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Agricultural Biotechnology Annual

Argentina Annual Biotechnology Report

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Report Highlights:
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. China's approval of GE events continues to be a top priority for Argentine foreign trade. For the first time a resolution approving a GE event included a requirement stating that the event must be approved in China before it can be commercialized. The seed royalty system continues to be a problematic issue in the country, and the Government of Argentina (GOA) decided that a targeted law addressed in Congress, is the appropriate legal mechanism for establishing a system that would meet the needs of all parties involved.

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 MY2015/15 is 24.94 million hectares, 150,000 more hectares from the previous year. 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. For the first time, in the Resolution approving Dow's event DAS-44406-6 (approved in April 2015) a statement was included saying that the event must be approved in China before being commercialized.

The seed royalty system has been problematic in the country for over six decades and recently spurred on by the recent spate of problems surrounding Monsanto's purportedly contentious royalty collection system, the Government of Argentina (GOA) is taking action to address the seed royalty system at large and has now decided that a targeted law, addressed in Congress, is the appropriate legal mechanism for establishing a system that meets the needs of everyone: the producers, the associations, the exporters, the seed companies, and the GOA.

On May 12, 2015, the Ministry of Agriculture announced the official regulation that applies to New Breeding Techniques in Plants (NBT). This decision does not alter the regulatory framework applicable to Genetically Modified Organisms (GMOs) 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.

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 a royalty collection system is still an important issue, the GOA has placed a priority on stimulating biotech research and innovation. At an international level, corn growers from Argentina, Brazil and the United States signed an agreement and created a partnership called MAIZALL, which represents an effective platform for enhancing industry to industry, government to government and public outreach. MAIZALL is intended to provide a mechanism through which producer organizations can collaborate on a global basis to address key issues concerning biotechnology, food security, stewardship, trade, and producer image.

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. As for cloned animals, there are three companies and one public institution 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 be in the forefront in the introduction of innovative technologies to farmers and this is demonstrated in several ways, such as the development of regulation of New Breeding Techniques, the development of several new GE varieties by local scientists: GE resistant sugar cane varieties, a new virus resistant potato, and new wheat and soybeans seeds with drought resistance also created by Argentine researchers.

GE Sugar cane varieties

The *Argentine National Advisory Committee on Agricultural Biotechnology (CONABIA*) has already granted approval to the Round-Up Ready (RR) and the Bt sugar cane varieties and the *National Service of Agricultural and Food Health and Quality (SENASA)* is currently performing the evaluation process. Both varieties have been developed by Argentine scientists from Obispo Colombres Experimental Research Station, and Santa Rosa Research Institute. It is estimated that the commercial approval for the RR variety may be granted by the end of 2015. Once approved these varieties would increase yields and therefore help in the development of regional economies.

In 2012 Argentina led a mission to Brazil with high level officials from the Argentine Ministry of Agriculture and accompanied by industry representatives and researchers 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 already 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. Mission members expressed confidence that the agreement with Brazil would be signed shortly.

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

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. The new venture, named *Trigall Genetics*, is targeting a 2016 launch for wheat varieties that contain the HB4 technology. These new varieties will be an important milestone for the Argentine agricultural sector since they will help confront the effects of the climate change. The GE wheat has not been approved yet in any country, therefore Argentina has good chance to be the first country in the world. CONABIA has already granted approval to the soybean variety which is currently under the evaluation of SENASA. 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

According to contacts within the industry, it is estimated that GE potatoes with virus resistance (*Potato Virus Y* PVY, and Potato Leaf Roll Virus PLRV) and herbicide tolerance, already approved by CONABIA and under SENASA's evaluation, might be commercially approved by the end of 2015. These viruses may cause crop losses of up to 70 percent in Argentina, and therefore this approval may be 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 thirty one biotech crop varieties approved for production and commercialization: six for soybeans, twenty two for corn, and three for cotton.

Introduction of biotech soybeans in the late 1990s sparked a rapid expansion of soybean production, which now surpasses 21.8 million hectares. The country´s total area cultivated with biotech varieties (soybeans, corn and cotton) in MY 2014/15 is 24.94 million hectares, 150,000 more hectares from the previous year.

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.

