USDA Foreign Agricultural Service
GAIN Report
Global Agriculture Information Network
Template Version 2.09

Required Report - public distribution

Date: 10/21/2005

GAIN Report Number: AR5033

Argentina

Biotechnology

Annual

2005

Approved by:
Kari Rojas
U.S. Embassy

Prepared by:
Andrea Yankelevich

Report Highlights:
Argentina is a major producer of agricultural products, and the third largest producer of soybeans, with an area of 15 million hectares estimated for the 2005 crop season. No other Latin American country has embraced Genetically Modified Crops (GMO) crops as wholeheartedly as Argentina. Argentina is also an important ally of the United States in international issues, and co-complainant with the United States in the World Trade Organization challenge to the European Union moratorium on GMO crop applications. The Argentine biosafety system is a useful model for other countries facing the challenging task of ensuring the safe and responsible use of agricultural biotechnology.

Includes PSD Changes: No
Includes Trade Matrix: No
Annual Report
Buenos Aires [AR1]
[AR]

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Executive Summary

Argentina is a major producer of agricultural products, and the third largest producer of soybeans, with an area of 15 million hectares estimated for the 2005 crop season. No other Latin American country has embraced Genetically Modified Crops (GMO) crops as wholeheartedly as Argentina. Soybean harvested area has increased from 36,000 has. (59,000 mt produced) in 1970 to 5.98 million has. in 1995/96 (12.43 mmt produced). The introduction of genetically engineered soybeans in the late 1990s sparked a further expansion of soy production, which now surpasses 14 million hectares. At least 98 percent of all this soy production is GMO.

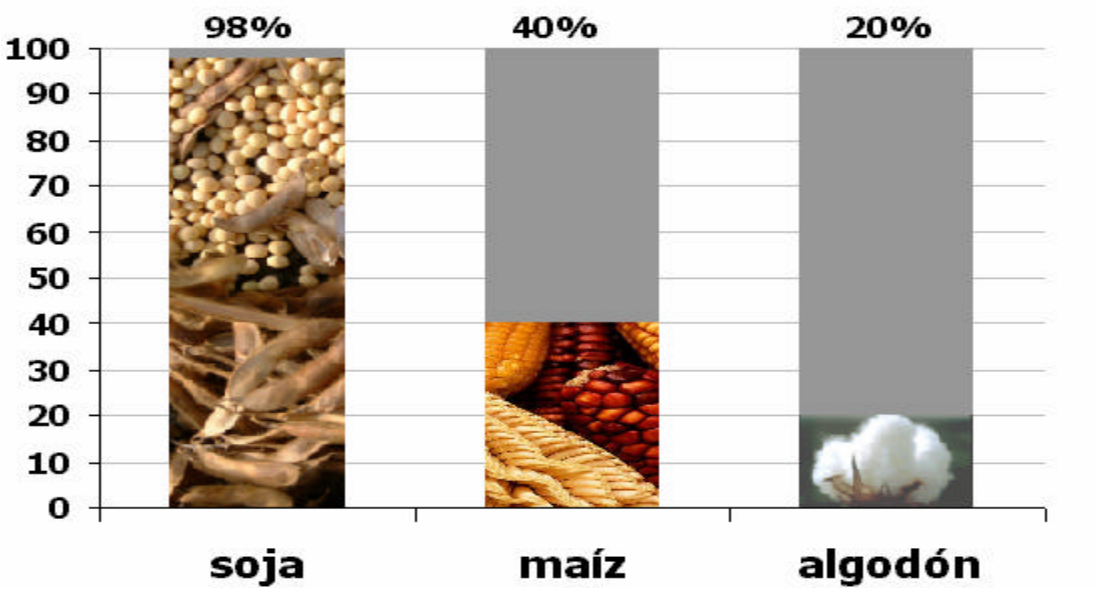
Argentina is also an important ally of the United States in international issues, and co-complainant with the United States in the World Trade Organization challenge to the European Union moratorium on GMO crop applications. However, there is a disagreement between Monsanto and the Government of Argentina (GOA) on a royalty collection system for Roundup Ready (RR) soybeans.

The Argentine biosafety system is a useful model for other countries facing the challenging task of ensuring the safe and responsible use of agricultural biotechnology. The key agency in the Argentine system is National Advisory Committee of Agricultural Biosafety (CONABIA), within the Secretariat of Agriculture, Livestock, Fisheries, and Food (SAGPyA), pursuant to Resolution 124/91. CONABIA is a multidisciplinary and inter-institutional organization with advisory duties. Its main responsibility is to assess, from a technical and scientific perspective, the potential environmental impact of the introduction of GMOs in Argentine agriculture. CONABIA reviews and advises the Secretariat on issues related to trials and/or the release into the environment of GMOs and other products that may be derived from or contain GMOs.

