's commercialization on Argentina's international trade. After reviewing the application, the agency's technical

report documents the following issues:

- Argentina's position in international trade of the crop for the past three years;
- an estimation of each exporting country's share of the market (i.e., what is the relevance to Argentina?);
- market position of competitors and changes therein;
- the situation in client countries in terms of regulatory status and consumer acceptability;
- any supporting or pertinent information.

The report documents the advantages and disadvantages of approving the crop, and the Directorate's decision. Thus DNMA makes a technical report that is, in fact, the final determinant on commercialization; DNMA's decision determines what GMO varieties seed companies can sell to Argentine farmers.

The CONABIA, SENASA, and DNMA reviews collectively form the basis for what is called a "Project of Resolution" prepared by CONABIA which, when signed by the Secretary of Agriculture, grants approval for commercial use of the GMO. Before actual sale, however, the applicant still must apply to INASE for a New Variety Registration as required by regulations controlling proprietary and commercial practices in the seed industry. Where the GMO has pesticidal properties, such as plants expressing genes encoding Bt endotoxin proteins, or has been modified to be herbicide tolerant, commercialization requires specific authorization from SENASA for its use. The entire approval sequence leading to commercialization is diagrammed in figures 1 and 2.

Figure 1. Field Test Approval Procedure

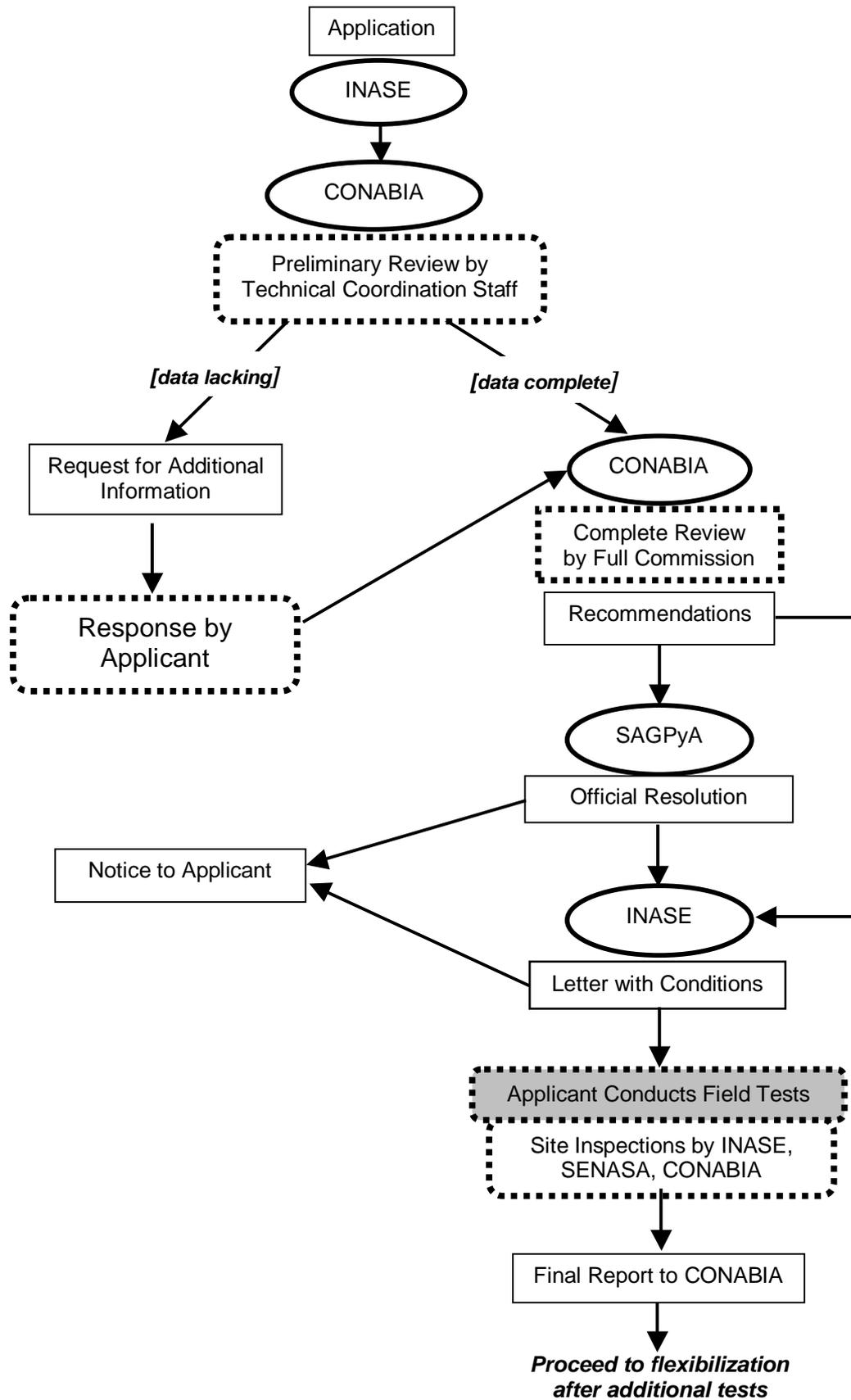
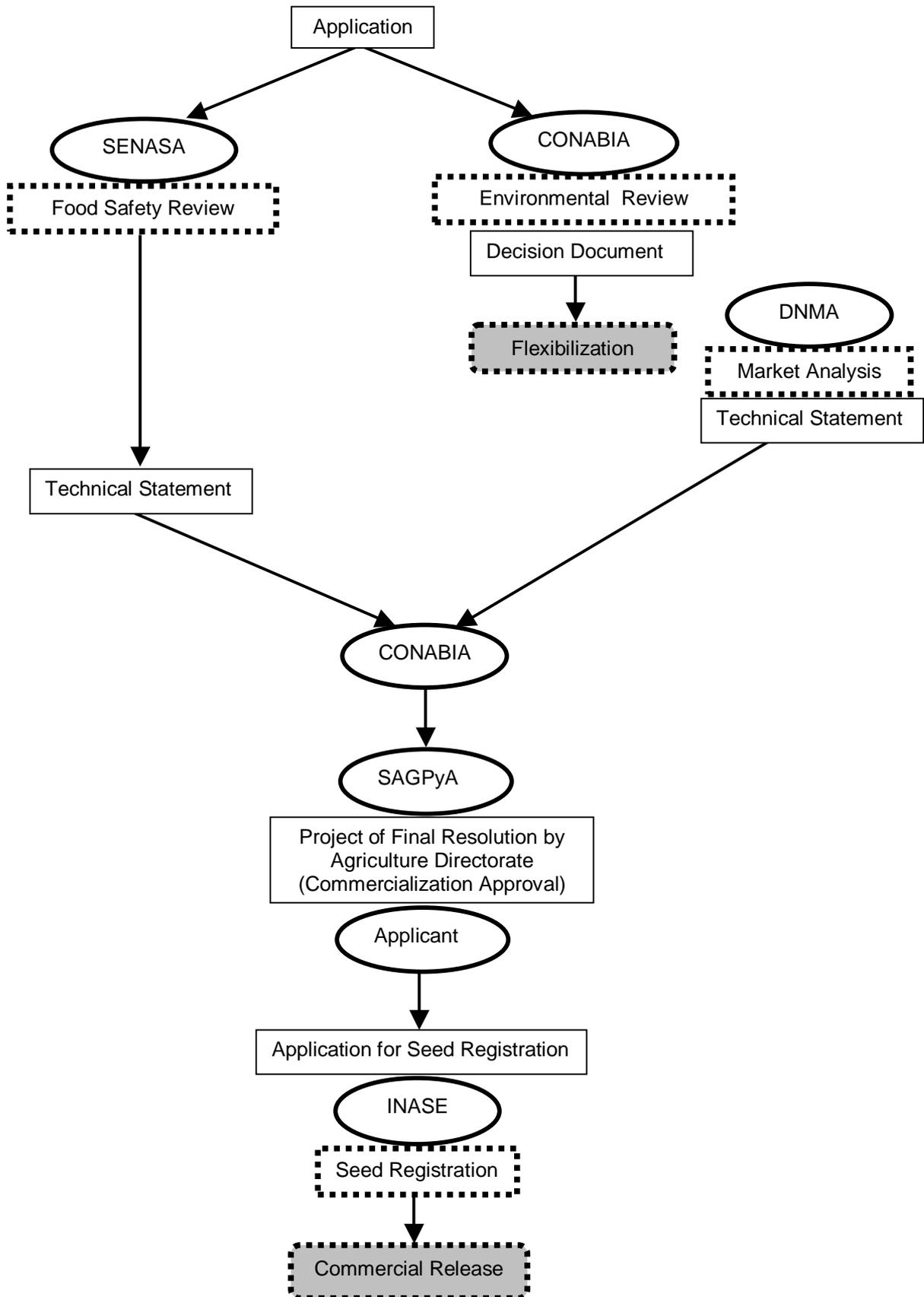


Figure 2. Commercial Release Approval Procedure



CONABIA in Action

CASE 3: INSECT-RESISTANT SUNFLOWERS

Argentina is the world's largest producer and exporter of sunflower. Planted-area, yield, and production figures have climbed steadily over the past three decades, reaching about three million hectares in 1999. The economic importance of sunflower for Argentina is reflected by the fact that several transnational companies are involved in active research on this crop, a great number of field trials are conducted every year, and one company has built in Argentina a modern, well-staffed and equipped facility as the center of its international research on this crop.

