USDA Foreign Agricultural Service
GAIN Report
Global Agricultural Information Network

Required Report - public distribution

Date: 12/23/2016

GAIN Report Number:

Argentina

Agricultural Biotechnology Annual

Argentina - Annual Biotechnology Report

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Report Highlights:
Argentina continues to be the third largest producer of biotech crops, producing 14 percent of the world´s total biotech crops. Two genetically engineered events (GE) created by Argentine researchers received final approval, the virus resistant potato and the soybean with drought resistance. China's approval of GE events continues to be a top priority for Argentine foreign trade. The seed royalty system continues to be a problematic issue; the Ministry of Agriculture submitted a new Seed Law proposal to Congress.

Section I. Executive Summary:
Argentina continues to be the third largest producer of biotech crops, after the United States and Brazil, producing 14 percent of the world´s total biotech crops. The country´s area cultivated with biotech varieties in MY2015/16 is 24.54 million hectares. Almost all soybean area is planted with biotech seed varieties, while 95 percent of corn area and 100 percent of cotton area are biotech varieties.

China's approval of GE events continues to be a top priority for Argentine foreign trade, since China is one of the most important markets for Argentine agricultural products. Since 2015 the GOA includes a statement in every final approval of a GE event saying that the event must be approved in China before being commercialized.

The virus resistant potato and new wheat and soybeans seeds with drought resistance, both events created by Argentine researchers, received final approval between late 2015 and early 2016.

The seed royalty system continues to be a highly problematic issue in the country, and after a year of intense debate there is still deep disagreement between the seed companies and the government. The Ministry of Agriculture submitted a new Seed Law Proposal to Congress in October 2016, but the seed companies are not satisfied with the content of the proposal.

Argentina is one of the first countries with a regulatory framework with specific working regulation for products derived from Innovative Biotechnology or New Breeding Techniques (NBTs). This regulation is the outcome of a 3 year debate which took into account the state of the art in NBTs and parallel discussions overseas. It is a product-by-product consideration of the genetic modifications in light of the concept of "novel combination of genetic material."

Argentina continues to be an important ally of the United States in international issues involving biotechnology and was co-complainant with the United States in the World Trade Organization challenge to the European Union moratorium on biotech crop applications. While the lack of an effective royalty collection system is still an important issue, the GOA has placed a priority on stimulating biotech research and innovation. At an international level, MAIZALL, the partnership created by corn growers from Argentina, Brazil and the United States continues to be an effective platform for enhancing industry to industry, government to government and public outreach.

Argentina is active in the development of genetically engineered animals for production of pharmaceutical products, but has not approved any genetically modified animals for food consumption. During 2016, the Ministry of Ag received requests for evaluation of GE animals focused on improving production. As for cloned animals, there are three companies and two public institutions in Argentina able to provide commercial cloning services, mostly for breeding animals. Argentina continues to be very proactive on the issue of somatic cell nuclear transfer (SCNT). The GOA is still in the process of determining its own policy on the technology.

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CHAPTER 1. PLANT BIOTECHNOLOGY

PART A: TRADE AND PRODUCTION

A) PRODUCT DEVELOPMENT

Argentina has a clear intention to continue to be in the forefront in the introduction of innovative technologies to farmers and this is demonstrated in several ways. With 14 GE events approved this year, The *Argentine National Advisory Committee on Agricultural Biotechnology (CONABIA*) set a new record of approvals (although many of those have not received commercial approval yet). It is important to note the development of regulations for Innovative Biotechnologies (NBTs), and the development of new GE varieties by local scientists such as GE herbicide tolerant safflower, and a herbicide tolerant fescue that are currently under evaluation. Final approval was granted to the virus resistant potato and to the soybean with drought resistance created by Argentine researchers.

GE Sugar cane varieties

CONABIA has granted approval to the Round-Up Ready (RR) and the Bt sugar cane varieties, while *National Service of Agricultural and Food Health and Quality (SENASA)* is still performing the evaluation process. Both varieties have been developed by Argentine scientists from Obispo Colombres Experimental Research Station, and Santa Rosa Research Institute. Once approved these varieties would increase yields and therefore help in the development of the economy in this sector. .

High level officials from the Argentine Ministry of Agriculture and accompanied by industry representatives and researchers traveled to Brazil in 2012 to evaluate the possibility of a private joint venture with Brazilian industry in developing a GE drought resistant sugar cane variety. Brazilian researchers - with the input of the Argentine scientists - are working on the development of this variety. However, approval is not expected until 2017, at the earliest. The Argentine industry expressed interest in this trait due to its potential to increase the current sugar cane planted area of 350,000 hectares to an estimated planted area of 5 million hectares in ten years from now. This increase in production would be mainly used for ethanol production.

New GE seeds with drought tolerance for wheat, corn and soybeans received commercial approval

Argentine researchers have isolated the drought tolerance gene (HB4) from sunflowers, and they have inserted it in varieties of corn, wheat and soybeans with promising results. It has been reported that after

three years of field testing in different regions of the country (with different soil conditions and different climates), yields are between 15 and a 100 percent higher than regular. In 2013, the Argentine firm Bioceres, which has been granted a license for the use and exploitation of this gene, signed a joint venture agreement with the French Company Florimond Desprez. These new varieties will be an important milestone for the Argentine agricultural sector since they will help confront the effects of the climate change. It was the first approval for HB4 and the world's first regulatory approval of an abiotic stress tolerance trait in soybeans.

GE potatoes with virus resistance and herbicide tolerance received final approval

GE potatoes with virus resistance (*Potato Virus Y* PVY, and Potato Leaf Roll Virus PLRV) and herbicide tolerance, received commercial approval at the end of 2015. These viruses may cause crop losses of up to 70 percent in Argentina, and therefore this approval is an important improvement for the potato industry.

B) COMMERCIAL PRODUCTION

Argentina is the world's third largest producer of biotech crops, after the United States and Brazil, with forty one biotech crop varieties approved for production and commercialization: eleven soybeans, twenty five corn, four cotton and one potato.

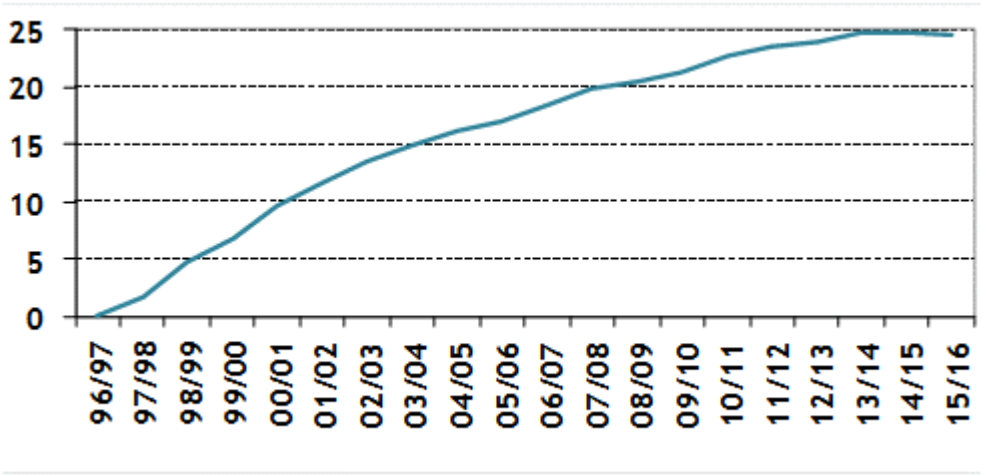
Introduction of biotech soybeans in the late 1990s sparked a rapid expansion of soybean production, which now surpasses 19 million hectares. The country´s total area cultivated with biotech varieties (soybeans, corn and cotton) in MY 2015/16 was 24.5 million hectares.

