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Approved by:

David Mergen
U.S. Embassy

Prepared by:

Andrea Yankelevich

Report Highlights:

Argentina continues to be the second largest producer of biotech crops (after the United States), with an area of 19.8 million hectares estimated for the 2007/08 crop season. Pioneer's stacked corn variety HX+LL+RR received approval from the Argentine Secretariat of Agriculture, Livestock, Fisheries and Food on May 28. This approval clears the way for the first triple stacked trait product to be used by Argentine farmers.

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Executive Summary	3
Biotechnology Trade and Production	3
Soybeans	3
Corn	4
Cotton	4
Oilseed - Rape	5
Cloned Cows: Cutting edge technology	5
Biotechnology Policy.....	5
Biosafety Regulatory System.....	5
Traceability.....	6
Labeling	6
Stacked events.....	7
Coexistence.....	7
Intellectual Property Rights – Royalties	8
Biosafety Law	8
International Negotiation Fora	9
Cartagena Biosafety Protocol	9
Codex Alimentarius and Other Agreements.....	9
Ongoing Issues at National Level	9
Marketing Issues	10
Public Perception – Consumer’s Attitude.....	10
Appendix A: Biotech Crops Approved in Argentina.....	11
Appendix B: Resolution 39	13
Appendix C: Commercial Release Approval Procedure for Biotech Events in Argentina.....	15
Appendix D: Field Test Approval Procedure For Biotech Events In Argentina.....	16

Executive Summary

Argentina continues to be the second largest producer of biotech crops (after the United States) in the number of hectares planted, with an area of 19.8 million hectares estimated for the 2007/08 crop season (soybeans, corn and cotton), an increase of 8 percent over the past crop season. Almost all soybean area planted is biotech, with 74% and 90% of corn and cotton area also biotech. No other Latin American country has embraced biotech crops as wholeheartedly as Argentina. Introduction of biotech soybeans in the late 1990s sparked a rapid expansion of soybean production, which now surpasses 17 million hectares. Argentina is now entering in a new stage of biotech development after approving the use and commercialization of stacked events.

Argentina continues to be an important ally of the United States in international issues involving biotechnology and co-complainant with the United States in the World Trade Organization challenge to the European Union moratorium on biotech crop applications. While the disagreement between Monsanto and the Government of Argentina (GOA) on a royalty collection system for Roundup Ready (RR) soybeans is still pending, the Government of Argentina (which created a new Ministry of Science and Technology) has placed a priority on stimulating biotech research and innovation.

The current Argentine Seed Law allows producers to successively use seeds on their own farms. Farmers cannot sell these seeds. This law is interpreted to mean that farmers only have to pay royalties on the original purchase of biotech seeds, but not when they replant seeds that have been selected and saved. But according to official numbers, 20 percent of the total area planted with soybeans in Argentina is sown with seeds purchased from authorized dealers; 30 percent with seeds saved by farmers for their own use, and the remaining 50 percent with seeds selected and sold illegally.

The National Seed Institute (INASE), in charge of overseeing seed production and sales and guaranteeing the transparency of the sector, was closed down in 2000 and reopened by the Secretariat of Agriculture in 2003. Since then, INASE officials have been assigned to draft a revamped seed law which contains a modification to the chapter dedicated to "self use". This draft was approved by the former Secretary of Agriculture last November, and has been passed to the National Congress for discussion.

The Office of Biotechnology, created in 2004, is the key biotechnology agency within Secretariat of Agriculture (SAGPyA) that coordinates all biotech activities and information.

Biotechnology Trade and Production

Argentina is the world's second largest producer of biotech crops after the United States, with twelve biotech crop varieties approved for production and commercialization: one for soybeans (Monsanto 40-3-2), two for cotton (Monsanto 531 and 1445) and now nine for corn (Ciba-Geigy 176, AgrEvo T 25, Monsanto 810, NK 603, Novartis Bt 11, Syngenta GA 21, Dow/Pioneer TC 1507, Monsanto NK603 x 810 and Pioneer 1507 x NK603). (Please See Attachment A)

Soybeans

Released in 1996, glyphosate tolerant (Roundup Ready) soybeans were the first biotech crop introduced into Argentine agriculture. Since its release, this technology has been adopted at a very high rate, with almost all of the 17 million hectares of soybeans planted for the

current season being biotech. The new technology facilitated the incorporation of double crop soybeans (following wheat) in many areas where only one crop was planted before the availability of the biotech varieties.