Although Argentina has an effective regulatory framework established through resolutions dictated by SAGPyA, as of yet, no Argentine law on agricultural biotechnology is in force.

Biotechnology Trade and Production

Percentage of GMO crops in Argentine Agriculture



Source: Ing. Cesar Petrusansky

Argentina is the world's second largest producer of GMO crops after the United States, with ten biotech crop varieties approved for production and commercialization: one for soybeans (Monsanto 40-3-2), two for cotton (Monsanto 531 and 1445) and now seven for corn (Ciba-Geigy 176, AgrEvo T 25, Monsanto 810, NK 603, Novartis Bt 11, Syngenta GA 21 and Dow/Pioneer TC 1507). (Please See Attachment A)

Soybeans

Released in 1996, glyphosate tolerant soybeans were the first transgenic crop introduced into Argentine agriculture. Since its release, this technology has been adopted at a very high rate, with an estimate for the current season of 15 million planted hectares, placing Argentina in the second place after the United States. The main reason for this rapid adoption is the great economic benefits that RR soybeans provide to the producer. Besides, when the adoption process started, the patent for Roundup (Monsanto´s commercial name for glyphosate) had expired several years earlier. Thus, there was already a significant increase in competition in the glyphosate market, which translated into significant price reductions. At the same time, the new technologies facilitated the incorporation of double cropping soybeans (following wheat) in many areas where only one crop was planted before the availability of the GMO varieties. (Trigo, Chudnosky, Cap & Lopez)

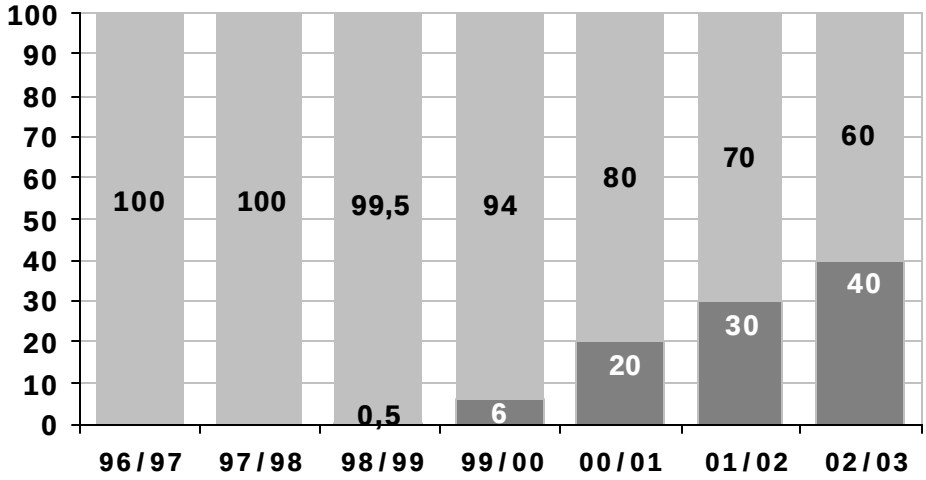
The Argentine soybean economy is geared almost entirely towards exports. Only two percent of the harvested soybean reaches the national market, whereas 30 percent is exported as grain and 68 percent is processed by the oilseed industry within Argentina. Ninety-three percent of soybean oil and ninety-nine percent of by-products (meals) are exported.

Corn

GMO varieties of lepidoptera tolerant and ammonium-glyphosate tolerant corn were commercially released for the first time in 1998. The adoption of these varieties has also been significant. In the case of Bt maize, benefits are derived from a net increase in production, resulting from the reduction of losses caused by insects and not from increases in the area planted.

The GOA forecasts that producers will plant between 2.5 million and 3.0 million hectares of corn this season, although those figures may dramatically change, as it is difficult to estimate the amount that will enter into the formal marketing chain.

Planted area with conventional maize and GM Maize (percentage of total)



Source: DNMA/SAGPyA

Cotton

Biotech cotton adoption represents 40 percent of planted area, according to SAGPyA. Total area estimated for the next crop season is 370,000 has.

Biotech cotton contains a gene from Bacillus Thuringiensis (Bt), a common soil microbe, allowing it to naturally protect itself against insect pests, thereby requiring fewer applications of chemical insecticides.