A study published in November 2016 estimates the total benefit generated by biotechnology in Argentina after (Eduardo Trigo & ArgenBio) as $ 127 billion total since its introduction in 1996. Sixty six percent of that total went to the producers, twenty six percent to the GOA, and eight percent to the technology providers (seeds and herbicides). From the Socioeconomic perspective, the report estimates that approximately 2 million jobs were created during that same period.

China's approval of GE events

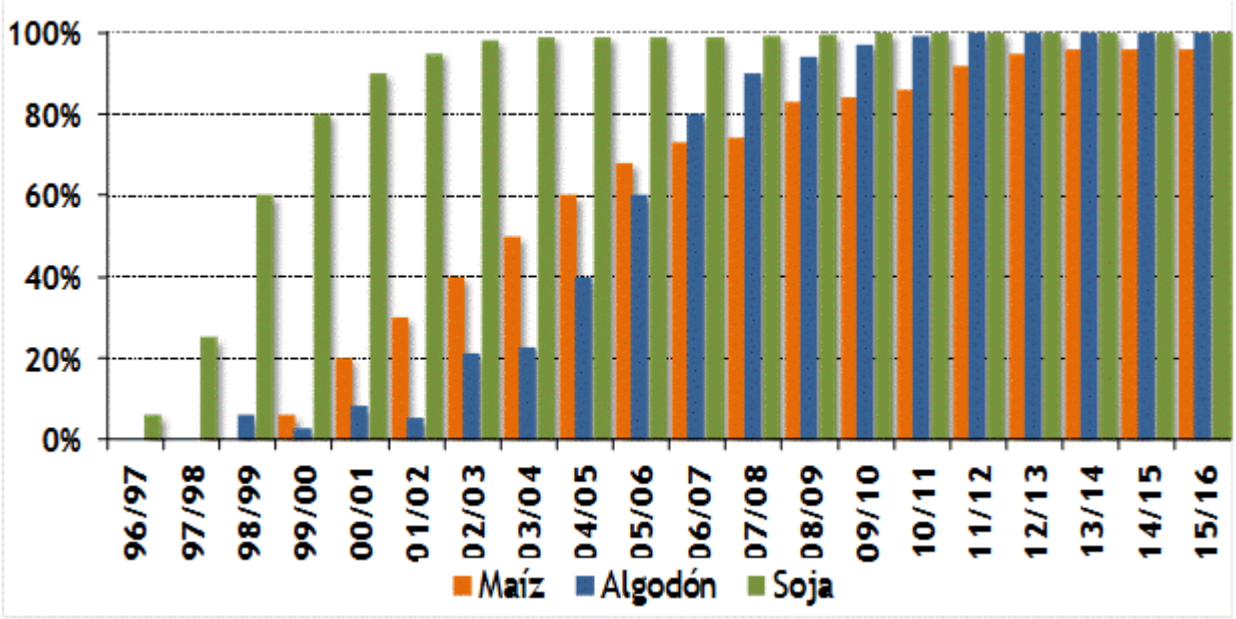
China's approval of GE events continues to be a top priority for the Argentine foreign trade, since China is one of the most important markets for Argentine agricultural products. The industry and government work together stressing to the Chinese authorities the importance to conduct the safety reviews of new events in a timely, science-based manner to avoid asyncrhonic approvals that lead to trade disruptions. A statement requesting that the event must be approved in China before being commercialized is included in approval resolutions since 2015.

Argentina: Evolution of the GE Area (in thousand hectares)
24,54 mi has total



Source: Argenbio

Evolution of GE Area (in percentage, per crop)



CORN COTTON SOYBEAN

Source: Argenbio

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 20 million hectares of soybeans planted for the 2015/2016 season being biotech. The new technology facilitated the incorporation of double crop soybeans (allowing soybeans to be planted following wheat harvest) in many areas where only one crop was planted before the availability of the

biotech varieties. Latest approvals include:
-High Oleic content and Glyphosate Tolerant (DP-305423 x MON-04032-6) from Pioneer Argentina, approved in October 2015
-Drought Resistant, (IND410 (Hb4) from INDEAR, approved in October 2015
-Glyphosate Tolerant, (MON-89788-1) from Monsato Argentina, approved in July 2016
-Lepidoptera Resistant, (MON-87701-2) from Monsato Argentina, approved in July 2016
-Lepidoptera Resistant and Glyphosate and Glufosinate toletant, (DAS-81419-2 x DAS-444Ø6-6 and DAS-81419-2) from Dow Agrosiences approved in October 2016

The Argentine soybean economy is geared almost entirely towards exports, with 20 percent exported as soybeans and the rest processed by the oilseed crushing industry. Ninety-three percent of soybean oil and ninety-nine percent of by-products (meals) are exported. For more detailed information on soybean production, Please see the Argentina Oilseeds and Products Annual Report in the Global Agricultural Information Network (GAIN) system.

Corn

Argentine farmers have been using stacked corn events for nine years. In 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. Latest corn approvals include:

-Lepidoptera resistant and Gluphosinate and Glyphosate Tolerant, (TC1507xMON810xMIR162xNK603) from Pioneer Argentina, approved in March 2016.
-Lepidoptera resistant and Gluphosinate and Glyphosate Tolerant, (MON-89034-3 x DAS-01507-1 x MON-00603-6 x SYN-IR162-5) from Dow AgroSciences Argentina S.R.L. approved in October 2016
- Lepidoptera resistant and Gluphosinate and Glyphosate Tolerant (SYN-BT011-1 x SYN-IR162-4 x MON-89034-3 x MON-00021-9) from Syngenta, approved in November 2016

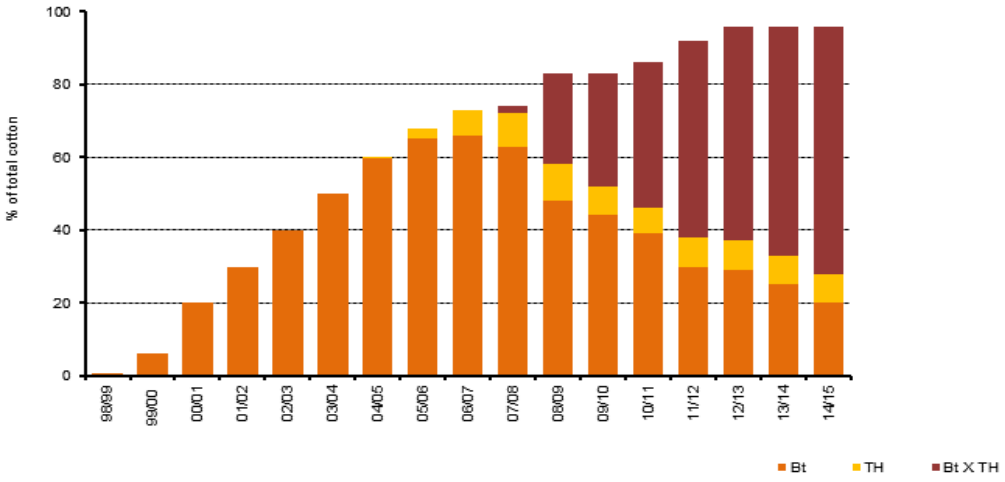
For more detailed information on corn production, Please see the Argentina Grain & Feed Annual Report in the Global Agricultural Information Network (GAIN) system.

Cotton

Biotech cotton adoption represents 100 percent of total cotton planted area . In the 2015/16 crop season 88 percent was planted with the stacked event (Bt x TH), and 12 percent was planted with the glyphosate resistant event (TH). Since the 2011/12 crop season, Argentine farmers have discontinued the used of Bt cotton variety.