Beginning in 1996, sunflowers genetically engineered for resistance to Lepidopteran insects, herbicide tolerance, and resistance to fungal and bacterial diseases, have been tested in greenhouse and field trials. In the field, CONABIA specified that flowers on transgenic plants were to be bagged, or the plants were to be grown in cages in order to keep out insect pollinators that could spread GMO pollen, as it is known that sunflower pollen can be carried by bees over distances as long as three kilometers.

The potential value of the new traits made it likely that GMO varieties would merit commercialization. Longer-term biosafety issues, however, are raised by the fact that wild *Helianthus* species capable of crossing with domesticated varieties are found along roadsides in nearly 15% of the commercial growing areas. Accordingly, CONABIA promoted an industry-sponsored Sunflower Biosafety Project to examine the impact of new traits on wild populations, review biosafety procedures particularly on ways to prevent outcrossing, update survey data on the occurrence and distribution of wild varieties, and address environmental safety questions.

Assessing the impact of GMO traits depends on an accurate distribution survey of wild *Helianthus* populations and an analysis of the potential effects on wild populations due to acquisition of certain new traits. Studies of distribution, genetic variability, and frequency of gene flow to wild species were begun in 1999. CONABIA recommended additional studies on the presence of pollinating and other beneficial insects in sunflower-field ecosystems. A review of biosafety measures included the specifications for types of bags and bagging materials that were acceptable for adequate isolation from insects. For in-cage trials, details of cage construction and placement in the field were formulated. Food safety of current transgenic sunflowers was deemed not a significant concern since composition of the oil (the main product) was unlikely to change significantly and the newly expressed proteins were well-characterized and found in numerous commercially grown GMOs. The first results from the Sunflower Biosafety Project, concerning gene flow from the crop to wild relatives and their distribution, was presented to CONABIA in July 2001.

In this case, CONABIA took a proactive stance in addressing biosafety issues likely to be raised by the expected requests for flexibilization and commercialization of transgenic sunflowers. The data and information gathered will help support a science-based review of those applications.

Mechanisms for Feedback

Monitoring and Reporting

Inspectors from INASE or SENASE visit all field releases, according to the type of GMO. The monitoring agency reports the inspection schedule and the names of the inspectors to CONABIA. Occasionally, Commission members also conduct site inspections. Every field test is visited at least once, more often two or three times. On the first visit, an inspector may want to verify proper isolation and containment before flowering, and check for compliance with conditions set by CONABIA. During harvest, the site may be inspected to assess disposal procedures, cleanliness of equipment, plowing under of field stubble, and burning of stalks, cobs, or other residues. Additional visit(s) are made in subsequent year(s) to confirm that the same crop is not planted in the field. This restriction is established for a number of

seasons, depending on the type of genetically modified crop, and is needed to prevent outcrossing from genetically modified volunteer plants into non-GM crops in later seasons. Fields cultivated with flexibilized varieties are inspected during planting, harvest and at the time when field residues are disposed.

After each visit, inspectors submit to CONABIA short reports on their observations of the release. In cases of noncompliance with the required conditions, the inspector must notify CONABIA and may impose additional measures necessary to ensure that biosafety requirements are met and prevent adverse effects on the adjacent environment. An effort is made to not compromise the purposes or integrity of the trial, if possible. If inspections reveal gross deviations from biosafety requirements that cannot be remedied, the inspector may demand termination of the release and immediate destruction of all material involved.

CONABIA requires the applicant to submit a final report after the conclusion of the test. The report is to emphasize any observed differences between the GMO and its non-modified parent material. A typical report includes (1) final design of the test; (2) observed phenotypic characteristics—germination, vegetative growth, macroscopic characteristics, yield; (3) results—efficacy of the new trait, additional observations; (4) susceptibility to disease; (5) consistency with expected results; (6) actual use or disposal of products and residues; (7) further use of the land; and (8) efficacy of the specified biosafety measures and any emergency measures that may have been taken. Inspectors assigned to the release also submit a written report for review by the Commission. During the postharvest surveillance time specified for the crop or particular trial, applicants must submit annual reports on the further occurrence of volunteer plants, weed growth, abnormal events, etc.

Pending Changes

Prompted by the intense debate about transgenic crops and its effects on public attitudes, several legislative initiatives were proposed in the national Congress during 2000. Members of the regulatory agencies participated as consultants and panelists in several public debates aimed at helping legislators to understand and elaborate the projects. The initiative entitled “Biotechnology and Agricultural Biosafety” proposes well-balanced support for the development and use of agricultural biotechnology in Argentina. More important, it proposes elevating the regulatory framework, currently based on Secretary of SAGPyA Resolutions, to a higher legislative category. Regulatory officials participated in the drafting of this proposal. This project, as well as other legislative initiatives concerning GMOs, is to be discussed by the Congress in course of 2002.

V. INTERACTIONS WITH THE PRIVATE SECTOR

Confidential Business Information (CBI)

Applicants may determine that some information required in the application is business sensitive and should be kept confidential. For example, the applicant may have a proprietary interest in the source or function of novel genes having commercial potential, or details of DNA constructs that contain newly developed promoters or other sequences. Critical biosafety-related information cannot be designated as CBI. In the opinion of CBI reviewers, companies tend to be overcautious in designating confidential material and often include

information that need not be kept confidential.

When a case contains confidential information, applicants submit one copy of the complete application to INASE, in which parts deemed CBI are clearly marked as such, plus 20 “CBI-deleted” copies, in which all the CBI sections have been blanked out. Only designated CBI reviewers (at least two public sector members of CONABIA approved by the applicant and having no involvement or interests related to the matter of the application) may see the complete copy. They conduct a preliminary review of the CBI copy for completeness and may ask the applicant for additional information in cases for which there is no background data with regard to the biosafety of identical or similar genes, and/or in which the novelty of the introduced genes precludes a direct and immediate biosafety evaluation. During review of the “CBI-containing” marked copy, the applicant has the right to require the presence of a representative, and outside experts may be called in when needed. All involved must sign a confidentiality agreement. The company representative may offer opinions on the content of the statement but may not participate in the review procedure. Reviewers prepare a document to state that they have examined the CBI and to explain their grounds for judging that—based on the information they have reviewed (but without revealing any data deemed confidential)—biosafety considerations have been properly addressed. A copy of the “CBI-deleted” application is then distributed, together with the CBI reviewers’ statement, to all CONABIA members in preparation for the next meeting, during which the application will be discussed and a decision made. To date, the Commission has received no complaints that CBI was handled improperly.

CONABIA in Action

CASE 4: UNAUTHORIZED INTRODUCTION

In October 1999, a researcher from a highly regarded American research institute arrived in Argentina with two 25g lots of transgenic tobacco seed; one expressed a mouse antibody, the other expressed a plant-transcription factor. The material was intended for basic studies on foreign gene expression in plants to be conducted at an Argentine research center; it was of no agronomic interest.

In the researcher’s application for a greenhouse test permit, required importation data (authorization for the import, number of the permit, country of origin, etc.) was not provided. Upon inquiry, it became clear that the researcher had not cleared the seeds through Customs, in violation of Argentina’s Sanitary and Phytosanitary (SPS) regulations under SENASA’s jurisdiction, nor had he secured a permit from CONABIA for the importation of GMOs. Since tobacco seeds can be imported into Argentina from the US under SPS rules, provided no exotic pests are introduced, the researcher subsequently asked SENASA for, and was given a plant-quarantine authorization.

CONABIA, however, did not follow suit and issue a belated release permit. Instead, the Commission demanded that i) the material be immediately sealed by INASE inspectors and placed in their custody; ii) the researcher obtain from the institution of origin a statement on the safety of the GMO material and the biosafety conditions under which materials should be handled; and iii) an inspection be made of the research facility where seeds were to be planted. This strong uncompromising response to a situation that in fact did not present any significant biosafety risk, served to prevent antibiotechnology groups to seize the opportunity and brandish the incident as evidence that breaches of GMO regulations are common. Demonstrating that biosafety rules are in force and that compliance is strictly enforced helps to defend other GMO-research projects and authorized releases against unwarranted challenges.