The Argentine soybean economy is geared almost entirely towards exports. Only two percent of harvested soybeans reach the domestic 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

On August 31, 2007 Argentina approved the first stacked gene, Monsanto's NK603x810. This approval marks the first time stacked traits have been approved in the country. In February 2007, the government simplified the approval process for stacked events, allowing applications for a transgenic crop combining two already approved events without a full analysis of the new crop. The seeds are modified to produce a substance toxic to corn borer parasites and for glyphosate resistance, widely used as a herbicide to control weeds.

On May 28, 2008 Pioneer received approval from the Argentine Secretariat of Agriculture, Livestock, Fisheries and Food for the company's stacked corn trait product containing the insect protection trait (*Herculex I technology*), resistance to the Ammonium Glufosinate (*Liberty Link technology*) and to Glifosate (*Round Up Ready Technology*). This approval clears the way for the first triple stacked trait product to be used by Argentine farmers.

This is also the first stacked trait product of Pioneer approved in Argentina. The stacked trait approval was issued after a product safety scientific review conducted by the Argentina regulatory bodies of CONABIA and SENASA.

Biotech 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.

Biotech corn adoption represents 74% of total corn planted area. In the 2007/2008 crop season the area planted with stacked events accounted for 2 percent of the total area (approx 82,000 hectares). The rest of the biotech corn planted corresponded to Bt corn estimated in 2.51 million hectares, representing approx 63 percent of the total planted corn in the country, and glyphosate tolerant 390,000 hectares or 9 per cent of the total corn.

Cotton

Biotech cotton adoption represents 90 percent of total cotton planted area. In the 2007/08 crop season, 43% of that cotton (124,000HAS) was plated with the glyphosate resistant event and the remaining 57% (162,000HAS) were planted with the Bt event.

Although seed containing the combination of Bt and RR technologies may be approved in the near future, some sources speculate that it may not be marketed due to concerns by seed companies about collecting fees and controlling illegal multiplication.

Research done by the National Institute of Agricultural Technology (INTA) 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. 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.

INTA is also conducting research of colored cotton varieties. The release in the market is expected in a few more years and will be focused on niche markets for small and medium producers.

Oilseed - Rape

The National Seed Institute (INASE) has forbidden thru Resolution 305/07 the import of biotech rapeseed and established the requirement for a certificate stating the absence of biotech seeds in rapeseed shipments.

Cloned Cows: Cutting edge technology

Argentina was the first country in Latin America to develop two generations of cloned cows, capable of producing Human Growth Hormone. In March 2006, CONABIA and SENASA (National Service of Agricultural And Food Health and Quality) approved the first step in the process to authorize the production of the human growth hormone from milk. The next step that needs to be completed is the approval by the Secretary of Public Health.

The cloned calves, Pampa Mansa II, Pampa Mansa III and Pampero, developed by the Biosidus Company, carry a gene that produces human growth hormone in milk. The milk produced by just one cow can meet the demand of the entire country. It is estimated that 1,000 Argentine children currently require such hormone therapy.

In 2007, Biosidus Company developed another line of cloned calves, this time to produce insulin. After several years of research and 4 million dollars investment, "Patagonia" was the first calve born. In this case, the insulin produced by 25 cows like Patagonia will meet the annual demand of the entire country at a lower cost (30% less than the currently used insulin). The intention is to produce enough insulin to be able to export in the near future.

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. 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 key office within SAGPyA that centralizes all biotech activities and information is the Office of Biotechnology, created in 2004. This office coordinates three technical areas: Biosafety Issues (the head is a member of CONABIA), Policy Analysis and Formulation and Regulatory Design.

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

- National Advisory Committee on Agricultural Biotechnology (CONABIA)

Role: Evaluate impact in the agricultural ecosystem. Ensures compliance with Resolution 39. (Please See Appendix B) and also with Resolution 60, that regulates stacked genes. 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 biotech crops in Argentine agriculture. CONABIA reviews and advises the Secretariat on issues related to trials and/or the release into the environment of biotech crops and other products that may be derived from or contain biotech crops.

- National Service of Agricultural And Food Health and Quality (SENASA)

Role: Evaluate the biosafety of food products derived from biotech crops 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. (Attachments C & D)

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. CONABIA is an advisory agency that operates pursuant to a resolution by the Argentine Secretary of Agriculture. In absence of a law governing its reviews, there are limits in its ability penalize those who do not comply with stipulated procedures.