In December 2009, Argentina approved the first cotton stacked gene, Monsanto's MON 1445 x Mon 531 (glyphosate tolerance and resistance to Lepidoptera). A variety from Bayer S.A. (BCS-GHØØ2-5 x ACS-GHØØ1-3 GHB614xLLCotton25) was the latest approval granted (approved in November 2015). The graphic below show the high rate of adoption of the Bt x TH event by the Argentine farmers.

Evolution of Area Planted with GE Cotton Varieties



C) EXPORTS

Argentina is a net exporter of GE commodities to numerous markets in the world, including the United States. Export documentation declare content of GE seeds. All events approved and commercialized in Argentina have already received approval from the U.S. regulatory system.

D) IMPORTS

As Argentina is a big producer of commodities imports are generally negligible. Occasionally Argentina imports from Brazil or from the United States.

E) INNOVATIVE BIOTECHNOLOGY (NBTs)

In 2015 the Ministry of Agriculture announced the official regulation that applies to Innovative Biotechnology/ New Breeding Techniques in Plants (NBT). This decision does not alter the regulatory framework applicable to GE events but rather sets forth proceedings to determine the cases in which a crop obtained by NBT that use modern biotechnology to generate genetic modifications are subject to GE rules and regulations.

Argentina is one of the first countries with a regulatory framework where a specific working regulation has been issued for explicitly dealing with products derived from NBTs. The regulation is the outcome of a 3 year debate which took into account the state of the art in NBTs and parallel discussions overseas.

Regulatory Framework for Gene editing and other New Breeding techniques (NBTs) in Argentina

Introduction

Innovative Biotechnology or "New Breeding Techniques" (NBTs) is a term recently developed in reference to emerging technologies for creating genetic diversity in plants using molecular biology techniques. As a category, "NBTs" is neither a science-based nor a strict regulatory term; actually, it does not have a strict definition. Although some lists of technologies have been put together to illustrate the concept (new plant breeding techniques), there is no unified universal list.

The term NBTs emerged as a way of referring to an array of technologies where their advocates expect those products will not be considered "genetically engineered" organisms (GE) in the usual regulatory sense, and therefore be exempted of the regulation for transgenic products. It is recognized that regulators still have to consider the issue, and therefore there is a need of debate and clarification.

Argentina's Regulatory System for Products Derived from NBTs

The Argentine regulatory system for GE events is one of the oldest and more recognized ones. CONABIA has been recognized by the Organization for Food and Agriculture of the United Nations (FAO) as Center of Reference for the Biosafety of GE events.

As one of the leaders among regulatory systems in the world, Argentina recognized early that products derived from Innovative Biotechnology were in the cutting edge of crop biotechnology. Policymakers and regulators debated for over 3 years and they finally produced a regulation specifically aimed to clarify the status of any product derived from NBTs under the current GE events regulation. The following are the main prevailing criteria that explain the basis of the new Argentine regulation,

Cartagena Protocol Definition

Argentina follows the definitions under the Cartagena Protocol on Biosafety (CPB) provided in its regulatory system. By the time the CPB was framed, Argentina was one of the few countries in the world with a full functioning regulatory system for GMO biosafety assessment.
The Argentine experience was taken into account in the formulation of the CPB and the current Argentine regulatory system is fully compatible with it. As a consequence, Argentina and most of its partners for transboundary movements of GE crops currently base their regulation on language similar to that in the CPB. Therefore, the solution found to the NBTs dilemma could be used in the same way by most other countries.

During the debate, policymakers and regulators noted that no difficulties emerged with interpreting the term "organism" or "modern biotechnology" (which in practice means the use of recombinant DNA at some step of the breeding process). Only the term "novel combination of genetic material" was a matter of debate regarding its interpretation.

As a conclusion, "novel combination of genetic material" should be the key to decide if a product derived from NBTs (where NBTs are novel techniques that use recombinant DNA as an aid during the breeding process) is considered or not a GE event.

Flexibility for Future Technologies

As mentioned before, there is no unified reference list of NBTs, nor should there be one since these technologies keep on emerging. For instance, in the seminal lists CRISPR-Cas9 was not included, since that technology was invented later, however it is currently one of the most promising NBTs In addition, although in scientific papers a technology name may be perceived as a clear denomination, discussion with policymakers in Argentina revealed that it was not easy to produce “satisfactory” (technically clear, fit to purpose) legal definitions of the various technologies.

As a conclusion, a new regulation on NBTs should not be based on a closed list or description of particular technologies, but instead it should be framed to be flexible and able to be applied to existing or fore coming technologies as much as possible.

Case by Case Analysis

As it has been noted in the previous paragraph, although certain technology names such as “Cisgenesis," “Reverse Breeding," “Site Directed Nucleases” may be satisfactory for a scientific discussion, when comparing different implementations of an NBT by different research groups, it is evident that differences from one case to another makes it difficult to adopt a definition of one of these technologies for regulatory purposes. For similar reasons, it is difficult to arrive to a “technology-broad” criterion regarding the regulatory status of end products since these can differ significantly.

As a conclusion, the analysis to establish if a certain NBTs-derived crop is a GE event or not can only be made product by product.

How Regulation Works

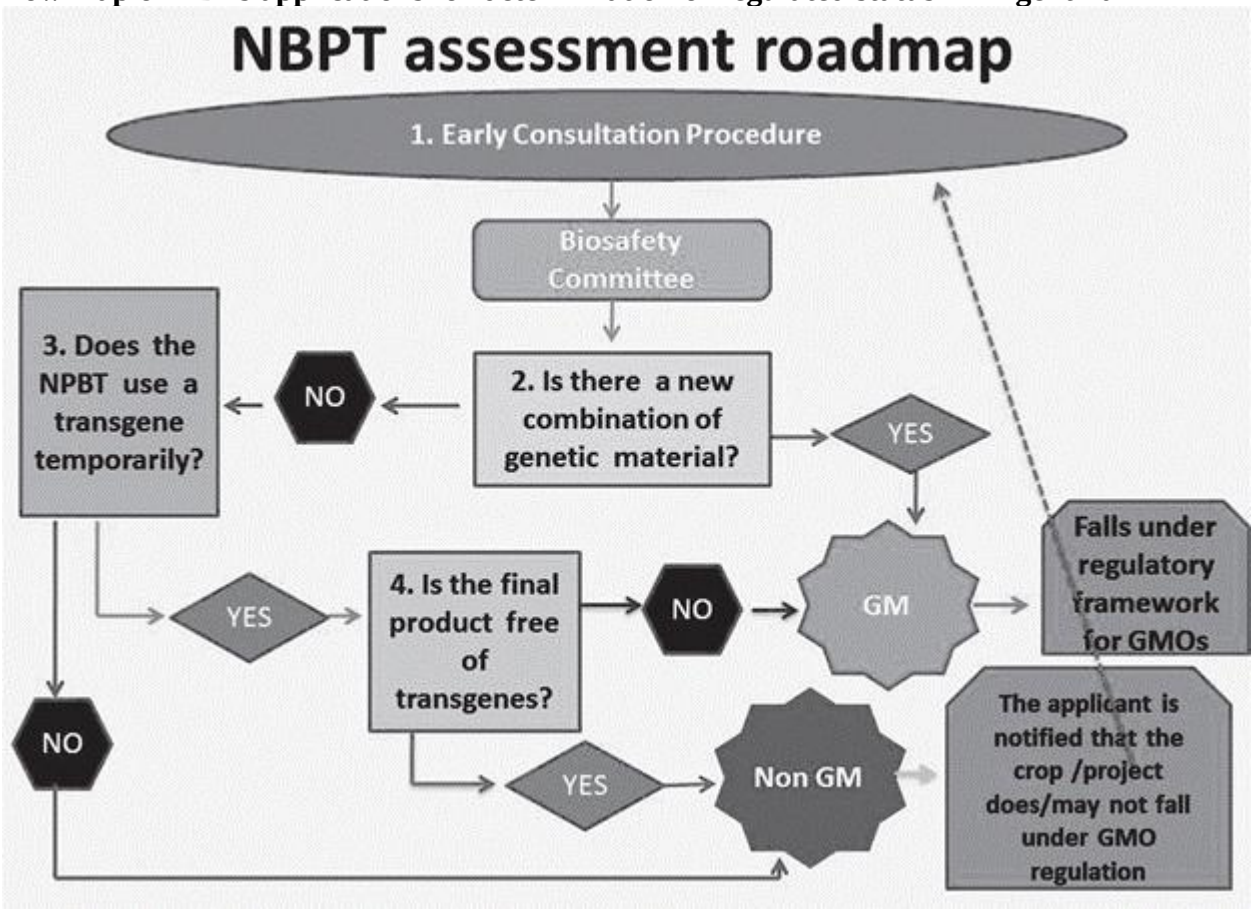
Resolution no. 173/15 of the Secretariat of Agriculture, Livestock and Fisheries (attached as an Appendix) establishes procedures to determine in which cases a crop obtained by breeding techniques involving modern biotechnology does not fall under GE events regulation.
To such end, applicants shall submit each product (NBTs-derived crop) to establish whether the result of the breeding process is a new combination of genetic material or not. A genetic change shall be always regarded as a new combination of genetic material when a stable and joint insertion of one or more genes or DNA sequences that are a part of a defined genetic construct have been introduced permanently into the plant genome. Also, if appropriate, it must be established the existence of enough scientific evidence to support the absence of the transgenes that may have been used transiently during the crop breeding process.