Post-Commercialization Monitoring: Insect-Resistance Management

Several Bt-maize varieties were shown to be protected against the stem borer *Diatraea saccharalis*. Known as Argentina's most important maize pest, *Diatraea* causes 10–15% field losses under conventional agronomic practices, and up to 30% under widely adopted direct-seeding (no-till) methods. Historically, in Argentina, there has been no widespread use of chemical pesticides for controlling the pest for a number of reasons, one of which is erratic performance resulting from the difficulty of determining optimal timing for the applications. Not surprisingly, farmers began buying seed of Bt varieties as soon as they were available. As elsewhere in the world, regulators and company scientists were concerned that widespread deployment of Bt genes, and consequent expression of Bt proteins, would exert a selection pressure that could accelerate the emergence of resistant pest populations. As a result (and despite the risk of being seen as having a conflict of interest), the seed industry, under the umbrella of the Argentine seed growers association's (ASA) Sustainable Productivity Program, engaged scientists to develop an insect-resistance management (IRM) plan based on the high-dose/refugia concept.

The proposed plan included technical recommendations for size, pattern and non-Bt lines to be used as refugia, and described the design of field and laboratory-based monitoring systems. The industry group accepted additional recommendations from CONABIA, e.g., to measure background levels of resistance in pest populations and current tolerance levels of the target pests, and to monitor these levels over time. ASA gives seed distributors and farmers an information brochure describing the nature of *Diatraea* in plain language, and describing the damage it causes, the basic concepts of managing pest resistance and planting refuges, and the economic advantages of implementing an IRM plan.

The companies formed a marketing managers group to work in the area of communications; they are responsible for distributing and implementing the IRM plan at the farm level. When buying seed, distributors must sign a statement saying that they are aware of the plan and its requirements. When farmers buy seed from a distributor, they sign a document (not legally binding) stating that they have received an instruction brochure. The plan may not be used as a competitive tool (e.g., claiming the need of different refugia sizes), and all companies' brochures must say the same thing. The IRM plan is an example of how a regulatory advisory body and industry can work cooperatively to respond to complex and dynamic technical problems. Preliminary observations by ASA representatives indicate a good level of farmer compliance with the plan. The first quantitative data on compliance became available in the second quarter of 2001. They have shown high degrees of compliance: 85 to 90% in the case of cotton (size of refuge is 20%, all farmers were surveyed), and 68% in the case of maize (size of refuge is 10%, and over 33% of farmers were included in the survey).

Private-sector Views of the Regulatory Framework

In the course of this study, two common refrains emerged from the private sector. First, companies were uniform in their appraisal of CONABIA—the Commission is working well and doing a good job. This opinion was to be expected given the significant participation of companies in the regulatory process. Working together fostered a cooperative (rather than adversarial) approach to resolving procedural issues and decision making. The second point companies emphasized was that it is essential for the regulatory system to have clear rules, and to be stable and consistent over time.

Compliance with biosafety regulations for field-testing GMOs adds certain costs to those associated with the testing of conventional crops. According to one company official, a rough estimate of costs for meeting Argentine regulatory requirements for a small field test include US\$ 400 for each of three to four inspections, plus another US\$ 20 per plot for field rental (to ensure needed isolation), and small amounts for destruction procedures and loss of useable seed. By comparison, similar field tests of conventional lines cost the company about US\$ 2 per plot. This example involved varieties developed, tested and released outside of Argentina; therefore, biosafety data and documentation for the imported seed was provided by the parent company. Both CONABIA and SENASA reserve the right to require additional data not included in the application package prepared by the originating company, which would impose further costs prior to release in Argentina. Thus the figures given in this one anecdotal case are not representative of the actual costs of regulatory compliance. A systematic study of such costs has not yet been undertaken.

VI. PUBLIC AWARENESS AND ATTITUDES

Public attitudes about biotechnology, its application to agriculture, and its use to modify food products are shaped by a number of forces independent of the technical details. Among these are the public's level of science literacy, the nature and sources of information available to the public, the history of new technology introductions, the (perceived) relative importance of biotechnology in light of national needs, and the public's trust in government authorities.

Awareness of biotechnology remains low in Argentina—public attention is directed to more pressing matters such as the high unemployment rate, a deteriorated job environment of low salaries and poor stability, the plight of farmers, political developments, slow growth of the economy, high health costs and low quality of public-health services, national and domestic security and education. Only a small segment of the general public is aware of scientific issues in general, even less so on the scientific research being carried out in the country. Presently, a few percent of Argentina's GMO production remains in the country, where it ends up in processed foods such as soymilk and maize-based snack foods. As there is no requirement for labeling and commodities are not segregated, consumers are unaware that they may be eating GMO-derived foods.

Public Perception

Newspapers and television are the leading sources of consumer information about GMOs. *Clarín*, the most widely circulated national newspaper in the country, regularly publishes useful, agriculturally oriented biotechnology information in its weekly rural section. At the same time, articles in the general interest and consumer sections often contain negative content supplied by opposition groups. A Greenpeace publicity campaign about labeling GMO-derived foods, launched in July 2000, received extensive coverage for several weeks. The subject was given a high profile in newspapers with front-page articles, color photographs of Greenpeace 'actions' staged in supermarkets, and two-page spreads on the centerfold. With time, a gradual shift towards more balanced reporting occurred, and subsequent coverage has included responses from the scientific and/or regulatory communities.

Credibility is a major determinant of how information is regarded by the general public. As a rule, Argentines do not view scientists with the same high regard they give farmers. Making

the situation even more difficult is a pervasive belief that the government does not always adhere to the highest standards of honesty and integrity, which may cast doubt on the validity of the regulatory framework. From interviews with officials from Greenpeace and other environmentalist NGOs, it appears that CONABIA is seen as an independent, transparent, science-based regulatory body, not linked to commercial or political interests. However, since promoting biotechnology is also in the interest of the companies developing GMOs, many people will believe that any activity in support of the technology (e.g., scientists appearing in TV interviews or writing articles supporting GMOs) was “bought” by the multinational companies who are bringing their products into the country. Stronger long-term government support for public sector research that leads to domestically developed GMOs may provide a counterbalance to this skeptical, if not cynical, view.

Most Argentines who are aware of agricultural biotechnology do not see any consumer benefits in the GMOs presently being grown. A Delphi survey polling the opinion of individuals representative of several sectors in the society showed that human health and agriculture, followed by the environment, are perceived as the areas in which biotechnology is likely to have its highest impact (Burachik 1995). However, concerns are raised regarding GMOs released into the environment, as well as the manipulation or misuse of information derived from human genome sequence data. Gene patenting was considered a risk, followed by genetic modification of plants, and genetic modification of animals, in increasing order. On the scope of regulations, respondents seemed to agree that *all* levels of research, from laboratory to greenhouse to environmental release, should be regulated. Asked which are the most appropriate institutions to be in charge of regulations, respondents ranked highest and nearly equally, the government and the technology institutions in the public sector. Ethics showed up as the main origin of problems but most respondents said that the benefits of biotechnology greatly outweigh its risks. Recently, several public perception surveys have been conducted but not yet published, among which the following:

- “Survey among Company Executives of the Food Industry about the Prospective (Contributions) of Advanced Biotechnology in Agriculture,” by the National University of Quilmes and CamBiotec, started in April 2000 (J. Dellacha, personal communication);
- Survey on “Biotechnology, Argentina and the Argentineans,” commissioned by ASA to a media company, and done in May-June 2001 (V. Castro, personal communication)¹⁶;
- A third survey was conducted in October 2000 by researchers at the Genetics Institute of INTA, titled, “Analysis of a Survey on Public Perception of GMOs.” (D. Lewi, personal communication).¹⁷

None of the above surveys have been fully published yet. These activities reflect an increasing recognition of the importance of public awareness and debate in the acceptance by society of new technologies.

In the past two years, activist groups have requested on at least four occasions that the government ban GMO-derived foods or at least make labeling mandatory because of purported health risks. The matter usually ends up in the hands of CONABIA where a considerable amount of staff time is spent preparing a thorough written response. As the response is directed to the activist group and does not receive wider dissemination, the effort

¹⁶ For a summary of the results of this survey, see www.porquebiotecnologia.com.ar.

¹⁷ The survey population consisted of (a) scientists from different biological disciplines; (b) nonscientists who are in frequent contact with scientists; (c) university students; and, (d) the general public. The intention was to relate the responses to the degree of education and available sources of information.

has little or no effect in terms of enhancing public understanding.

Efforts to Inform the Public

Until recently, only a few people from academia participated in public awareness activities. The impact of this infrequent media exposure was generally low, and may even have been counterproductive where the proponent may have appeared condescending or insensitive to public concerns. This picture is changing now as more scientists and allied spokesmen are talking with the media and developing better communication skills.