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 analysis on a private basis.

Labeling

There is no specific regulation in Argentina in reference to labeling biotech 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. There is no regulation governing the use of labels such as "BIOTECH FREE" or "NON-GMO".

The policy of the SAGPyA on labelling in international fora is that it should be based on the type of food product derived from a specific biotech seed 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

In 2007, under Resolution 60 which complements resolution 39, Argentina approved a different treatment for stacked genes. Approval is based in a case by case evaluation under which the applicant needs to submit a letter simultaneously to SAGPyA (Office of Biotechnology) and to SENASA requesting authorization for commercialization of the specific stacked event.

The evaluation is based on possible effects when the individual events affect related metabolic patterns. Also, in order to evaluate the possible effects of the stacked event in the ecosystem, as well as the food biosafety evaluation, CONABIA and/or SENASA will determine whether they request additional information from the applicant.

Coexistence

The Argentine Seed Association (ASA), created in 1999 the Insect Resistance Management Program in Bt. The objective of the program is to promote a responsible use of technology in order to delay any potential resistance development and immediately detect any change in the susceptibility of insect populations by putting in place a refuge system. To carry out this goal, the program is based on three pillars:

Research: Scientists from INTA (National Institute of Agricultural Technology) conduct permanent studies to improve the understanding of pest biology and to monitor the sensitivity to the Bt protein. The goal is to continuously improve tools used to evaluate recommendations regarding resistance management provided to farmers and used to detect any possible change in the susceptibility of the insect population.

Communication: Farmers, as users of the technology, have a key role in its preservation; therefore their knowledge is fundamental to achieve a responsible and successful management of Bt corn varieties.

Evaluation of a proper use of technology: The periodic evaluation of farmers adoption of refuges allows an assessment of the success of the program and to improve the tools to adjust communication.

CONABIA approved this system and periodically receives reports submitted by the Argentine Seed Association (ASA).

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.

Argentine Intellectual Property (IP) laws are based on UPOV-78, which provides strong protection for the right of farmers to save and replant seeds, and exempts them from providing explanations on how selected seeds were used. 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.

Monsanto, grower organizations, and commodity exporters have not reached agreement on a solution to the continued high level of saved and illegally traded RR soybeans. 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 fully collect 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.

Due to continued illegal seed sales, Monsanto initiated legal actions in European Countries in 2005 against unlicensed shipments of soybeans, soybean meal, and other soy products containing the RR gene.

The Argentine Government developed a new seed law with the goal of ensuring that providers of technology are adequately compensated, although details of the law have not been made public. Contacts report that the initial proposal has already reached the National Congress, but due to the ongoing dispute between the government and the rural sector, the Congress has not started its consideration of the law.

Biosafety Law

Argentina does not have a biosafety law in place. Initial discussions on developing a biosafety law took place in 2001, but due to the institutional and economic crisis that broke out in 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, the Cartagena Biosafety Protocol (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 in this respect.

Codex Alimentarius and Other Agreements

Argentina is actively working to reach consensus on biotech labelling and traceability, and actively participating to avoid potential trade disruptions and unnecessary cost increases. Other important international negotiation areas are the creation of an ad-hoc group on agricultural biotechnology within the framework of the MERCOSUR.

Ongoing Issues at National Level

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

The GOA has Developed a 15 year Strategic Plan

The plan proposes to diversify the application of biotechnology, both in the number of tools and in productive activities. It advocates creating an appropriate environment (in political, legal and public acceptance issues) for the creation and development of biotechnology-based companies, and also to improve the consolidation of the existing ones. It proposes to assist increasing agricultural production, while preserving and improving the quality of life of the present and future generations. One of the strengths of the plan resides on its flexibility: the accomplishment of the plan has been based on the implementation of a scheme that is built almost simultaneously along its execution, including the revision of objectives, goals and main actions.

Another strength of the plan is the collective bias of its elaboration: stakeholders of the agricultural and livestock activity took part in different discussions, and they contributed with relevant elements that promoted both the quality and the general acceptance of the document. For several agricultural biotechnology strategic concerns, a regional treatment has been anticipated with the purpose of preserving the regional integration, with attention to local issues, where the relationship with neighbor countries is defined in terms of technological cooperation and commercial exchange or competition.

Biotech Promotion Law

This law (N. 26.270) was implemented to promote biotech initiatives, to stimulate, through fiscal benefits, research, development and investment in products, services or biotech processes.