The procedure includes a 60-day time limit and in the end the applicant receives a reply from the authorities stating if the product described falls under the GE regulation or not.
In case the crop is not required to be regulated as a GE event but its features and/or novelty lead to a significant risk hypothesis, this must be also reported by the regulatory commission and such report is channeled to the appropriate regulator of varieties obtained by “conventional ”breeding for consideration.

For projects: Applicants are also allowed to file preliminary inquiries, aiming at anticipating whether a hypothetical expected product would fall under the GE event regulation. This is applicable to projects

still in the design stage. In these cases, the governmental assessment is performed partially on the basis of expectations from the developer, so it will have only a preliminary status. When the new crops are finally obtained, the applicant must still submit factual determinations about the genetic modification actually generated. Only in the event that the product possesses those features anticipated in the preliminary inquiry, the earlier assessment regarding its regulatory status would remain.

Flow map of NBTs applications for determination of regulated status in Argentina



Source: Direction of Biotechnology, Ministry of Agriculture, Livestock, Fisheries and Food

Animals and Microorganisms

The term NBTs is not really used yet beyond plant products. This is because, as mentioned before, the regulatory debate has emerged in relationship with plant products; additionally, regulatory systems for GE plants are in general more developed and sophisticated because more quantity and variety of such products are continuously presented to regulatory systems worldwide for evaluations at different stages.

Nevertheless, it is important to recognize that regulatory frameworks in most cases begin with the same definition of GE events, irrespective of biological kingdom. Therefore, criteria developed for products derived from plant NBTs should be applied to new breeds of animals and microorganism strains developed with the aid of "modern biotechnology" tools.

F) FOOD AID RECIPIENT COUNTRIES

Argentina is not a recipient of food aid recipient and it is not likely to be in the near future.

PART B. POLICY

A) REGULATORY FRAMEWORK

In 2012, Argentine Secretary of Agriculture announced the implementation of the new regulatory framework for agricultural biotechnology in Argentina. The goal with this revamped regulatory system was to reduce the approval time for new events to 24 months. Before the implementation of the new regulatory framework, the approval process used to take approximately 42 months, which is considered very long taking into account the current dynamics of the biotech industry and the fact that Brazil is approving trials at a faster rate than Argentina. According to contacts within the **National Advisory Committee on Agricultural Biotechnology (CONABIA),** the flow of applications has tripled since 1999, while outdated regulations held back field trails and commercial release.

The new regulatory framework for Agricultural Biotechnology was implemented in 2012. It has already accomplished the expected goal of reducing the approval times, and proved to be successful in reducing bureaucracy. Not only there were several events approved after the implementation, but also, the Secretary of Agriculture invited the industry to provide technical suggestions in order to improve even more the efficiency of the new system. These are clear examples of the GOA intention to avoid bureaucracy and prove its commitment to technological development.

The evaluation of new events 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, applying scientific and technical criteria. The Argentine regulation is based upon the characteristics and behaviors identified in the GE event. Regarding the processes used to obtain it, the aspects that may differ with the behavior of the same non-GE organism (conventional counterpart) are taken into consideration, both regarding the agro-ecosystem as well as its safety as food for human and animal consumption.

The key office within the Ministry of Agriculture that centralizes all biotech activities and information is the Biotechnology Direction, created in 2009. This office coordinates three technical areas: biosafety issues (the head is a member of the National Advisory Committee on Agricultural Biotechnology, CONABIA), policy analysis and formulation, and regulatory design.

The approval process for commercialization of biotech seeds involves the following agencies within the Ministry of Agriculture:

-*National Advisory Committee on Agricultural Biotechnology (CONABIA)*
Role: Evaluate impact in the agricultural ecosystem. 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. It 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 on biosafety and the related regulatory processes. It ensures compliance with Resolutions 701/2011 and 661/2011 (please see links below). These new resolutions supersede Resolution 39/2003. CONABIA is a multidisciplinary and inter-institutional organization with advisory duties.

Under the new regulatory framework, the evaluation time for CONABIA is now set at 180 days. Previously there was no timeframe and the approval by this agency could take up to two years. Another difference with the new regulatory system is the inclusion of an instance of prior consultation. Also, the use of electronic forms has been included, where before the companies had to hand deliver documents. This will allow all agencies to access documents at the same time, further speeding up the approval process.

CONABIA has reviewed over 1500 permit applications since its creation, developing new capacities as the sector required. CONABIA is an advisory agency that operates pursuant to a resolution by the Argentine Ministry of Agriculture. In absence of a law governing its reviews, there are limits in its ability to penalize those who do not comply with stipulated procedures.

Resolutions 701/2011 and 661/2011:
http://www.senasa.gov.ar/contenido.php?to=n&in=1001&ino=1001&io=18873
http://www.senasa.gov.ar/contenido.php?to=n&in=1001&ino=1001&io=18840

-*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. They focus on whether the product has been approved or not and, as a result, whether the addition of this event to Argentina's export supplies might represent a potential barrier to the access to these markets. Under the new framework, the DNMA will evaluate the commercial impact on export markets within 45 days. Again, previously there was no time frame for this evaluation.

-*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 a final decision.