Through a research project done by the National Institute of Agricultural Technology (INTA), it was found that in the leading cotton-growing regions of Argentina, biotech cotton required almost 64 percent fewer applications of insecticide when compared to its conventional counterpart.

In Argentina, this research showed that the average cotton grower had a $65 per hectare advantage (approximately $26 per acre) using biotech cotton versus conventional cotton. Similar economic advantages have been found in the United States from the use of biotech cotton.

Biotechnology Policy

Biosafety Regulatory System

Argentine biosafety regulatory system is based on the evaluation of the product and not of the process through which it was obtained. Therefore, the evaluation takes place on a case-by-case basis, taking into consideration the process only in those cases where the environment, the agricultural production or the health of humans or animals could be at risk.

The approval process for commercialization of GMOs involves different agencies within SAGPyA:

-National Advisory Committee on Agricultural Biotechnology (CONABIA)
Role: Evaluate of impact in the agricultural ecosystem. Ensures compliance with regulation 39. (Please See Appendix B)

-**National Service of Agricultural And Food Health and Quality (SENASA)**
Role: Evaluate the biosafety of food products derived of GMO crop for human and animal consumption.

-**National Direction of Agricultural Food Markets (DNMA)**
Role: Evaluate commercial impact on export markets by preparing a technical report in order to avoid a negative impact on Argentine exports. DNMA mainly analyzes the status of the event under study in the destination markets in terms of whether the product has been approved or not and, as a result, whether the addition of this event to Argentina's export supply might represent a potential barrier to the access to these markets.

-**National Seed Institute (INASE)**
Role: Establish requirements for registration in the National Registry of Cultivars.

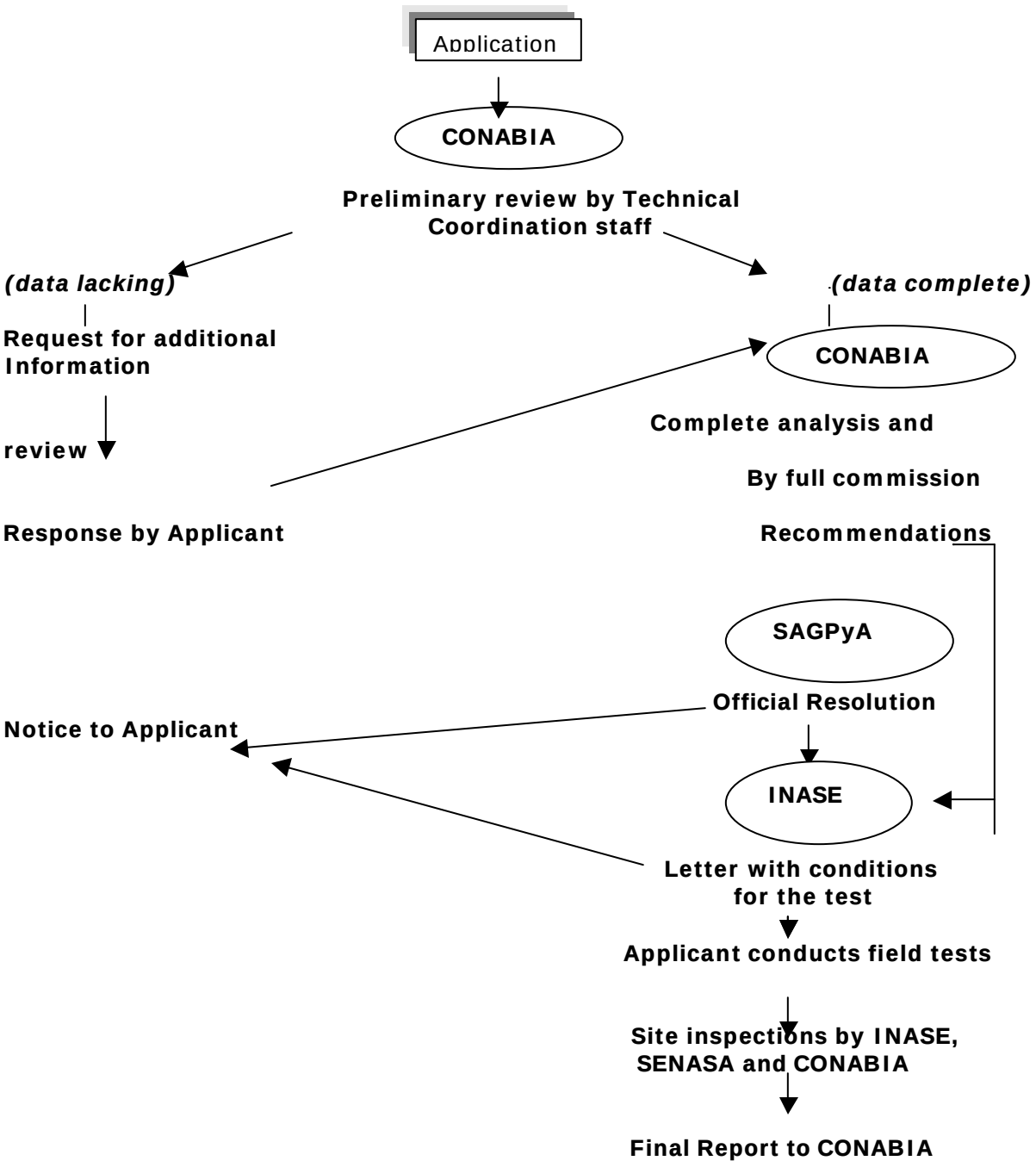
Upon completion of all of the steps mentioned above, CONABIA's Office of Technical Coordination compiles all pertinent information and prepares a final report to the Secretary of Agriculture, Livestock, Fisheries and Food for final decision.