Marketing Issues

Public Perception – Consumer's Attitude

Most Argentine scientists and farmers are optimistic and enthusiastic about the prospects of using biotechnology to improve yields and nutritional value of crops while decreasing the input of chemical pesticides. As yet, Argentine consumers do not see biotech products as a benefit to themselves but they can see these products as economically productive to farmers and multinationals and are hesitant about supporting the technology. As Argentina has been a leader in the adoption of biotechnology, there is a need for dialogue and communication among scientists, farmers, private companies, consumers, government, and regulatory organisms.

Under the *UNEP-GEF* project (United Nations Environment Program – Global Environment Facility), SAGPyA performed and released a survey among producers and consumers that provided the following results:

Producers: (survey conducted at the two most important local farming shows)

90% of the consulted producers reported that, (although some showed confusion and hesitation), they knew, worked with or at least heard about biotech,

75% stated that consumption of biotech foods DO NOT present any risks to the human health,

12% expressed that they know the Argentine regulatory system, and half of them considered that it is safe,

57% stated that if the GOA were to decide to segregate, they would still use biotech seeds,

82% stated that biotechnology is a tool that solves problems that no other technology has been able to solve, and

49% stated that biotechnology does not present a serious ethical problem.

Consumers (survey conducted in various supermarkets):

80% are informed mainly thru TV, 55% thru radio and 50% thru newspapers,

13% DO NOT read the label of a product before purchasing it,

60% have confidence in what they consume,

64% of the consulted consumers stated that, albeit reporting some confusion and hesitation, they heard about biotech foods,

43% agreed with the use of biotechnology in agriculture

40% stated that consumption of biotech products poses some risks to human health

94% of all consulted (both producers and consumers) stated that the government should provide more information regarding the benefits and risks of biotech products.

Appendix A: Biotech Crops Approved in Argentina

Crop	Trait Category	Event	Applicant	Resolution
Soybean	Glyphosate Herbicide Tolerant	"40-3-2"	Nidera S. A.	SAPyA N° 167 (25-3-96)
Maize	Resistant to Lepidoptera	"176" *	Ciba-Geigy	SAPyA N° 19 (16-1-98).
Maize	Glufosinate Amonium Tolerant	"T25"	AgrEvo S. A.	SAGPyA N° 372 (23-6-98)
Cotton	Resistant to Lepidoptera	"MON 531"	Monsanto Argentina S.A.I.C.	SAGPyA N° 428 (16-7-98).
Maize	Resistant to Lepidoptera	"MON 810"	Monsanto Argentina S.A.I.C.	SAGPyA N° 429 (16-7-98).
Cotton	Glyphosate Herbicide Tolerant	"MON 1445"	Monsanto Argentina S.A.I.C.	SAGPyA N° 32 (25-4-01).
Maize	Resistant to Lepidoptera	" Bt 11"	Novartis Agrosem S.A.	SAGPyA N° 392 (27-7-01).
Maize	Glyphosate Herbicide Tolerant	" NK 603 "	Monsanto Argentina S.A.I.C.	SAGPyA N° 640 (13-7-04).
Maize	Resistant to Lepidoptera and Glufosinate Amonium Tolerant	"TC 1507"	Dow AgroSciences S.A. and Pioneer Argentina S.A.	SAGPyA N° 143  (15-03-05)
Maize	Glyphosate Herbicide Tolerant	"GA 21" *	Syngenta Seeds S.A.	SAGPyA N° 640  (22-08-05)
Maize	Glyphosate Herbicide Tolerant and Resistant to Lepidoptera	NK603x810	Monsanto	SAGPyA N° 78  (22-08-05)

				(28/08/07)
Maize	Glyphosate and Glufosinate Herbicides Tolerant and Resistant to Lepidoptera	NK603x1507	Dow Agrosiences and Pioneer Argentina	SAGPyA N° 434  (28/05/08)

- *Production and Commercialization in compliance with Res. 178/07 INASE*
- **Source: CONABIA**

For a complete list of 2006 evaluations, please visit:

http://www.sagpya.gov.ar/new/0-0/programas/conabia/liberaciones_ogm_2006.php

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, n° 20.247/73 and its regulatory decree), and Animal Health (Law of Veterinarian Products, and Supervision of Creation and Commercialization. n° 13.636/49).

The Secretariat of Agriculture (SAGPyA) is the authority that issues the licences for experimentation on and/or release into the environment of genetically modified plant organisms, relying on prior advice 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.