B. APPROVALS

Biotech Crops Approved in Argentina

Crop	Trait Category	Event	Applicant	Resolution
Soybean	Glypohosate Herbicide Tolerant	"40-3-2"	Nidera S. A.	SAPyA N° 167 (25-3-96)
Soybean	Resistant to Glufosinate Amonium	A2704-12	Bayer S.A.	(2011)
Soybean	Resistant to Glufosinate Amonium	A5447-127	Bayer S.A.	(2011)
Cotton	Resistant to Lepidoptera	"MON 531"	Monsanto Argentina S.A.I.C.	SAGPyA N°428 (16-7-98).
Cotton	Glypohosate Herbicide Tolerant	"MON 1445"	Monsanto Argentina S.A.I.C.	SAGPyA N° 32 (25-4-01).
Cotton	Resistant to Lepidoptera and Glyphosate Tolerant	MON 1445 x MON 531	Monsanto	(2009
Corn	Resistant to Lepidoptera	"176"	Ciba-Geigy	SAPyA N° 19 (16-1-98).
Corn	Glufosinate Amonium Tolerant	"T25"	AgrEvo S. A.	SAGPyA N° 372 (23-6-98)
Corn	Resistant to Lepidoptera	"MON 810"	Monsanto Argentina S.A.I.C.	SAGPyA N° 429 (16-7-98).
Corn	Resistant to Lepidoptera	" Bt 11"	Novartis Agrosem S.A.	SAGPyA N° 392 (27-7-01).
Corn	Glypohosate Herbicide Tolerant	" NK 603 "	Monsanto Argentina S.A.I.C.	SAGPyA N° 640 (13-7-04).
Corn	Resistant to Lepidoptera and Glufosinate Amonium Tolerant	“TC 1507”	Dow AgroSciences S.A. and Pioneer Argentina S.A	SAGPyA N° 143

Corn	Glypohosate Herbicide Tolerant	"GA 21"	Syngenta Seeds S.A.	SAGPyA N° 640 (22-08-05)
Corn	Glypohosate Herbicide Tolerant **and** Resistant to Lepidoptera	NK603x MON810	Monsanto	SAGPyA Nº 78 (28/08/07)
Corn	Resistant to Lepidoptera and Glufosinate Amonium and Glyphosate Tolerant	1507 x NK603	Dow AgroSciences S.A. y Pioneer Argentina S.R.L.	SAGPyA Nº 434 (28/05/08
Corn	Glypohosate Herbicide Tolerant **and** Resistant to Lepidoptera	Bt11 x GA21	Syngenta Seeds S.A.	(2009)
Corn	Resistant to Lepidoptera	"Mon89034"	Monsanto	(2010)
Corn	Glypohosate Herbicide Tolerant **and** Resistant to Lepidoptera	"Mon 88017	Monsanto	(2010)
Corn	Glypohosate Herbicide Tolerant **and** Resistant to Lepidoptera and Coleoptera	"Mon89034x88017"	Syngenta Agro S.A.	(2010)
Corn	Resistant to Lepidoptera	MIR 162	Syngenta Agro S.A.	(2011)
Corn	Resistant to Lepidoptera and Glypohosate and Glufosinate Herbicide Tolerant	Bt11xGA21xMIR162	Syngenta Agro S.A.	(2011)

Corn	Glifosate tolerant and herbicides that inhibit ALS	DP-098140-6	Pionneer Arg. S.R.L.	(2011)
Corn	Resistant to Coleoptera	MIR 604	Syngenta Agro S.A.	(2012)
Corn	Resistant to Lepidoptera and Coleoptera, and Glypohosate and Glufosinate Herbicide Tolerant	Bt11xMIR162xMIR604xGA21	Syngenta Agro S.A.	(2012)
Corn	Resistant to Lepidoptera and Coleoptera, and Glypohosate and Glufosinate Herbicide Tolerant	Mon 89034 x TC 1507 x NK603	Dow Agro Sciences	(2012)
Corn	Resistant to Lepidoptera and Glypohosate	Mon 89034 x NK603	Monsanto	(2012)
Soybean	Resistant to Lepidoptera Glypohosate	Mon 87701 x Mon 89788	Monsanto	(2012)
Soybean	Resistant to Imidazolinones	CV 127	Basf	(2013)
Corn	Resistant to Lepidoptera, Glypohosate and Glufosinate Herbicide Tolerant	TC1507xMON810xNK603 y TC1507xMON810	Pioneer Argentina	(2013)
Corn	Resistant to Lepidoptera, Glypohosate and Glufosinate Herbicide Tolerant	Bt11xMIR162xTC1507xGA21 and all the intermediate stacked	Syngenta Agro S.A.	(2014)
Soybean	Resistant to 2, 4D, Glypohosate and Glufosinate	DAS-44406-6	Dow AgroSciences S.A.	(2015)

Potato	Virus Resistant	SY233	Tecnoplant S.A.	(2015)
Soybean	High oleic content and glifosate tolerant	DP-305423 x MON-04032-6	Pioneer Argentina S.R.L.	(2015)
Soybean	Drought resistant	IND410 (Hb4)	INDEAR S.A.	(2015)
Cotton	Resistant to Glypohosate and Amonium Glufosinate	BCS-GHØØ2-5 x ACS-GHØØ1-3 GHB614xLLCotton25	Bayer S.A.	(2015)
Corn	Resistant to Lepidoptera, Glypohosate and Glufosinate	TC1507xMON810xMIR162xNK603	Pioneer Argentina S.R.L.	(2016)
Soybean	Resistant to Glypohosate	MON-89788-1	Monsanto Argentina	(2016)
Soybean	Resistant to lepidoptera	MON-87701-2	Monsanto Argentina	(2016)
Corn	Resistant to Lepidoptera, Glypohosate and Glufosinate	MON-89034-3 x DAS-01507-1 x MON-00603-6 x SYN-IR162-5	Dow Agro Sciences Argentina	(2016)
Soybean	Resistant to Lepidoptera, Glypohosate and Glufosinate	DAS-81419-2 x DAS-444Ø6-6 y DAS-81419-2	Dow AgroSciences Argentina S.R.L	(2016)
Corn	Resistant to Lepidoptera, Glypohosate and Glufosinate	SYN-BT011-1 x SYN-IR162-4 x MON-89034-3 x MON-00021-9	Syngenta Agrosciences	(2016)

Source: CONABIA

C) FIELD TESTING

Argentina allows field testing of GE crops, but field crops currently being tested by CONABIA are confidential.

D) STACKED EVENTS

Approval of stacked events is based on a case by case evaluation under which the applicant must to submit a letter simultaneously to the Ministry of Agriculture (Direction of Biotechnolgy) and to the National Service of Agricultural and Food Health and Quality (SENASA) requesting authorization for commercialization of the specific stacked event.

The evaluation is based on possible metabolic interactions between the individual events contained in the stacked event. 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.

E) 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.

F) COEXISTENCE

There is neither policy in place nor rules proposed on coexistence.

G) 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.

The policy of the Ministry of Agriculture 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.

H) TRADE BARRIERS

There are no trade barriers that could negatively affect trade of GE products.

I) INTELLECTUAL PROPERTY RIGHTS

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.

Seed Law – New proposal

Seed royalties were a highly controversial issue in 2016 after the introduction of Monsanto's Intacta soybean variety and a new royalty collection system throughout the country. The Ministry of Agro-Industry initially blocked implementation of the system of testing for unauthorized use and collecting royalties at the point of sale, but subsequently reached an agreement in June on how the system would be implemented for the 2016 crop.

In October 2016, the Ministry of Agro-Industry submitted to Congress a proposal to amend the existing Seed Law to address the issue of intellectual property rights. (Please see text in Attachment II) The seed companies have raised several concerns about the proposed changes and continue to have high

level discussions with the government over the proposal.

The proposed law shields a broad range of producers from paying royalties after the first year of use (between 20 and 30 percent of production by the Ag Ministry's estimates), while allowing the seed companies to try to collect under the Patent Law for the remaining producers for up to 3 years after the initial purchase. The law would also prohibit owners of patents from blocking other companies from using their technology to develop and market new seed varieties.

Biosafety Law

Argentina does not have a biosafety law in place. Initial discussions on developing a biosaftey 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. Private sources have indicated that due to the current conditions at Congress, a Biosafety Law is considered a long term objective.