For the first time, in the approval Resolution of Dow's event DAS-44406-6 (approved in April 2015) it was included a statement requesting that the event must be approved in China before being commercialized. When consulted, the Argentine Government authorities stated that this inclusion does not mean that the requirement will be included in every approval resolution from now on, although they

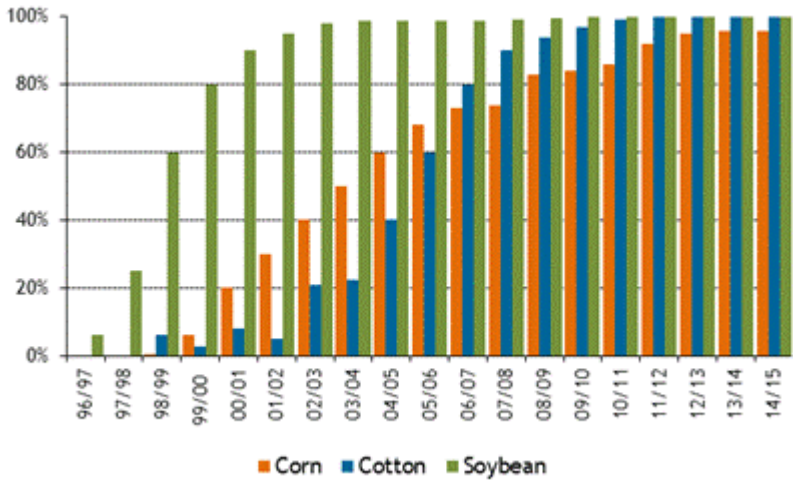
might request the companies to sign a document (that should be included as part of the dossier) agreeing not commercialize an event approved in Argentina before it is approved in China.

Argentina – Evolution of GE Area (in thousands hectares)

	Soybean		Corn			Cotton			Total
	TH	Bt X TH	Bt	TH	Bt X TH	Bt	TH	Bt X TH	
96/97	370	-	-	-	-	-	-	-	370
97/98	1.756	-	-	-	-	-	-	-	1.756
98/99	4.800	-	13	-	-	5	-	-	4.818
99/00	6.640	-	192	-	-	12	-	-	6.844
00/01	9.000	-	580	-	-	25	-	-	9.605
01/02	10.925	-	840	-	-	10	-	-	11.775
02/03	12.446	-	1.120	-	-	20	0,6	-	13.586
03/04	13.230	-	1.600	-	-	58	7	-	14.854
04/05	14.058	-	2.008	14,5	-	55	105	-	16.241
05/06	15.200	-	1.625	70	-	22,5	165	-	17.082
06/07	15.840	-	2.046	217	-	88	232	-	18.423
07/08	16.600	-	2.509	369	82	162,3	124	-	19.846
08/09	17.000	-	1.536	320	800	72	210	-	19.938
09/10	18.182	-	1.408	256	992	42,3	47	367	21.294
10/11	18.700	-	1.599	287	1.640	7,7	55,9	552,3	22.842
11/12	18.800		1.400	400	2.400	-	69	506	23.575
12/13	19.120	-	1.322	365	2.689	-	52	378	23.926
13/14	20.438	62	975	312	2.457	-	66	484	24.794
14/15	20.500	634	700	280	2.380	-	54	396	24.944