Over the past year and continuing today, ASA has been contributing articles to the weekly agriculture section of national newspapers describing how genetic engineering is done, what benefits it has brought Argentine farmers, what new products are under development and how they will benefit consumers, and so on. In 2000, ASA began a public-information campaign intended to convey a better image of GMOs and the products derived from them. They have prepared a folder for general distribution that describes the research targets member companies are pursuing, created a CD-ROM for educational use, and coordinated meetings between scientists and the media. The project has annual funding of US\$ 170,000. ASA maintains a biotechnology-focused Website¹⁸ “Why Biotechnology?” that carries frequently asked questions, relevant documents, and statistics on GMO plantings in Argentina, and news taken from newspapers and news agencies around the world. While the quality of the information presented is high, most of it comes from foreign sources and is not focused on what is happening in Argentina.

Government leaders are among the most important target groups for educational efforts. The Argentina Forum of Biotechnology (FAB) plans to have a series of breakfast meetings with the Minister of Health, Secretary of Agriculture, Secretary of the Environment, and other high level officials. The meetings will be opportunities to discuss the basics of biotechnology and its application to agriculture and human health research and product development, with an emphasis on the technology’s role in agricultural production, protection of and treatments for human health, veterinary uses, and environmental and economic impacts. The meetings will also extend to people involved in the food industry, journalists, and consumer representatives. The first round of activities, promoted by ASA, the FAB and some academic institutions, occurred in August, 2000; it consisted of

1. a meeting of experts from the public sector and CONABIA with the General and Quality Managers of the main food industries, explaining the conceptual grounds of the Argentine regulatory framework for GMO-derived food (i.e., the precautionary approach and the concept of substantial equivalence) and the results of analyses made on foods bought from grocery stores (a current Greenpeace target);
2. a meeting with people attending an International Food Fair, with a special section devoted to GMO-derived food;
3. several meetings with students from Universities;
4. meetings with industry and agriculture affairs advisors to the parliamentary representatives of several political parties at the national level;
5. a meeting with parliamentary representatives from the Province of Buenos Aires.

Since then, several meetings have been organized in which scientists and staff from

¹⁸ The Website maintained by ASA: <http://www.porquebiotecnologia.com.ar>

regulatory bodies talk about GMOs for different audiences (nutritionists, farmers, university students, etc.). CONABIA's staff members also participated in courses on GMO regulation and public-perception issues given in other countries (Chile, Colombia, Venezuela, Uruguay). It is expected that these and other actions already programmed for the near future will help counteract campaigns against GMOs and bring some rationality into the discussions.

The use of GMO crops, particularly herbicide-tolerant soybeans and insect-resistant maize, added an estimated US\$ 400 million to Argentina's agricultural income in the 1999/2000 season. (J. Kiebusch, personal communication). Such economic benefits, and the arrival of more consumer-oriented GMOs, such as foods with enhanced nutritional quality, currently at the field testing stage, will likely contribute to a more receptive and accepting public. Amid the preponderance of negative information campaigns conducted in the media, a growing interest in listening to regulators and scientists is emerging. Proponents are being invited more and more often to deliver talks at professional conferences (e.g., the Latin American Nutrition Congress), meetings of international organizations, foreign embassies, provincial agriculture secretaries, and TV programs. CONABIA is considering to place on its Website brief public-oriented documents about flexibilizations and short summaries on releases in order to achieve greater visibility as a biosafety advisory body and help build a more informed public.

VII. EVALUATION AND FINDINGS

This study to assess the efficacy of Argentina's biosafety system entailed a thorough review of policies and procedures associated with the introduction and commercial use of GMOs. The study identified the following three areas as warranting further consideration by key stakeholders:

1. the general policy environment surrounding agricultural biotechnology and, more specifically, the functions of the relevant regulatory agencies;
2. the organization and operation of the biosafety system; and
3. the status of public awareness and acceptance.

Policy Environment

Following national elections in October 1999, a period of adjustment for new government officials and their advisors, combined with general economic difficulties across government agencies, hindered normal operations of the biosafety system. People involved in the day-to-day operations of biosafety committees show notable commitment to and apply high standards for timely and responsible biosafety decision making. However, it appears that a cautious approach prevailed at higher levels within the government, partially induced by the anti-GMO policies and negative consumer attitudes of the EU. As a result, concrete actions on biotechnology matters were postponed during 1999 and 2000 pending a more comprehensive, strategic analysis of the impact of the technology on the Argentine economy. This situation changed in 2001, breaking a *de facto* moratorium that lasted almost three years. During this period, ASA and the food industry chamber (Coordination of Manufacturers of Food and Beverages) were asking relevant government officials to make positive public statements, with limited success.

Grupo Bio, a "bio-group," was formed in 2000 by eighteen institutions representing interests or activities in agriculture, the seed and commodities trade, the stock exchange, food

manufacturers and the Argentine Biotechnology Forum. The purpose of this group, whose weight in terms of production and trade comprises up to 7.3% (US US\$ 20,400,000) of the GNP, is to meet with government officials for the proposal and promotion of appropriate policies and to help in the diffusion of the benefits of biotechnology to the general public (J. Dellacha, personal communication).

The combined effects of negative attitudes about GMOs in Europe and changes in senior staff appointments in key government agencies have led to the aforementioned slowdown in the authorization for commercial release of new biotechnology products in Argentina. Some applications to flexibilize crops for large-scale production had to wait many months for final signature. This slowdown of approvals for large-scale releases has not prevented biosafety regulators from continuing to review field-test and greenhouse-release applications, which can go forward only with the Secretary's signature. Significantly, the state of uncertainty has not prevented important work on food-safety guidelines and public information from proceeding. An important meeting held in August 2000 between the Secretary and under-Secretary of Agriculture, their technical and legal advisors, and members of CONABIA seems to have clarified matters and built the basis for a more trustful and cooperative atmosphere. This development was instrumental in helping speed up biosafety administrative proceedings. New senior officials in SAGPyA, who took office after the recent national elections and subsequent administrative changes, have publicly expressed strong support for agricultural biotechnology¹⁹. The newly appointed Secretary translated this support into actions, resuming a smooth flow of procedures and decisions.

CONABIA

CONABIA is not a decision-making authority but rather an advisory body to the Secretary of SAGPyA. In the August 2000 meeting between Commission members and senior officials, the Secretary's Chief of Advisors suggested that CONABIA be given executive power so that field-release permits and flexibilizations could be granted directly by the Commission. The proposal had a mixed reception. While some members thought it was a good idea for which the time was ripe, others saw it as an attempt by government officials to remove themselves from responsibility. This view was accompanied by concern that such a move would introduce other considerations into CONABIA's decision making, with the risk of leaving behind the scientific focus of their work.

The proposal mentioned above was not advanced by the new administration that took office in 2001. Instead, the current Secretary of SAGPyA appointed a National Advisory Commission on Policies for Agricultural Biotechnology (CNAPBA), with representatives from CONABIA, INASE, SENASA, INTA, DNMA, and several external senior advisors, with the mandate of defining guidelines concerning broader policy issues.²⁰

The potential for conflict of interest is part and parcel of Argentina's biosafety system. Nearly all members of CONABIA either 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, acting on established rules, to remove himself from

¹⁹ Clarín Rural, March 31, 2001, p.2.

²⁰ Resolution SAGPyA No. 219/2001

taking part in a decision. Such connections also make it difficult to find independent, disinterested members to review applications containing CBI. For this reason it has been customary that for the most part, only CONABIA's scientific advisory staff member and an INASE official review CBI applications.

SENASA

Field tests and flexibilizations of GMO crops were well underway when SENASA's jurisdiction over GM food safety was determined in 1997. Resolution No. 511/98, establishing guidelines for food- and feed-safety review, describes approval procedures and requirements only in broad terms. The lack of details led to uncertainty within SENASA and among applicants over data requirements, acceptability of data from other countries and similar matters. Typically, applications contained a large body of technical data that had been prepared by the parent company for regulatory approval in other countries, primarily the US and the EU. Review of the technical information was to be done by SENASA's officers who were proficient in regulating general food matters, but did not have sufficient professional background to critically examine the multidisciplinary data involved in the safety assessment of GMO-derived foods. As a result, applicants were often asked to provide additional data, which contributed to delays in making food-safety decisions.

Since the inception of the technical advisory committee, a broader range of relevant expertise is being brought to bear on GM-food safety reviews. By 2001, TAC had reached a good output level, applications being reviewed in much shorter timeframes. In addition, it has established the usual practice of calling on external consultants from public institutions (INTA, universities) to advise on specific matters, e.g., levels of natural toxicants in locally grown crops.