J) CARTAGENA BIOSAFETY PROTOCOL

In the international biotechnology negotiation arena, the Cartagena Biosafety Protocol (CBP) is probably the most significant issue. GOA officials are very active in working with the other countries of the region towards harmonization. Argentina signed the Biosafety Protocol in May 2000 in Nairobi, Kenya, but has not yet signed its ratification. Argentina is still undergoing a consultation process, analyzing and debating with all the involved sectors the position the country will take in this respect. However, it has become public that Argentina is firmly working towards ratification in the near future.

K) INTERNATIONAL TREATIES/FORA

Codex Alimentarius and Other Agreements

During 2009 Argentina chaired the Codex working group on methods of analysis for GM foods. In addition, the country is actively working to reach consensus on biotech labelling and actively participating to avoid potential trade disruptions and unnecessary cost increases.

MaizALL Alliance between Producers in Argentina, Brazil and the United States

As corn exporting countries whose producers cultivate biotech crops, Argentina, Brazil, and the United States face many of the same barriers to the global sale of corn and corn co-products. As a result, producer organizations from these countries formed an international corn alliance called MaizALL to work together on the following issues:

1. Global asynchronous and asymmetric approvals: The governments and industry of Argentina, Brazil, and the U.S. need to present a unified voice in advocating to foreign governments of major importing countries to synchronize global approvals of biotechnology products and foster the development of policies that manage instances of low level presence (LLP) of not yet approved biotech events.
2. Harmonization of regulatory policies in the Americas: Recognizing the need for harmonization of global regulatory approval processes for new biotech events, the U.S. and South American corn sector would like to see a harmonization of regulatory policies in the Americas with the end objective of

mutual recognition of biotech approvals.
3. Communication on Modern Agriculture: There is consensus on the need to provide better consumer understanding of production agriculture, including the benefits of biotechnology and advancing the global acceptance on the capacity to produce grain for feed, food and fuel.

L) RELATED ISSUES

Ongoing Issues at National Level: The GOA 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.

M) MONITORING AND TESTING

There is no monitoring system in place. Exporters should provide an affidavit stating the content of the shipment. Only in the case of canola (not approved in Argentina), the National Seed Institute (INASE) requires the affidavit and performs tests of the content of the shipment.

N) LOW LEVEL PRESENCE POLICY

Like-Minded Group on Innovative Agricultural Technologies with a focus on GE crops

A group of representatives of exporting countries met in Argentina in 2010 with the intention of setting the scope, aim and priority issues of a like-minded group on innovative agricultural technologies with a focus on cloning and GE crops. Recognizing that agricultural production will need to substantially increase to meet global food demand; understanding that innovative agricultural technologies need to continue to play a critical role in addressing these challenges, and emphasizing the regulatory approaches should be science based, the group was successful in setting the basis for collaborative work especially in the areas of research and education, promotion of utilization of Codex regulations, and support of science based assessments of food, feed and environmental safety. As of 2016, the Like Minded Group continues to be very active.

PART C. MARKETING

A & B) MARKET ACCEPTANCE AND PUBLIC PRIVATE OPINIONS

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. Argentine consumers do not see biotech products as a benefit to themselves but they can see these products as economically productive to farmers and multinational seed companies. Therefore Argentine consumers are still 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 organizations.

C) MARKETING STUDIES

There are no relevant country specific studies on the marketing of GE plants and pant products.

CHAPTER 2. ANIMAL BIOTECHNOLOGY

Argentina produces both GE and cloned animals.

PART E: PRODUCTION AND TRADE

GE Animals

Argentina was the first country in Latin America to develop two generations of genetically modified cows capable of producing Human Growth Hormone. The cloned (but also transgenic) 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. CONABIA 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 approval by the Secretary of Public Health, which is still pending.

There were several projects carried out by Biosidus Company since 2007 but they were discontinued as the company underwent several difficulties which made them unable to continue the research projects. Those projects were: a line of cloned calves to produce insulin and the production of a hormone for bovine growth from cloned and transgenic calves.
Scientists from the National Agricultural Research Institute (INTA), and from the University of San Martin presented the first genetically modified calf that has two human genes introduced in its sequence, which guide the production of two proteins (lactoferrin and lysozyme) contained in human milk. The presence of this proteins in milk, offer infants better antibacterial and antiviral protection, and also better iron capture than the normal cow's milk provides.
The calf was born on April 6, 2011, and fifteen months later using artificial lactation induction the scientists confirmed that both proteins (lactoferrin and lysozyme) are present in its milk.

GE Salmon

In April 2016, US based company AquaBounty Technologies began field trials of its genetically engineered "AquAdvantage" salmon in Argentina. This salmon grows faster than the conventional one, and has a better food conversion. Since mid-2014, the company has been working with local regulatory agencies to prepare for field trials. The company states that AquAdvantage will improve productivity and sustainability for an important food product and opens the door for the application of similar and

new approaches to global protein production.
In 1989, a research team at Memorial University of Newfoundland, Canada discovered that a novel application of molecular genetics could significantly increase the growth of Atlantic salmon. By integrating a Chinook growth hormone gene into the genomics of an Atlantic salmon, they discovered that they could reduce the time to market from three years to 18 months. The company states that "AquAdvantage" will improve productivity and sustainability for an important food product and opens the door for the application of similar and new approaches to global protein production.

Cloned Animals

Research and Development Activity

Cloning research started in Argentina around 1994 in the Institute of Biology and Research Medicine (IByME) with a project for production of in vitro calves. This project was a collaborative effort with the Roslin Institute of Edinburg, Scotland, and later with a Japanese Research group through the Japanese Agency JAICA. In those early years, the project could not get sufficient financial support and it did not work beyond the in vitro experimentation stage. There was no production of embryo cloned cells in Argentina before "Dolly the sheep" in England in 1997, but afterward there was an increase in the number of groups interested in financing cloning research. In addition some private companies began cloning focusing on animals with high genetic value for breeding purposes.

In 2002, the Argentine company Biosidus was the first one in the country to successfully achieve animal cloning. This company obtained genetically modified cows for the production of pharmaceuticals. In 2006, the company Goyaike (partner of the US Cyagra) also successfully cloned cattle with the aim of selling the cloning services to ranchers. Later, the National Institute of Agricultural Technology (INTA), and the University of San Martin produced cloned cattle as well. More recently, the Argentine company New Millenium, cloned goats, sheep, pigs, and cattle, while BioSidus was able to clone a polo horse. Also the Argentine companies Kheiron and Crestview Genetics have been very successful in cloning polo horses.

In 2012, researchers from the University of Buenos Aires (UBA) announced that they are improving techniques to clone animals from regional endangered species. At the moment this group of scientists is working with felines and they have already been successful in producing cheetah and tiger in-vitro embryos. The techniques used by the Argentine scientists aroused the attention of researchers from the Indian government, who after spending a month working at the UBA lab, would implement the same method in their country to create the largest "frozen zoo" in the world.

There are three companies and one public institution in Argentina able to provide commercial cloning services, mostly for breeding animals. There are over 350 animals cloned in the country and to facilitate control (mainly of the ownership of those animals) the Argentine Rural Society has created a Genealogic Registry. It is very unlikely that cloned animals will enter the food chain in the near future as they are still very expensive to produce.