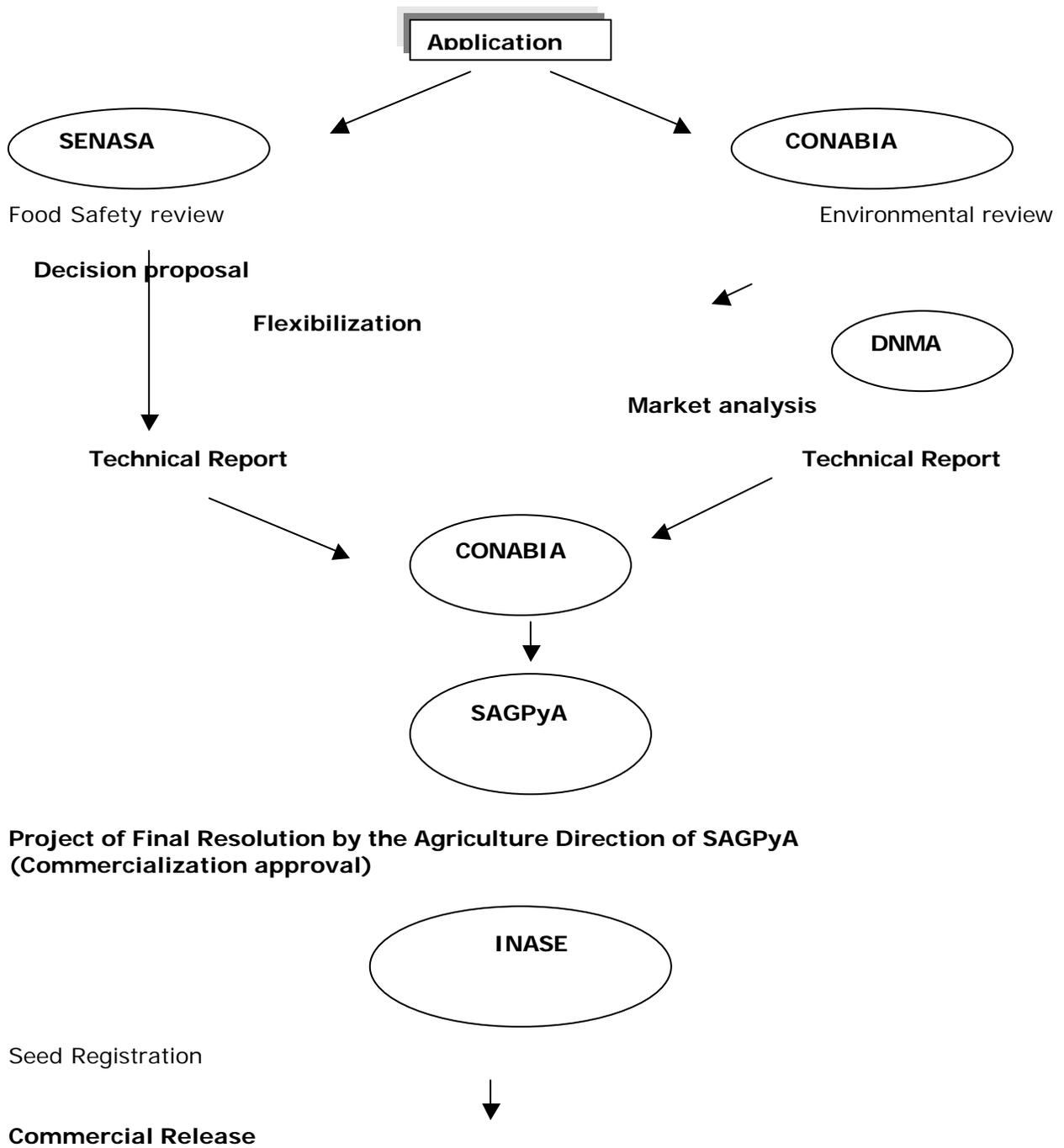
- Upon evaluation of the application, CONABIA shall decide on the suitability of permitting the release of the GMO in question, and shall submit its decision for the approval of the Secretary of Agriculture, Livestock, Fisheries and Food.

- 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, flexibility for the conditions under which the above mentioned permits are granted. Upon receiving approval of the flexibility status permit 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.

Appendix C: Commercial Release Approval Procedure for Biotech Events in Argentina



Appendix D: Field Test Approval Procedure For Biotech Events In Argentina