The Biosafety System

Guidelines

The Argentine biosafety system is based on guidelines, not on legislation. This gives the system flexibility and allows for changes needed to keep up with scientific advances. On the other hand, compliance with guidelines is not legally enforceable; there is no way to prosecute offenders in the rare cases of noncompliance that have occurred. Legal enforcement measures can be a double-edged sword. Stringent penalties for failure to comply with biosafety measures sends an alarming message to the public that even small-scale plantings of transgenic crops present an immediate and significant threat to people or the environment or both. Yet, in most places, only the threat of swift and strong punishment deters from noncompliance with regulatory requirements that cost time and money. Publicizing and exercising punitive authority sends a message that biosafety is taken seriously, offenders will be held accountable, and the public need not worry that companies are making their own rules.

Anticipating a certain amount of unauthorized and/or concealed GMO plantings, regulators are looking to put some 'teeth' into the biosafety rules. A biosafety law that carries penalties for violations is expected to reach Parliament in 2002 (Briozzo, personal communication). Depending on the severity of the infraction, options may include confiscation and/or destruction of field materials, assessment of fines, suspension of application privileges for a defined period or until evidence of reform and procedural improvement is provided, or other

measures commensurate with the seriousness of the infraction.

The existing biosafety system is centralized; all reviews for all levels of GMO activity are carried out by the pertinent national Commissions. A few institutions have set up institutional biosafety committees, however these are more involved with chemical, radiation and medical waste safety than with recombinant DNA research. The national guidelines do not call for the establishment of IBCs.

People

During the course of this study, it became evident that members of CONABIA have a sense of mission and adhere to a code of conduct regarding conflict of interest. This sense of responsibility, openness and fairness is reflected in the uniformly positive light in which others see the Commission. Environmental and consumer activists credit CONABIA with having the proper expertise for biosafety review, doing a reasonably good job in evaluating proposals, and being open and accessible. The Commission is approaching a full complement of representatives with the naming of a delegate by the Secretary of Natural Resources and Environmental Policy in 2000. One deficiency in membership remains. The Ministry of Health has been invited to send representatives, but delegates attended only a few early meetings. Representation from this agency, recently requested again, will strengthen the institutional coherence of the system.

The TAC constituted at SENASA in 1999 has a mixed membership; about half have a technical background, while the other half represent consumer, farmer, or industry interests. Agency authorities recognize that some disciplines (e.g., food toxicology) still are not represented, and are looking for appropriate candidates to fill these gaps. At present, the technical members take the lead in conducting the actual food-safety reviews; they present their views to the full TAC for discussion. The nontechnical members are expected to ask questions inspired by their own perspectives, which would tend to reflect public attitudes and opinions. Their input helps to shape a science-based food-safety report that is acceptable to the general public. As they become more familiar with the relevant issues, nontechnical members may take a more active role in the review process. Actually, an increasing participation of the nontechnical members has been experienced along the two years the TAC has been working, with a favorable impact on the overall quality of the review process.

Review and Approval Process

There is an expected range of 30 to 60 days turnaround time for greenhouse and field test approvals by CONABIA. By the last quarter of 2001, the whole process took an average of 35 days, as the new administration speeded up the approval process. In cases where the submitted application lacks necessary information, the time needed for providing it to the Commission will determine the longer review period. Discussions with company representatives indicated they are generally satisfied working within this timeframe.

Proprietary or business-sensitive information, supplied in the original application submitted to INASE but marked as confidential, usually is revealed to two members of CONABIA. Other members are disqualified on the basis of potential conflict of interest arising from their various linkages with biotechnology companies. In effect, the entire burden of risk assessment and risk management pertaining to the CBI falls on those two people.

The EU is the primary market for many Argentine commodities, however approvals there for

new GMOs were in fact suspended since 1998 and only resumed in April 2001. Given that marketing approval is the determining step in commercializing GMOs in Argentina, the question has been raised whether or not the entire approval process should start with the market review. Proponents argue that such a strategy would prevent “wasted effort” on products that will not be approved at the last stage of commercialization, and would limit the possibility for unapproved varieties to be grown in Argentina. The alternative view holds that it would be a mistake to put marketing approval as the entry door to GMO-product approval. Two reasons are cited: first, markets are volatile, and whatever is unwanted or unprofitable now could be in demand tomorrow. To deny technical review now for a commodity that could be approved tomorrow may result in a lost opportunity to do business. Second, there will be a negative impact on research if only what is marketable now will be developed. National research programs and the private sector have to be prepared for market changes with products positioned to take immediate advantage of new opportunities. Thus it is important to continue R&D activities in GMO product development, including greenhouse and field-testing. The alternative leads to a halt in further GMO research.

Several key members of CONABIA participated in a 1998 program sponsored by the Canadian International Development Agency (CIDA) to evaluate useful applications of Canada’s experience in biosafety and adapt them to Argentina’s conditions. The possibility for a second phase in the program is under consideration.

Mechanisms for Feedback

Most members of CONABIA stay informed about new scientific developments in biotechnology and biosafety through access to current scientific literature in print and online. Internet connections are generally available, but at present may be subject to certain limitations in use. Some members are invited to attend national, regional and/or international biosafety and scientific meetings, and have built up a valuable network of colleagues overseas. One member participated as a primary lecturer in a capacity building program for biotechnology regulators conducted by the United Nations University Programme for Biotechnology in Latin America and the Caribbean (UNU/BIOLAC)²¹. With rare exceptions, funding for travel is not available through the Secretary; meeting participants must either be sponsored by the host organization or secure support through their home institutions (e.g., a University).

As is the case in most other countries, small-scale field tests and large-scale flexibilized releases are not used as a source of scientific feedback to support biosafety decision making. This policy is in keeping with the objectives of such releases, which are intended for efficacy testing, agronomic evaluation, seed multiplication, or the like. To require applicants to conduct risk assessment or monitoring studies as a condition of approval would be a major expansion of regulatory authority.

Procedural feedback provides insight into administrative or logistical aspects of the biosafety system that may be unclear or present bottlenecks to any of those involved. This study provided the first occasion on which feedback from “customers” of the biosafety system was actively sought. University, private-sector and research-institute scientists, research administrators, government regulators, and representatives from industry and farmer organizations all responded favorably to requests for interviews. Many were pleased, and a

²¹ http://www.unu.edu/capacitybuilding/Pg_biolac/pg.html

few surprised, by the opportunity to answer questions and make suggestions for improving the system. Their input constitutes a major part of this report.

Public Awareness and Acceptance

From information about GMO grain production and exports found in newspaper articles, interested consumers can easily deduce that some processed foods (soy milk, maize-based snack foods) being sold in grocery stores contain some percentage of ingredients derived from transgenic soybeans or maize. Nonetheless, the majority of people are only marginally aware of genetically modified crops and food. As there is no requirement to label GM foods in Argentina, most consumers presumably are unaware of the possible GMO content in some of the foods they buy. Many of the people interviewed for this study were aware of the potential for opponents to turn this situation into a major anti-biotechnology public relations campaign. During the course of the study, in fact, the level of public awareness began changing due to increased activity by opposition groups. Against this negative shifting background, proponents are beginning to increase their visibility. Members of CONABIA, SENASA spokespersons, academic scientists, and government officials are speaking out, making positive statements about biotechnology in media interviews and speeches. Individual agencies and organizations are beginning to develop their own public information initiatives having variable content, target audience, visibility, and budget.

VIII. RECOMMENDATIONS

Argentina's means of evaluating the environmental and food safety of genetically modified organisms meets many of the criteria for an effective biosafety system (Traynor 1999). Guidelines and regulations are transparent and flexible so as to allow revision when needed; reviewers are competent and bring diverse and relevant expertise to a science-based review process; new scientific information is quickly incorporated and feedback on policies and procedures is sought to improve the system.

During the biosafety system's almost ten years of operation, the context for biotechnology has been changing in terms of government policy, trade and market conditions, progress in regulatory harmonization, and emergence of the Cartagena Protocol on Biosafety. It is against this dynamic background that the present study was undertaken to assess the efficacy of Argentina's biosafety policies and procedures. Based on the findings described above, the major recommendations of this report are to

1. clarify and strengthen national and institutional policies.
2. modify biosafety procedures to enhance timeliness and transparency.
3. strengthen the scientific base for decision making through risk assessment research.
4. design and implement a coordinated program to address public awareness and acceptance.
5. invest in building human resource capacity.

Policies

Clarify and strengthen national and institutional policies. Farmers embrace biotechnology for the competitive edge GM crops give them in global markets. Its methodologies are used in numerous publicly funded agricultural research programs. Its potential to reduce or

eliminate major constraints to crop productivity and to enhance food quality are widely known within the research community. The recognized importance of ensuring that GMOs are used safely has led to the establishment of a biosafety system. What has been lacking in this otherwise positive scenario is clear and consistent support from high-level government officials. The year 2000 and part of 2001 were marked by a lack of decisions regarding the request to commercialize GM-crop varieties and products. The situation draws attention to the need for a legal framework that supports the biosafety system, sets time limits for responding to requests, and strengthens interactions between CONABIA and those having legislative authority.