It is worth noting that CONABIA is a multi-sectorial organization made up by representatives from the public sector, academia and private sector organizations related to agricultural biotechnology. CONABIA members perform their duties as individuals and not as representatives of the sector they represent, and they are active participants in the international debate of biosafety and its related regulatory processes.

CONABIA has reviewed over 500 permits since its creation, developing new capacities as the sector required. Regarding its legal and institutional framework, CONABIA is an advisory agency that operates pursuant to a resolution by the Argentine Secretary of Agriculture. In absence of a law, this fact prevents the establishment of an adequate system of penalties of those who do not comply with stipulated procedures.

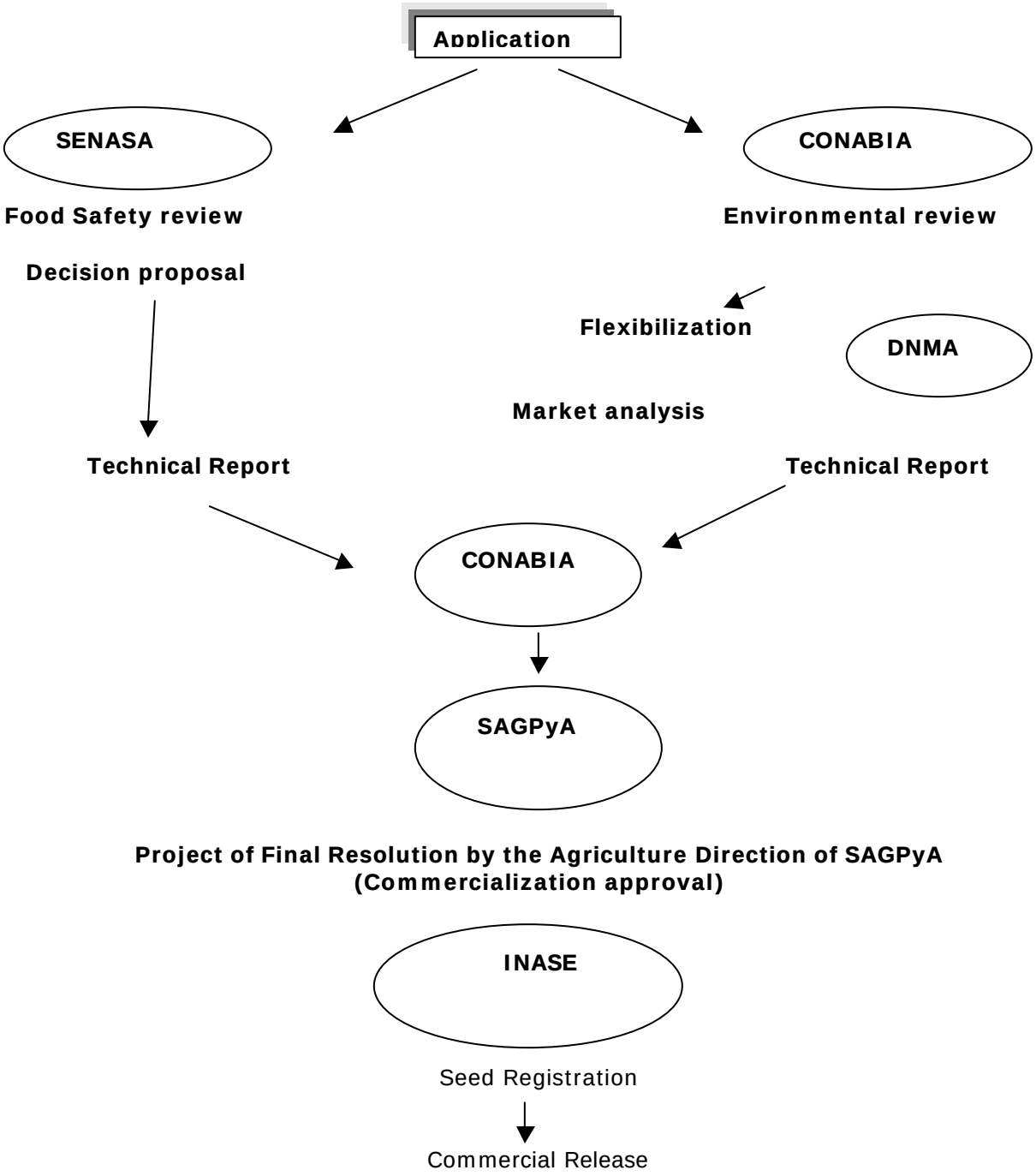
In sum, Argentina was among the earliest countries to establish a biosafety regulatory framework, and there is consensus regarding its effectiveness adjusting to new developments.