PART F. POLICY

A) REGULATION

The regulatory system applied to transgenic animals is the same used to evaluate plant events, that is, the evaluation takes place on a case-by-case basis. The only agency involved is in this phase is CONABIA. In the event of evaluations for pharmaceutical use, there is another agency involved, the National Administration of Medicines, Food and Medical Technology (ANMAT in Spanish).
The norm applied is Number 57 from 2003. Original text may be found at:
http://www.minagri.gob.ar/SAGPyA/areas/biotecnologia/
On 2013, the Argentine Government under Resolution 177/2013 issued a form that is required to be completed by importers of GE animals intended for lab use. Please see below link to Resolution and form: http://www.infoleg.gob.ar/infolegInternet/verNorma.do?id=213576
For cloning, Argentina is currently in the process of determining its own policy on the technology. Argentina agrees with the United Sates position that cloned animals pose no extra risk to the food supply compared to the conventional ones. The current Argentine approach is that there is no need for specific regulation on such foods, should they ever enter the food chain, as they would be subject to general safety requirements under existing legislation.

B) LABELLING AND TRACEABILITY

There are over 350 animals cloned in the country and to facilitate control (mainly of the ownership of those animals) the Argentine Rural Society has created as a guide a Genealogic Registry. However, this is not the official traceability system adopted by the GOA. It is very unlikely that cloned animals will enter the food chain in the near future as they are still very expensive to produce.

C) TRADE BARRIERS

There are currently no identified trade barriers to trade of GE or cloned animals.

D) INTELLECTUAL PROPERTY RIGHTS

The country does not yet have IPR legislation.

E) INTERNATIONAL TREATIES/FOR A

Argentina has been very proactive on the issue of somatic cell nuclear transfer (SCNT) cloning. GOA representatives have conducted bilateral meetings with representatives of other countries, including the United States. There is also collaboration between scientists of different Argentine research centers (mainly UBA, the University of San Martin, and INTA) and their counterparts in the United States, Canada, Australia, New Zealand and the European Union among others.

JOINT STATEMENT ON ANIMAL CLONING FOR LIVESTOCK PRODUCTION

Intergovernmental meetings to continue exchanges regarding the regulatory and trade-related aspects of livestock cloning in agriculture and food production took place in Buenos Aires in December 2010, March and November 2011, and April and September 2012. Representatives of the governments of Argentina, Brazil, New Zealand, Paraguay, Uruguay, and the United States recognize the increasing pressure being put on limited resources to meet the growing challenges to food security, the importance

of innovation for agriculture, and the essential role that agricultural technologies play in addressing these challenges of meeting the demands of a growing world population. They also note that regulations for somatic cell nuclear transfer (SCNT) livestock cloning, as with other technologies in the agricultural sector, may impact trade and technology transfer, and accordingly invite other governments to consider supporting this document.

The following points are identified:

1. Regulatory approaches related to agricultural technologies should be science-based, and no more trade-restrictive than necessary to fulfill legitimate objectives, and should be consistent with international obligations.
2. Expert scientific bodies around the world have reviewed the effects of SCNT cloning on animal health and the safety of food derived from livestock clones. There has been no evidence indicating that food from clones or the progeny of clones is any less safe than food from conventionally bred livestock.
3. The sexually-reproduced progeny of SCNT clones are not clones. These progeny are the same as any other sexually-reproduced animal of their own species. There is no scientifically justifiable basis for imposing a regulatory differentiation between the progeny of clones and other animals of the species.
4. Restrictions specifically aimed at food from the progeny of clones – such as bans or labeling requirements – could have negative impacts on international trade.
5. Any audit and enforcement measure addressed to progeny of clones would be impossible to apply legitimately and would result in onerous, disproportionate and unwarranted burdens on livestock producers.

Done in Buenos Aires, March 16th, 2011

PART G. MARKETING

A&B) MARKET ACCEPTANCE & PUBLIC/PROVATE OPINIONS

There haven't been reactions in favor or against the development of transgenic animals. The main reason may be that the first cows produced were intended for pharmaceutical use, and that in general produces less reaction.

C) MARKET STUDIES

There are no relevant market studies on animal biotechnology in the country.

APPENDIX I: Resolution 173

Innovative Biotechnology/NBTs

BUENOS AIRES,
Having reviewed file No. S05:0001472/2015 of the Registry of the Ministry of Agriculture, Livestock and Fisheries, and Food

WHEREAS:
Decree No. 763 dated August 17, 2011 of the Ministry of Agriculture, Livestock and Fisheries (MAGYP) sets forth the guidelines for the activities involving Genetically Modified Organisms (GMO) in the Republic of Argentina.
Pursuant to article 3.A of the Resolution No. 763/11, risk assessment, design of biosafety measures and risk management during each stage of GMO assessment hereof shall be conducted by the National Advisory Commission on Agricultural Biotechnology (CONABIA), which Executive Secretariat is held by the Biotechnology Directorate of the National Directorate of Processes and Technologies of the Under secretariat of Added Value and New Technologies under the Secretariat of Agriculture, Livestock and Fisheries (SAGYP) under the MAGYP.
Article 3 of Resolution (SAGYP) No. 437 dated August 06, 2012 sets forth as actions pertaining to CONABIA, among others, to advise the Secretary of Agriculture, Livestock and Fisheries on "risk assessment, design of biosafety measures and risk management in the various stages of assessment, authorization and release into the agro-ecosystem of genetically modified organisms "and "every issue to be submitted to its scientific evaluation".
Resolution (SAGYP) No. 701 dated October 27, 2011 sets forth the requirements and proceedings that must be met by biosafety assessments for the release of GM-plants into the agro-ecosystem.

Resolution No. 701/11 defines GM-plant as a plant organism bearing a combination of genetic material obtained through the application of modern biotechnology.
Such regulation defines event as "the combined and stable insertion into the plant genome of one or more genes or DNA sequences that are part of a defined genetic construct".
The development of agricultural biotechnology is a key tool for the addition of value in the agribusiness value chain in the Argentina Republic.
In the Argentina Republic, as in the rest of the world, mayor advances are being produced in the development of new breeding techniques in plants (NPBT).

The characteristics of the crops derived from these techniques are of such heterogeneity that demand a prior scientific assessment in order to determine whether any such crop falls under the rules and regulations applicable to GM-plants or, on the contrary, are not subject to such regulations.

This decision does not alter the regulatory framework applicable to GMO but rather sets forth proceedings to determine the cases in which a crop obtained by NBT that use modern biotechnology to generate genetic modifications are subject to GMO rules and regulations.
CONABIA, after extensive debate in several of its meeting during 2013 and 2014 has rendered its agreement to this regulation during its ninth meeting of the year 2014, which took place on November 25, 2014.
The General Directorate of Legal Affairs of the Ministry of Agriculture, Livestock and Fisheries has expressed its legal opinion.

The Secretary of Agriculture, Livestock and Fishery has the authority to render this resolution pursuant to Decree No. 357 dated February 21, 2002 as amended.

Therefore,

The Secretary of Agriculture, Livestock and Fisheries hereby orders as follows:

Article 1.- The proceedings to determine in which cases a crop obtained by new breeding plant techniques (NBPT) using modern biotechnology techniques, does not fall under GMO rules and regulations pursuant to Resolution (MAGYP) No. 763 dated August 17, 2011 and its complementary regulations are hereby enacted.

Article 2.- In order to determine whether a specific case is subject to the proceedings herein, Applicants shall submit such case for the assessment of CONABIA through a Previous Consultation Stage ("ICP") pursuant to Resolution No. 701/11. During the ICP the Applicant shall submit data on the breeding methodology used to obtain and select the crop, on the new trait or characteristic introduced, and on evidence of the genetic changes present in the final product.
Within the ICP, the applicant shall request CONABIA to establish whether the result of the breeding process is a new combination of genetic material. A genetic change shall be regarded as a new combination of genetic material when the assessment establishes that a stable and joint

insertion of one or more genes or DNA sequences that are a part of a defined genetic construct have been inserted into the plant genome.

Article 3.- GM-plant offspring shall be regarded as a GM-plant unless the scientific data allows to draw a different conclusion. Thus, in addition to the provisions contained in Article 2 herein, applicants shall inform if any event that is no longer present in the crop to be introduced into the agro-ecosystem was used during the breeding process and include evidence of the absence of the event(s) under consideration during the in ICP.