Presently the biosafety system operates in the absence of a national policy on biosafety. Ideally, such a policy would (1) promote the safe use of biotechnology products; (2) call for a balanced approach to weighing potential environmental and human health risks against the benefits that could be realized; and (3) underscore the importance of stakeholder input. Other considerations in the use of the technology, such as social and economic consequences, are more properly addressed through a policy on biotechnology applications.

In order to formulate appropriate policies, policy makers need to be educated about what biosafety is and why it is an inseparable part of the biotechnology applications already in use in Argentina, as well as those likely to be adopted in the future. Policy makers also need to understand the legal rights and responsibilities imposed by the Cartagena Protocol, which Argentina has signed and is expected to ratify. Perhaps most importantly, they need to recognize the role of a biosafety system in demonstrating to the public that due consideration is being paid to potential effects of GMOs on the environment and human health. CONABIA and SENASA's TAC are in the best position to raise policy makers' awareness, and in fact have taken some steps in that direction. The logical next step would be for these agencies to initiate a joint effort to prepare a draft policy statement on biosafety, to be presented for consideration by national authorities. The recent appointment of the "policy" Commission (CNAPBA), with representatives from CONABIA, INASE, SENASA, INTA, DNMA, and several external senior advisors, is an important step in that direction.

Argentina's process for environmental and food-safety reviews has in the past experienced some difficulties where institutional mandates for CONABIA and SENASE were not always clearly drawn or matched by requisite expertise. Another factor impinging on the effectiveness of the biosafety system is the fact that, whereas the latter is a fully empowered regulatory agency, CONABIA is an advisory committee lacking true decision making authority. As a result, *ad hoc* actions on the part of one body have in some cases given the appearance of overlapping the institutional role of another, particularly in respect to food-safety review. Significant improvements in this area began taking place during the course of this study, most notably in the formation of SENASA's TAC and appointment of technically trained experts, and through initiatives to review and revise food-safety regulations.

Whereas CONABIA's official mandate is to conduct environmental risk assessments and associated actions, its unofficial mandate includes a number of responsibilities that need to be recognized and given the institutional support that currently is lacking, such as (1) identifying risk assessment data needs and facilitating risk assessment research (see below); (2) serving as a public information resource; (3) advising local and national government officials; (4) assisting biosafety committees in other countries on request; (5) promoting regional regulatory harmonization; and (6) advising the Foreign Office in international negotiations.

Procedures

Modify biosafety procedures to enhance timeliness and transparency. In Argentina, as in the rest of the world, most commercial GMOs are products of private-sector research and development. Companies operate on a timeline for getting new products through each stage on the way to the market place, and thus for planning purposes need to know how long regulatory decisions will take. Government agencies within the biosafety system would improve the regulatory environment by adhering to a set timetable for review and decision making. For GMOs likely to be flexibilized or commercialized, the sometimes lengthy food-safety assessment may proceed more efficiently if it is begun during, rather than after, the period of field-testing. Costs and benefits of initiating a review earlier in the approval process should be examined by SENASA.

The food-safety TAC recently finished a review of existing regulations with an eye to developing a more consistent and complete procedure that also conforms to emerging global standards for the risk analysis of foods derived from modern biotechnology. The TAC is following the development of a new section being added to the Codex Alimentarius on foods derived from modern biotechnology²². Documents produced by the Codex meetings during 2000 and 2001 are being analyzed at SAGPyA by a “Codex Committee” having broad membership that includes SENASA, CONABIA, DNMA, the Foreign Affairs Ministry, the FAB and other stakeholders from the private sector. Position documents from this Committee are submitted to the authorities for use by the delegates attending at the relevant meetings. If the final Codex document is adaptable to Argentina’s needs, it would be a strategic move to align the country’s food-safety regulations with it.

Review of confidential business information should be shared by more than two members of CONABIA; this would serve to distribute the responsibility and make the process more open and transparent. Accordingly, effort should be made to add new members who do not have ties to the agricultural biotechnology business sector. In addition, instituting regular ‘customer service’ meetings would serve to keep stakeholders informed of regulatory actions and evolving policies in CONABIA and the SENASA TAC.

Decision Making

Strengthen the scientific base for decision making through risk-assessment research. Biosafety decisions necessarily are made in the absence of full knowledge. For example, in agricultural regions intended for GMO release, information about the distribution of non-crop species and the nature of their ecological interactions may not be available. In these cases, biosafety committees must use all available information, but ultimately must rely on their educated but subjective judgments as to how the GMO will affect the existing agro-ecosystem. Here the door is opened for criticisms that biosafety committees are engaged in guesswork, and/or their actions are subject to corporate or political influence.

New knowledge and better understanding of how a GMO will affect its local environment are key to assessing potential risk and developing strategies to minimize consequences that are unwanted, unintended, or unacceptable. Filling in gaps in this knowledge is critical to keeping biosafety assessments firmly grounded in science. Properly designed and controlled

²² Joint FAO/WHO Food Standards Programme. Codex Ad Hoc Intergovernmental Task Force On Food Derived From Biotechnology. First Session, Chiba, Japan, 14–17 March 2000.

monitoring studies can be an important source of biosafety-related scientific feedback from both small- and large-scale releases. Field studies in agroecological research are needed to generate data pertaining to the nature, magnitude, and probability of a specific risk, and applicable to a particular risk assessment or risk management issue.

To strengthen the scientific basis for biosafety review, CONABIA should identify and prioritize the kinds of ecological data needed to support review and decision making, focusing initially on those crops and traits likely to come before the Commission in the near term. Needed information may include, but is not limited to (1) surveys of the distribution and prevalence of major pest insects, plant viruses, and weed species in agricultural regions of Argentina; (2) ecological data on the effects specific diseases and pests have on the survival, persistence, and spread of crop-related weed species; (3) baseline levels of resistance to Bt toxins in target pest populations; and (4) inventories of threatened, endangered, or beneficial species found in cultivated ecosystems.

Risk-assessment research targeted to Argentina's biosafety data needs merits continuous funding as part of the total agricultural research budget. Until they are addressed through scientific research, concerns about safety will continue to slow, and may even halt, public acceptance of agricultural biotechnology. One approach to funding this type of research is by eliminating research known to be duplicated within the public sector through better coordination of institutional research priorities and projects. Public funding for redundant projects conceivably could be redirected into risk-assessment research. Other funding mechanisms are possible, e.g., establishing a dedicated risk-assessment research account funded by corporate contributions and administered strictly by CONABIA or another public entity.

At present, the subject of monitoring for long-term environmental effects has not been taken up by the regulatory system. Concerns about impending but unforeseen consequences of GMO releases can be addressed only through legitimate, structured long-term observation and testing. One approach to conducting monitoring studies would be to call panels of experts to develop scientifically sound monitoring plans for representative (not all) large-scale releases. Responsibility for approving such protocols should rest with CONABIA, however responsibility to oversee their implementation should rest with another body that is independent of industry interests. Monitoring studies cost money, and thought must be given to who pays and through what mechanism.

Public Awareness

Design and implement a program to address public awareness and acceptance. The public controversy surrounding biotechnology and GMOs will not begin to be resolved until people have access to credible and accurate information from trusted sources. The private sector in biotechnology, dominated by large multinational companies, is widely regarded as lacking credibility in public relations. This view is based in part on their history of overselling the technology while dismissing any concerns, and the perception that companies place profit ahead of consumer health and safety.

In Argentina, most consumer and environmental advocacy groups are well regarded by the public. Some NGOs, having sharply raised their visibility by astute use of the media, are particularly effective in getting their message heard. Echoing the opposition arguments arising in Europe, some of the “information” disseminated about biotechnology and GM

foods suffers from gross inaccuracies, false assumptions, and unsupportable extrapolations. Not surprisingly, though, given the technical nature of the subject, most reporters and editors are incapable of distinguishing fact from fiction, and give broad exposure to the NGOs' claims. Providing accurate information to the public thus becomes the responsibility of research institutes and government agencies.

A proactive, multifaceted information strategy is needed immediately to counteract the well-funded, well-organized opposition campaigns being mounted in Argentina as in the rest of the world. An effective information strategy begins by educating the media, since reporters and editors are not only channels of information to the public, but also act as filters and as marketers of information as a product. An information program designed to inform—not convince—the public would also make it more aware of the existence and functions of CONABIA and SENASA, and remove any impression that “no one is looking at the risks.” Public statements from senior government officials supporting biotechnology will send a strong message that it is part of Argentina's agricultural agenda.

The public's interest in labeling deserves an open discussion on the merits, costs, benefits, and feasibility of requiring foods derived from transgenic crops to be labeled. The current situation, in which most people are unaware that a small number of the foods they buy may have some GMO content, could potentially be used by opponents to alienate consumers. Issues such as threshold limits of GMO content, the nature and language of label information, and alternatives to labeling are matters that must be addressed in a forum that promotes public input and participation. Related to this is the issue of GMO segregation, which could be implemented to maintain a source of non-GMO-derived foods. This issue will become more visible when GM-derived foods are approved for commercial use within Argentina. It is recommended that an independent entity be commissioned to do a cost/feasibility study of commodity segregation before the need arises.