FIELD TEST APPROVAL PROCEDURE FOR GMOs IN ARGENTINA



Source: Trigo, Cap et al

COMMERCIAL RELEASE APPROVAL PROCEDURE FOR GMOs IN ARGENTINA



Source: Trigo, Cap et al

Traceability

There is no official system in place. At this stage, only private companies (authorized labs) have the capability to perform the required tests. For example, the National Institute of Agricultural Technology (INTA) does it on private basis.

Labeling

There is no specific regulation in Argentina in reference to labelling GMO products. The current regulatory system is based on the characteristics and identified risks of the product and not in the production process of that product. Therefore, there is no regulation governing the use of labels such as "BIOTECH FREE" or "NON-GMO", which are voluntarily used by the producer.

According to SAGPyA, for the implementation of a regulatory labelling system, the discussion should be based on the type of food product derived from a specific GMO taking into account that:

- Any food product obtained through biotechnology and substantially equivalent to a conventional food product, should not be subject to any specific mandatory label.
- Any food product obtained through biotechnology and substantially different from a conventional food product for any specific characteristic may be labelled according to its characteristics as food product, not according to aspects concerning the environment or production process.
- Differential labelling is not justified, as there is no evidence that demonstrates that food products produced through biotechnology may represent any risk for the consumers' health.
- In the case of agricultural products, as the majority of them are commodities, the identification process would be complicated and expensive. The increased production costs as a result of labelling, would end up being paid by the consumers, without assuring that this would represent better information or increased food security.

Stacked events

No defined policy as of yet.

Coexistence

Refuge system is in place.

Intellectual Property Rights – Royalties

Argentina is a major producer and exporter of agricultural biotechnology products, yet it does not have an adequate and effective system in place to protect the intellectual property rights of new plant varieties or plant-related technology. Penalties for unauthorized use of protected seed varieties are negligible. Judicial enforcement procedures in Argentina likewise are ineffective as a mechanism to prevent the unauthorized, commercial use of protected varieties.

Monsanto, grower organizations, and commodity exporters are at an impasse regarding a solution to the continued high level of saved and illegally traded RR soybeans, which has depressed Monsanto's Argentine operation revenues. In January 2004, Monsanto announced that it would cease investments in and sales of RR soybeans in Argentina. The central issue, according to Monsanto, was its inability to collect fully RR-technology-related royalties from Argentine growers. Monsanto applied for and was denied a patent on RR soybeans, a decision it appealed unsuccessfully with the Argentine Supreme Court. Argentine law

currently allows farmers to save seed from one harvest and to use it the following year if a royalty is paid to the original seed breeder. However, it is illegal to sell, trade, or pass saved seed from one producer to another.

In May 2004, Argentina's National Seed Institute implemented Resolution 44/2004, requiring that each sack of seed be labeled with quantity, unit price, total sales price, and seed species, type or variety. However, the illegal seed sales continued and Monsanto articulated that if an acceptable solution could not be reached with producer organizations and commodity exporters by March 2005, Monsanto would begin to enforce royalty payments on unlicensed Argentine soybeans exports at ports of destination in countries in which Monsanto holds a patent on RR soybeans. In March 2005, Monsanto informed Argentine soybean and product exporters of imminent enforcement actions on unlicensed shipments of soybeans, soybean meal, and other soy products containing the RR gene. This move by Monsanto provoked heated reactions from GOA and Argentine farm organizations.