Article 4.- The Biotechnology Directorate will conduct a preliminary assessment on the data furnished by applicants in a period that shall not exceed sixty (60) calendar days, and proceed to list the matter for debate in the following CONABIA meeting. On the basis of the information filed during the ICP, CONABIA will establish whether a new combination of genetic material has been created. Also, if appropriate, CONABIA will determine if there exists enough scientific evidence to support the absence of the event(s) used transiently during the crop breeding process. Both the Biotechnology Directorate and CONABIA may request the Applicants to file additional data and information in order to complete their assessments.

Article 5.- Upon CONABIA finding that a new combination of genetic material has not been created and, if applicable, that no unauthorized events subsist in the crop, the SAGYP, through the Biotechnology Directorate shall notify the Applicant that the product does not fall under the scope of Resolution No. 763/11 and its complementary regulations.
Notwithstanding the aforementioned, CONABIA may still recommend the Secretary of Agriculture, Livestock and Fisheries, the adoption of follow-up measures for an individual crop taking into account its features and/or novelty on scientific and technical grounds.

Article 6.- Applicants must be registered under the National Registry of Operators with Genetically Modified Plants Organisms (RNOOVGM) set forth by Resolution (ex-SAGPYA) No. 46 dated January 7, 2004 before filing for the ICP. Non-registered applicants shall file equivalent documents with the Biotechnology Directorate in order to prove the applicants' legal standing. If the product is considered a GM-Plant, applicants must register under the RNOOVGM before filing their first application for GM-Plant release.

Article 7. - Applicants may file for a preliminary inquiry aiming at anticipating whether a hypothetical expected product derived from new plant breeding techniques in projects still in the design stage would fall under the scope of Resolution No. 763/11 and its complementary "2015 - AÑO DEL BICENTENARIO DEL CONGRESO DE LOS PUEBLOS LIBRES" regulations. In these cases, no registration under the RNOOVGM or equivalent documentation shall be required and CONABIA shall perform a preliminary assessment and provide an indicative answer that the Biotechnology Directorate will notify applicants. If such new crops are obtained, they shall be subjected to the provisions hereinabove in order to establish whether they possess the new features anticipated in the preliminary inquiry.

Article 8.- This resolution shall come into full force and effect as from the day after its publication in the Official Gazette.

Article 9.- Be it communicated, published, given to the National Directorate of the Official Registry and filed.-.Sgd.: G DELGADO. Secretary of Agriculture, Livestock and Fisheries.

RESOLUTION SAGYP No. 173

Disclaimer: The English version of this regulation is offered for illustrative purposes only and should not be regarded as an official translation; since English is not the official language of the Republic of Argentina, in case of disagreement between the Spanish and the English version, the Spanish version shall fully prevail.

Attachment II
Seed Law Proposal (Final to Congress on October 13, 2016)

[Seal:] ARGENTINE HOUSE OF REPRESENTATIVES – INCOMING CORRESPONDENCE DESK – OCTOBER 2016 - *SEC* PE No. 30 TIME: 07:55 pm

BUENOS AIRES, October 13, 2016

TO THE HONORABLE ARGENTINE CONGRESS,

I hereby submit for consideration by this Honorable Congress the Bill of Amendment to the Seeds and Phytogenetic Creations Law No. 20,247, which was enacted into law and promulgated on March 30, 1973.

As such Law was passed in the 70s it fails to take into account the new production realities, technological advances in the field of seed production and research, new organizational and corporate forms related to the agricultural business, crop diversification or the change in the agricultural boundaries as a result of genetic improvement.

Based on such changes and taking into account the importance of agriculture to our country, it is deemed necessary to consider the role of each one of the players involved in the agricultural chain in the new productive context and fairly balance the interests of all and each of such players and public and private interests, and further empowering the Government in its capacity as representative of the general interest in any potential event where such interest may be at risk, as guarantor and comptroller of such system.

For such purposes, the bill declares that compliance with the sections that constitute exceptions to the seed breeder's right is a question of public order, as is the method of collection of payments for intellectual property rights, since such compliance is required in order to avoid distortions in the commercialization chain, thus affecting an activity with a high impact on society at large.

On the other hand, various factors have been considered for purposes of the proposed amendments, such the dynamics of the seed business, the public policies so far promoted by the ARGENTINE GOVERNMENT in the industry, the needs of players involved in the production and commercialization chain, the national and international impact, the rules and regulations with which their provisions are combined, among others.

Based on the foregoing, the proposed amendment to Law No. 20,247 seeks to maintain the spirit of the law then taken into account by the lawmakers while updating certain provisions and making them consistent with current production reality, including the regulations of aspects that were not contemplated at the time of enactment thereof.

Accordingly, the MINISTRY OF AGRICULTURE has given priority –among its objectives- to manage the seed market regularization, to the transparency in all links of the production chain, to the innovation and dissemination of technologies, access to such technologies by potential users and fair compensation to intellectual property right holders, balancing the interests of all and each of the players, from a broad perspective including growers, breeders, multipliers, and holders of new technologies.

In this context, the ARGENTINE GOVERNMENT must optimize control over development of seed production and commercialization activities through the NATIONAL SEED INSTITUTE, an autarchic agency reporting to the MINISTRY OF AGRICULTURE, which has principal authority in this field.

The proposed language continues to adhere to the "1978 Act" - the Act of October 23, 1978 of the International Convention for the Protection of New Varieties of Plants – of UPOV (International Union for the Protection of New Varieties of Plants) to which our country has adhered pursuant to Law No. 24,376, enacted on October 20, 1994.

The exception to the breeder's right contained in Section 27 of Law No. 20,247 remains in full force and effect in the bill. Such exception is related to saving seed by the farmer, who may save and use the harvested product for no consideration. The restriction of this farmer's right takes place when certain conditions are met in relation to the difference between the new planting and the area planted in the original period and where growers exceed certain levels of income.

In addition and so that the holders of intellectual property rights – whether breeder's rights or

patents over the technology contained in the variety- may obtain a return on the investment and development of technologies used in improving the new varieties, this bill contains a provision to secure collection of fees for all intellectual property contained in the seed and the products resulting from use thereof and/or the built-in technology, in the price paid upon purchasing the seed, which provides for transparency and control of the seed market in the national territory.

On the other hand and in furtherance of predictability in planning the activity by each of the players in the chain, the bill further provides for the obligation to establish the additional value that the holder of intellectual property rights or its licensee may require on account of intellectual property upon purchase of the seed, in the contemplated events, for use of the seed and the products resulting from use thereof.

The farmer's exception remains unchanged for family farmers or natives and for small farmers. In addition, in the event of extensive farming, most of the growers remain exempt from any payment subsequent to purchasing the seed. For large scale growers, the breeder may require payment in the event that the new planting takes place over an area in excess of the hectares planted in the original period and for THREE (3) multiplications subsequent to the purchase for the originally acquired area.

In sum, this bill seeks to fairly integrate the needs of all players, providing certainty to the grower in relation to the method of payment and price, while maintaining most growers (small growers, family farming and natives) released from payment for saving seed and encouraging development of germplasm, innovation and incorporation of technologies, providing for predictability in the business and efficient tools and resources to attain the objectives of control, auditing and transparency in the seed market, which is a commitment undertaken by the NATIONAL EXECUTIVE BRANCH OF POWER.

Let God protect your Honorability.

MESSAGE No. 126

[Signature] Ricardo Buryaile, CPA – Minister of Agriculture

[Signature] Marcos Peña – Chief of Ministers Cabinet

[Signature]