Human Resources

Invest in building human resources. Argentina is fortunate in having a strong biological research base with highly trained scientists. Some of them are or may become involved in their own institutional biosafety committees. IBC members need technical training in risk assessment and risk-management procedures, awareness of risk issues, evaluating potential risk in a particular combination of crop + trait + location, estimating probability, anticipating environmental impacts, methods of risk management, monitoring and the like.

Training should be an ongoing process for two reasons. First, it takes time and practice to become a confident and competent biosafety reviewer. Invaluable experience is gained by evaluating release applications involving diverse GMOs, engineered with typical or unusual traits, in a variety of locations having different ecological and environmental characteristics, under the guidance of more experienced teachers. Second, biosafety is a moving target. The rapid pace of technical advances and the widening scope of engineered traits and recipient organisms taxes even the most dedicated biosafety official. Thus, periodic training in new biosafety issues helps reviewers stay informed.

Over time, some of Argentina's scientists will become members of, or *ad hoc* advisors to, CONABIA and SENASA-TAC. It would be a worthwhile investment to cultivate this "next generation" of biosafety officials through an informal mentoring process. One way to do this would be for current committees to begin to identify and recruit individuals qualified to join

CONABIA or the TAC. Potential new members are invited (perhaps even required) to attend meetings as observers in order to become familiar with the issues and deliberations of the committees, and learn how they operate on a practical level. This "training in advance" would help ensure continuity within the system, and allow a smooth transition through changes in personnel.

At the institutional level, basic biosafety training for researchers and program directors would enhance their awareness of what biosafety is and why it's important. Regardless of commercial intent or not, they should understand the environmental safety issues that may be raised by GM crops and products derived from their own research. By anticipating potential concerns, scientists are in a better position to make more informed decisions regarding the details of the intended genetic modifications and the design of their experiments conducted in the environment.

CONCLUDING REMARKS

Argentina was among the earliest countries to establish a biosafety system for regulatory oversight of genetically engineered agricultural crops. In the time since 1991, the system has evolved to meet the changing demands for regulation of a growing number of GM crops, foods and products, and has expanded to address new categories of GM organisms, e.g., animals. New legal instruments, redefined mandates, enhanced procedures, and increased support and visibility all have contributed to the emergence of an effective, rational and well-respected biosafety system.

Regulatory agencies and advisory bodies within the system operate under a combination of pre-existing and newly written laws, regulations and decrees that address environmental and human health safety, and assess economic impacts on markets and trade. The next step in the biosafety system's evolution may well be adoption and implementation of a Biosafety Law, which would provide a legal basis for enforcement and authorize the imposition of sanctions or penalties in cases of non-compliance.

As documented in this report, Argentina has taken a broadly based yet flexible approach to implementing a national biosafety system for GMOs. Where indicated, recommendations are made suggesting additional measures that could help to strengthen it. In total, the organization and operation of the Argentine biosafety system make it a useful model for other countries facing the challenging task of ensuring the safe and responsible use of agricultural biotechnology.

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ANNEX 1. DOCUMENTS REVIEWED

1. On the formation of CONABIA: Resolutions of the Secretary of Agriculture, Livestock and Fisheries (SAGyP, the name at the time) N°s 124 (1991), 669 (1993) and 328 (1997).
2. On the procedures to grant “Flexibilized” status (also referred to as “Flexibilization”): Resolution of the SAGyP N° 131 (1998).
3. On the review procedure regulating the three-way review process: (environment risk assessment, food safety and agrifood market impact): Resolution of the Secretary of Agriculture, Livestock, Fisheries and Food (SAGPyA) N° 289 (1997). This is the most relevant regulatory document in the context of the present study.
4. On procedures for decision making at CONABIA: Disposition of the National Director of Production, Agricultural and Forestry Economy (DNPYEAF) N, SAGPyA N° 4 (1999).
5. On isolation distances for genetically modified plant field trials: Resolution N° 226 (1997), of SAGPyA.
6. On the regulatory approach, requirements and official forms to request field release permits: Resolutions of SAGyP Nos 656 (1992) and 837 (1993), precedents to the above mentioned 289 (1997).
7. On information requirements and review procedure for GMOs containing more than one transformation event: Disposition of the DNPYEAF, N°7 (1999).
8. On procedures for new variety registration (to be done after commercialized release has been granted): Disposition of the DNPYEAF, N°8 (1999).
9. On the format and information to be included in CONABIA Decision Documents: Disposition of the DNPYEAF, N°9 (1999).
10. On the information requirements for food-safety review: Resolution N° 511 (1998), and Annexes, from the SAGPyA (now under review for modifications).
11. On the institution of the technical advisory committee on the use of GMOs (the advisory body in charge of modifying food-safety data requirements and intended to perform reviews in the future): Resolution N° 1265 (1999) from the President of SENASA.
12. Previous Legislation:
 - a) Act-Decree N° 6704 (1966), on Health Protection of Agricultural Production;
 - b) Seed and New Plant Varieties Act N° 20,247 (1973);
 - c) Veterinary Products Act N° 13,636 (1949).

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ANNEX 3. APPLICATION FOR THE REQUEST OF FLEXIBILIZED CONDITIONS FOR RELEASE²³ INTO THE ENVIRONMENT OF GENETICALLY MODIFIED PLANTS FOR FIELD TRIALS²⁴

Resolution of the SAGyP Nº 131 (1998)

Note 1: The following is the information that should be submitted with the Application requesting Flexibilized Conditions for Field Trials and/or Large-Scale Release Into the Environment of Genetically Modified Plant Organisms (GMPOs). The information listed herein, organized as indicated below, will constitute the document for the analysis of the Application.

Note 2: In answering to each item, the petitioner should give a clear and consistent summary of the information requested. All items must be filled in.

Note 3: The petitioner may include additional and/or detailed information in a separate document (the Support Document). All additional information provided in the Support Document related to the items listed on the Application should be clearly and unambiguously identified with an appropriate cross-reference system.

Note 4: The Application must be completed in Spanish. The Support Document, or parts thereof, may be written in Spanish or English.

I. SUMMARY / PRESENTATION

1. Denomination of the event.

2. Characteristics of the GMPO.

2.1. Name or identification of the line.

2.2. Phenotype (e.g. insect resistant, herbicide tolerant, etc.).

3. Confidential information statement:

Identify the number of the pages omitted in the "public" presentation, and state that they are included in a closed envelope marked "Confidential Information".

4. Brief description of the GMPO:

- Scientific name of the recipient organism.
- Description of the inserted genes or nucleotide sequences (whether or not they are expressed):

Name:

Function:

Name of the donor organism(s):

²³ The term "release" in this document refers to the "introduction into the environment for reproduction, propagation and/or multiplication".

²⁴ "Flexibilization" means that the applicant only needs to notify the release for the purpose of inspections (at planting, harvest and residue disposal). No isolation distances are required.

- Description of the regulatory sequences and their function in the inserted construct:
Name:
Function:
Name of the donor(s):

5. Uses of the GMPO:

Describe its uses, indicating any differences versus their nontransgenic counterpart.

5.1. Traditional uses.

5.2. New or additional uses.

6. Conditions under which the flexibilization is requested.

Indicate if extensive, large-scale growing of the transgenic crop requires conditions differing from those traditionally used to produce the non-transgenic varieties.

II. APPLICATION / DOCUMENTATION

1. List of abbreviations.
2. Index.

A. GENERAL INFORMATION

A.1 Characteristics of the GMPO.

A.1.1 Name or identification of the line.

A.1.2 Phenotype (e.g. insect resistant, herbicide tolerant, etc.).

A.2 Date of submission of application.

A.3 Information on the petitioning institution.

Name.

Address.

Name of the contact person(s) handling the Application.

A.4 Information on the institution and persons who developed the GMPO.

A.5 Characterization of the GMPO.

The Petitioner should include in this item a description of:

A.5.1 expressed proteins and/or RNAs and the resulting phenotype.

A.5.2 advantages afforded by the introduction of the foreign gene.

A.5.3 general description of the results from previous releases in Argentina and in other countries, with regard to biosafety issues.

A.6 Equivalence statement:

The petitioner will state that the GMPO is equivalent to the similar, nontransgenic counterpart, except for the phenotype contributed by the newly introduced gene, and should include reference to the studies—included as addenda—that support this statement. The equivalence should refer to (a) compositional analysis, processing technology, derived products, and byproducts; (b) agricultural practices including growing and management practices, geographic areas, environment conditions, etc.; and (c) equivalence from the standpoint of the end users of the products and byproducts.