Since then, SAGPyA, Monsanto and interested parties have tried unsuccessfully to reach an agreement on royalties collection.

The lack of effective enforcement options for plant variety rights, combined with the absence of patent protection for a significant range of biotech inventions, renders Argentina's intellectual property system inadequate from the perspective of the biotechnology industry.

Biosafety Law

During 2001, the SAGPyA actively cooperated with members of the Argentine Congress in drafting a biosafety law. This draft represented a major improvement on the current situation, since it clearly set forth a conceptual framework, as well as issues and instances to be considered as participants in risk analysis procedures. But due to the institutional and economic crisis that broke out on December 2001, the draft was never discussed in Congress and there is no evidence that it will be in the near future.

International Negotiation Fora

Cartagena Biosafety Protocol

In the international biotechnology negotiation arena, CBP is probably the most significant issue. Argentina signed the Biosafety Protocol in May 2000 in Nairobi, Kenya, but has not yet signed its ratification. Argentina is currently undergoing a consultation process, analyzing and debating with all the involved sectors the position the country will take to this respect.

The overlapping of environmental and human health concerns, as well as commercial implications, have resulted in an extremely difficult negotiation for the countries that, like Argentina, are commodity exporters.

It has to be taken into account that although Argentina has not ratified the BCP, it will have to comply with the commercial obligations when negotiating with countries that are parties.

The CBP has been signed and ratified by 117 countries, 16 of which are developed countries. It is important to mention that most of the undeveloped countries that ratified the CBP, do not posses biosafety regulatory systems and are currently evaluating their possibilities to adjust to the obligations of the CBP. Argentina considers that prior to setting basis of

commercial issues, the countries that ratified the CBP should have their respective biosafety framework in place.

Codex Alimentarius

Argentina is strongly working to reach consensus on GMO labelling and traceability, and actively participating to avoid potential trade disruptions and unnecessary cost increases.

Other Agreements

Other important international negotiation areas are the creation of an ad-hoc group on agricultural biotechnology within the framework of the MERCOSUR and the Memorandum of Understanding on biotechnology signed between the GOA and the government of China. During President Kirchner's visit to China in 2004, The Argentine Secretariat of Agriculture, Livestock, Fisheries and Food signed a MOU with the Chinese Ministry of Agriculture, in reference to agricultural biotechnology and biosecurity. The objective of the MOU was to move forward the cooperation, stimulating communication and understanding related to biotechnology policies in both countries. Argentina recently signed a bilateral cooperation agreement with Nicaragua as well.

Through all these agreements, Argentina is trying to create a coordinated dialogue framework for the application of biotechnology policy and biosafety, in a way to avoid negative impacts of trade.

National Fora

-Creation of a Biotechnology office within SAGPyA with the objective of centralizing all the information and activities.

-CONABIA's development of a 15 year Strategic Plan
The Strategic Plan anticipates a future scenario, which is the context of the vision proposed. Policies are defined and an action plan is outlined for the realization of that vision. Objectives are classified by areas of strategic concentration to define the main issues addressed.

- Announcement of a Biotech Promotion Bill
The Argentine Minister of Economy recently anounced a bill to promote biotech initiatives. The project is to stimulate, through fiscal benefits, research, development and investment in products, services or biotech processes.

Marketing Issues

Public Perception – Consumer's Attitude

While Argentine scientists and farmers are optimistic and enthusiastic about the prospects of using biotech to improve yields and nutritional value of crops while decreasing the input of chemical pesticides, Argentine consumers are concerned about the introduction of GMOs into the human diet, possibly due to a lack of knowledge about genetic engineering as compared to conventional plant breeding and the extensive testing being done to insure the safety of a GMO crop. As yet, Argentine consumers do not see GMOs as a benefit to themselves but they can see these products as economically productive to farmers and multinationals. Therefore, they are hesitant about supporting the technology. As Argentina has been a

leader in the adoption of biotechnology, there is an urgent need for dialogue and communication among scientists, farmers, private companies, consumers, government, and regulatory organisms.

Mirror Policy

Argentine Secretary of Agriculture, Miguel Campos, announced his decision to approve Monsanto's Roundup Ready Corn (RR corn) for commercialization, even before the European Union (EU) granted the import authorization. This generated a controversy within the agricultural sector, as the exporters raised their concerns regarding the impact the approval could have in the European market. This represents a step forward against the "mirror policy" with the European Union, or a risky step, as it might represent the potential loss of the European market.

Up until now, Argentina has not approved any commercial GMO plant material unless approved in the European Union. The Argentine media has highlighted that this approval breaks the trend in the Argentine policy towards GMOs and puts away fears about the negative commercial consequences of approving GMOs without the green light from Europe.

Capacity Building and Outreach

2002

A. FAS Buenos Aires organized a biotechnology seminar that was successful in terms of attendance (over 300 participants).

B. Through Cochran funds, FAS Buenos Aires sponsored two-week biotechnology training in the United States for Argentine Government officials, organized by ICD and Michigan State University.

C. FAS Buenos Aires organized a series of lectures byDr. Quiros, Davis University, targeting Argentine Universities, Schools and consumers in general.

2004

A. FAS Buenos Aires selected two Argentine journalists to participate in a US Grains Council activity in Hawaii, where they learned about the papaya industry.

B. The Agricultural Counselor accompanied State's Biotech Negotiator to participate in a series of biotechnology round tables organized by FAS Buenos Aires.

C. Through Cochran funds, FAS Buenos Aires sponsored a two-week biotechnology-training course in the United States for one representative of CONABIA, organized by ICD and Michigan State University.

D. Two Argentine producers attended the Farmer-to-Farmer workshop at the University of Zamorano in Honduras.

E. FAS Buenos Aires sponsored the trip of an Argentine expert to participate in a seminar in Santiago, Chile, directed to the Chilean Parliament.

F. FAS Buenos Aires organized a series of lectures in several local universities for Dr. Bruce Chassy, expert in Nutrition and Biotechnology.

2005

A. The Agricultural Counselor accompanied State's Biotech Negotiator to participate in a series of biotechnology discussions organized by FAS Buenos Aires.

B. FAS Buenos Aires in concert with FAS Santiago organized and accompanied a Southern Cone CODEL to the United States to demonstrate how the United States uses and regulates agricultural biotechnology.

C. FAS Buenos Aires organized a biotechnology workshop in several Argentine provinces, targeting universities and media. Dr. Wayne Parrott, from Georgia University was the invited speaker.

D. FAS Buenos Aires participated in the organization of the NABI/CAS meeting in Buenos Aires.

E. FAS Buenos Aires participated in the meeting of the parties prior to CBP in Canada.

F. FAS Buenos Aires selected one Argentine journalist to participate in a US Grains Council activity in the United States.

Proposed Activities

FAS Buenos Aires proposes a continuation of education and outreach as well as a more targeted information campaign. Specific activities may include:

- Workshops in different cities to target audiences around the country,

- A two-day conference directed mainly to Congressmen, but also to media, academia and government officials among others,

- Activities with local universities to demonstrate the benefits of Biotechnology in Argentina

- Continue Cooperator, Cochran, and International Visitor program activities,

- Special activities designed for consumer association leaders and consumers in general,

- Workshops especially directed to medical doctors and nutritionists, explaining the innocuousness of biotech products;

- Workshop in risk assessment that will be directed to Argentine, Paraguayan and Uruguayan experts.

- Technical workshop to discuss treatment and analysis of stacked biotech events.

- Work with Senators and Representatives on the regional forum created after the Southern Cone Reverse CODEL; and,

- Meetings to develop lines of communication between the GOA and the USG during the review process of biotech events.

APPENDIX A: GMO Crops Approved in Argentina

Crop	Trait Category	Event / Applicant	Trait Description	Status
Soybean	Herbicide Tolerant	40-3-2 Monsanto	Glyphosate Herbicide Tolerant	Approved Feed Food Commercialization
Maize	Herbicide Tolerant	T 25 AgrEvo	Resistant to Glufosinate Ammonium	Approved Feed Food Commercialization
Maize	Insect Tolerance	176 Cyba-Geigy	Resistant to lepidoptera	Approved Feed and/or Food Commercialization
Maize	Herbicide Tolerance	NK 603 Monsanto	Gliphosate Herbicide Tolerant	Approved Feed and/or Food Commercialization
Maize	Insect Tolerance	MON 810	Resistant to lepidoptera	Approved Feed and/or Food Commercialization
Maize	Insect Tolerance	Bt 11 Novartis Agrosem S.A:	Resistant to lepidoptera	Approved Feed and/or Food Commercialization
Maize	Insect and Herbicide Tolerance	TC 1507 Herculex DowAgro Sciences	Resistant to European Corn Borer and to Glufosinate Ammonium	Approved Feed and/or Food Commercialization
Maize	Herbicide Tolerance	GA 21 Syngenta	Gliphosate Herbicide Tolerant	Approved Feed and/or Food Commercialization
Cotton	Insect Tolerance	Mon 531 Monsanto	Resistant to lepidoptera	Approved Feed and/or Food Commercialization
Cotton	Herbicide Tolerance	MON 1445 Monsanto	Gliphosate Herbicide Tolerant	Approved Feed and/or Food Commercialization