A.7 History of previous tests and releases into the environment:

A.7.1 In Argentina.

A.7.2 In other countries.

State dates, countries, authorization numbers, approval granting authorities, and mention the characteristics of the GMPO (if any) that were shown to differ from those of the nontransgenic counterpart, in addition to those resulting from the transgenic phenotype.

A.8 Instructions or recommendations for growing the crop, for the handling of products derived thereof, and for the storage practices (for products, byproducts, and waste derived from the crop), if different from those that are habitual for the nontransgenic counterpart.

A.9 Suggested packaging, labeling and processing technology, if different from the nontransgenic organism.

A.10 Actions required in the event of an accidental release or inappropriate use.

B. CHARACTERIZATION OF THE GMPO

B.1 The recipient organism:

B.1.1 Names.

B.1.2 Phenotypic characteristics.

B.1.3 Geographic distribution and natural habitat.

B.1.4 Genetic stability and factors affecting it.

B.1.5 Outcrossing potential.

B.1.5.1 to related cultivated species.

B.1.5.2 to other related wild species.

B.1.5.3 to related species.

B.1.5.4 to other organisms.

B.1.6 Reproductive features and factors affecting them.

B.1.7 Survival in the environment and factors affecting it.

B.1.7.1 Survival or dormancy structures.

B.1.7.2 Specific factors affecting survival capacity.

B.1.8 Dispersal features and factors affecting them.

B.1.9 Interactions with other organisms in the environment.

B.1.10 Pathogenic, toxic or other characteristics that may be harmful to human or animal health (e.g. antinutrients, toxicants, allergenic factors, etc.).

B.1.11 History of previous genetic modifications of the recipient organism.

B.2 The genetic modification

B.2.1 Technique used in the transformation.

B.2.2 Characterization of the vector (or vectors).

B.2.2.1 Nature and origin.

B.2.2.2 Description of the various elements in the construct (or constructs).

Table

| Genetic Element | Origin (donor) | Size (kb) | Function (in the construct) |
|-----------------|----------------|-----------|-----------------------------|
| | | | |

(VECTOR MAP)

- B.2.2.3 Detailed description of the construct.
- B.2.2.4 Aminoacid sequence of the products from the expression of the newly introduced genes.
- B.2.2.5 Nucleotide sequences or regions of the construct whose products or functions are unknown.
- B.2.2.6 Gene transfer properties.
- B.2.2.7 Mobilization, conjugation, recombination and integration properties.
- B.2.2.8 Regions of the vector which are inserted into the GMPO.

B.3 The insert

- B.3.1 Molecular analysis of the insertion into the genome of the GMPO (number of integration sites, number of copies of each gene, incorporation of truncated genes).
- B.3.2 Origin and function of each element inserted in the GMPO.
- B.3.3 Information on whether the insert (that is, any of its elements) expresses a function not required for the expression of the new phenotype of the GMPO.

B.4 The donor organisms

- B.4.1 Pathogenic characteristics (only those resulting from the expression of the elements within the construct used in the transformation process).
- B.4.2 Other harmful characteristics to human or animal health (with the limitation stated in the item above).
- B.4.3 Potential for and/or history of natural transfer (i.e. in both, natural habitats and conditions) of the genetic elements within the construct, from the donors to other organisms. Here, mention is required of the likelihood or frequency of the transfer, and of the possible or already identified phenotypes acquired by the recipient organism(s) as a result of the transfer.

B.5 The GMPO

- B.5.1 Newly introduced phenotypic features.
- B.5.2 Phenotypic features of the non-transgenic recipient organism which are not expressed in the GMPO.
- B.5.3 Genetic stability.
 - B.5.3.1 Segregation data and analysis of progeny.
 - B.5.3.2 Molecular analysis (Southern blot, PCR, etc.).
- B.5.4 Characteristics of the expression of the foreign genetic elements.
 - B.5.4.1 Products whose expression are analyzed (including all genetic elements, wholly or partially introduced into the GMPO).
 - B.5.4.2 Characteristics of the expression (e.g., constitutive, tissue-specific, etc.).
 - B.5.4.3 Plant tissues in which the introduced genes are expressed, and their expression levels.
 - B.5.4.4 Time course of the changes in the expression levels throughout the plant cycle.
 - B.5.4.5 Biological activity of the expressed proteins.
- B.5.5 Techniques to detect the GMPO in the environment.
 - B.5.5.1 Molecular methods.
 - B.5.5.2 Biological methods.
- B.5.6 Effects on human health.
 - B.5.6.1 Toxicity or allergenicity of the GMPO, including the products and byproducts derived thereof (through processing by traditional industrial technology) and its metabolic products. Information under this point should refer to all products (including but not limited to foodstuffs), and to whether there are (or may be) interactions of these products with other normal ingredients in the human diet.
 - B.5.6.2 Characteristics of the non-transgenic organism which are modified

in the transgenic in such a way as to being hazardous or pose a health risk.

- B.5.6.3 On the basis of the technologies currently used for processing the non-transgenic counterpart, state the levels of expression of the new proteins which are expected or have been measured in the products or (processing) fractions of the GMPO which are intended for human consumption, as well in their byproducts and waste.
- B.5.6.4 Comparison of the GMPO versus the nontransgenic counterpart with regard to the properties considered in B.5.6.1.

B.6 Interaction of the GMPO with the environment

- B.6.1 Survival in the environment (properties of the non-transgenic recipient, specifically versus the corresponding survival features observed in the GMPO).
 - B.6.1.1 Germination rate and dormancy properties and structures.
 - B.6.1.2 Plant vigor (plant growth characteristics, agronomic quality, susceptibility to disease, insect and environmental stress factors).
 - B.6.1.3 Existing or potential adaptive advantages and competitiveness of the GMPO versus the non-transgenic counterpart, in natural habitats and under normal conditions, and in agro-ecosystems where the same species or other geographically compatible crops are grown.
 - B.6.1.4 Reproductive structures and rates.
 - B.6.1.5 Propagation structures and properties.
- B.6.2 Quantitative information on interactions.
 - B.6.2.1 Susceptibility to disease, pests and insects.
 - B.6.2.2 Survival capacity (volunteer plants).
 - B.6.2.3 Yield.
 - B.6.2.4 Effects on non-target organisms (birds, beneficial insects, and mammals).
- B.6.3 Environmental impact of an agroecosystem constituted by the GMPO.
 - B.6.3.1 Effects of the GMPO on the flora and fauna.
 - B.6.3.2 Effects resulting from changes in agricultural practices (if they exist).
 - B.6.3.3 Crop management of the GMPO with regard to the effects listed above.
 - B.6.3.4 Specific procedures needed for the management of the environmental effects of the GMPO.

C. IMPACTS EXPECTED FROM THE PRODUCTION OF THE GMPO AT A COMMERCIAL SCALE

C.1 Environmental impact

- C.1.1 Effects on the flora and fauna. Petitioner should present a list of the organisms for which this issue is relevant.
- C.1.2 Management of potential unwanted effects (e.g. development of resistance to Bt by insects previously Bt sensitive).
- C.1.3 Proposal for a "Follow-up Research Program" to monitor possible long-term effects on the environment (indicating which are the effects to be investigated).

C.2 Effects on human health

- C.2.1 Concepts and research programs developed to assess the safety of the new proteins expressed in the GMPO.
- C.2.2 Toxicity assessment.
 - C.2.2.1 Digestion behavior in simulated gastric juice, at different pHs: digestion kinetics, characterization of the resulting fragments and their biological activity, if pertinent (e.g., if an antibiotic resistant

- marker gene is expressed).
- C.2.2.2 Acute toxicity of the newly expressed proteins in laboratory animals; measurement of the NOEL (no-effect level), if possible.
- C.2.2.3 Estimation of the Acceptable Daily Intake (ADI), and its comparison with the normal intake for humans on usual diets.
- C.2.2.4 Assessment of the allergenic potential.
- C.2.2.5 Aminoacid sequence homology of the new proteins with other relevant proteins known to be health hazards (toxins, allergens, etc.). State: i) if any of the later proteins show an homology with the new proteins exceeding 40%; and ii) if exists any homology between the new proteins and the epitope sequences which have been reported as allergenic.
- C.2.3 Proximate composition of all tissues the GMPO, and their comparison with the reference values of the non-transgenic counterpart.
 - C.2.3.1 Proteins and their aminoacid composition.
 - C.2.3.2 Lipids and their fatty acid composition.
 - C.2.3.3 Carbohydrates and their characterization (if pertinent).
 - C.2.3.4 Other components (minerals, vitamins, etc.).

D. OTHER RELEVANT INFORMATION

The petitioner must include as a separate annex:

1. All support information, such as copies of the scientific papers, etc. quoted in the several sections of the application.
2. All other information that the petitioner may consider relevant in support of his request.