Source:CONABIA

Appendix B: Resolution 39

Specifies the conditions under which environmental releases of transgenic material should be conducted. Resolution 39 is part of the general regulatory system governing the existing agricultural regulations in Argentina related to Plant Protection (Decree-Law of Agricultural Production Health Defense. n° 6704/66 and its amendments), Seeds and Phytogenetic Creations (Seed and Phytogenetic creations law, nº 20.247/73 and its regulatory decree), and Animal Health (Law of Veterinarian Products, and Supervision of Creation and Commercialization. nº 13.636/49).

SAGPyA is the authority that issues the licences for experimentation on and/or release into the environment of genetically modified plant organisms, relying on the previous opinion from CONABIA.

- Licences are issued in the following cases:

a) Laboratory-greenhouse trials;

b) Field trials; and or

c) Pre-commercial multiplication of GMOs

- Fifteen (15) copies of the appropriate application must be submitted to CONABIA. The procedure begins in the National Seed Institute at the following address: Paseo Colon 922 - 3° floor - office 349. zip code 1063 - Capital Federal, Buenos Aires, telephone no.: 54-11-4349-2433/2420/2498. fax: 54-11-4349-2417.

- Each copy of the application must be signed by a legally responsible person of the applicant organization, who will assume responsibility for the compliance with all of the conditions under which the pertinent authorization is granted.

- Information included in the summary of the application shall be contained in all other sections of the application, as it is required.

- The assertions in the additional information form must be accompanied by the supporting literature references. All information should be provided in the original language.

- The form must be written in the Spanish language.

- Supplementary information may include reports presented to the competent authorities of foreign countries, with the amendments and additions that may be relevant for the local conditions, as well as references to previous reports presented to CONABIA.

- Upon evaluation of the application, CONABIA shall decide on the suitability of permitting the release of the G MO in question, and shall submit its decision for the approval of the Secretary of Agriculture, Livestock, Fisheries and Food.

- At the end of the period for which the authorization was granted, the applicant shall submit to CONABIA a final report.

- An authorized experiment will be deemed correctly concluded, upon compliance with the following conditions:

-Correct risk management by the applicant,

-Consistency between the conditions under which the authorization was granted and the conditions observed at the site of experimentation, and/or release by the inspectors appointed by the competent authority; and

-Submission of the final report.

-Any applicants who had already obtained authorizations for experimentation and/or release into the environment of GMOs, may request through a letter addressed to CONABIA, filed at the National Seed Institute, the flexibility status of the conditions under which the above mentioned permits are granted. Upon granting the flexibility status from the Secretary of Agriculture, Livestock, Fisheries and Food, further releases into the environment will only require the submission of the following information: the area sown, the date of sowing, the site of release, and the harvest date. CONABIA will only recommend that inspections be made at harvest and of the measures taken for the final disposition of the material.

-Obtaining the flexibility status permit will not mean an authorization for seed commercialization. Seed commercialization is subject to the following terms and conditions:

- Authorization to follow more flexible conditions for the granting of permits for release into the environment of GMO material.

- Compliance with the requirements set forth by the National Seed Institute for registration of the material in the National Cultivar Registry and in the official certification regulations.

- Compliance, if applicable, with the requirements set forth by SENASA regarding authorizations for the commercialization of agrochemical products.

- A letter addressed to the Technical Coordination of CONABIA at Paseo Colón 982 - 2° floor - office 220 - zip code 1063 - Federal Capital. Telephone no.: 54-11-4349-2222/2226, fax no.: 54-11-4349-2224, requesting the initiation of the procedure necessary to comply with the requirements under the jurisdiction of SENASA in connection with the use of transgenic material and its derived products for human and animal consumption. SENASA may request from the applicant any information it may deem necessary for the purposes of carrying out the pertinent evaluations.

- Thereupon, CONABIA will request the technical review of the National Direction of Agricultural Food Markets regarding the convenience of commercialization of the GMO material.

-Upon completion with all of the steps mentioned above, CONABIA's Technical Coordination will compile the pertinent information for the purposes of preparing a final report to the Secretary of Agriculture, Livestock, Fisheries and Food for its final decision.