Source: Argenbio

Argentina - Evolution of GE Area

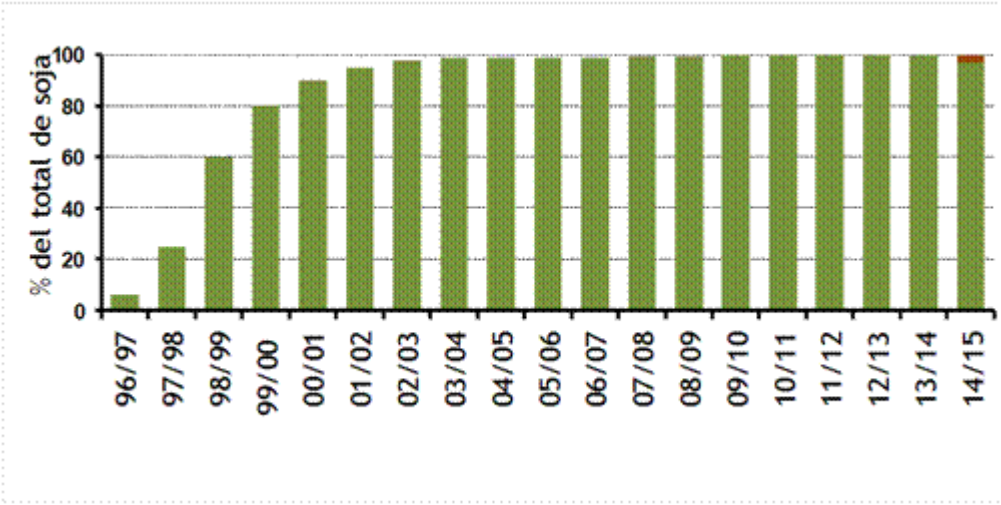


Soybeans

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 21.8 million hectares of soybeans planted for the 2014/2015 season being biotech. In this last crop season, 20.5 million and 634,000 hectares were planted with TH and Bt X TH soybeans respectively. 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.

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.

Argentina - Evolution of GE Soybeans



2014/2015: -97% TH soybean -3% Bt X TH soybean

Source: Argenbio

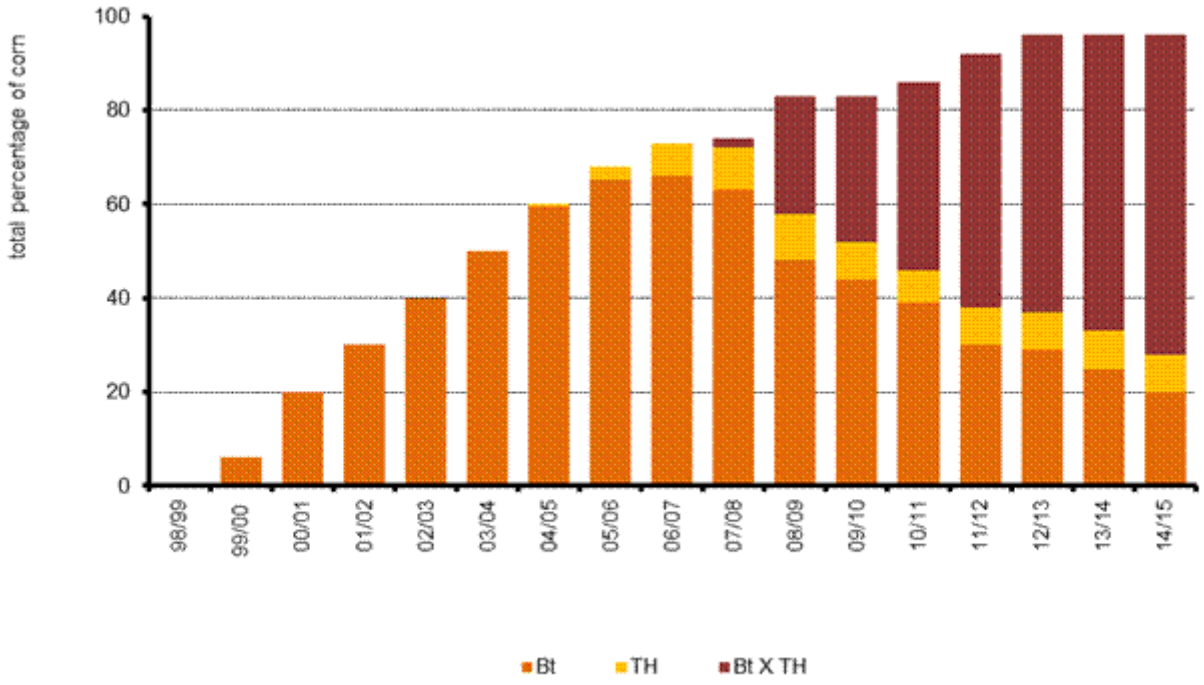
Corn

Argentine farmers have been using stacked corn events for eight 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. On that same year Argentina approved the first stacked gene, Monsanto's NK603x810. Recent corn approvals include Pionner's TC1507xMON810xNK603 y TC1507xMON810 (approved on October 2013) and Syngenta's Bt11xMIR162xTC1507xGA21 (approved on April 2014).

Biotech corn adoption represents 95 percent of total corn planted area, 3.36 million hectares. In the 2014/2015 crop season the area planted with stacked events (Bt x TH) accounted for 71 percent of the total area (approx. 2.380 mill hectares). The rest of the biotech corn planted corresponded to Bt, estimated in700,000 hectares, representing approximately 20 percent, and glyphosate tolerant variety (GA 21) with 280,000 hectares planted, accounting for nine percent of the total biotech corn.

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

Evolution of Area Planted with GE Corn Varieties



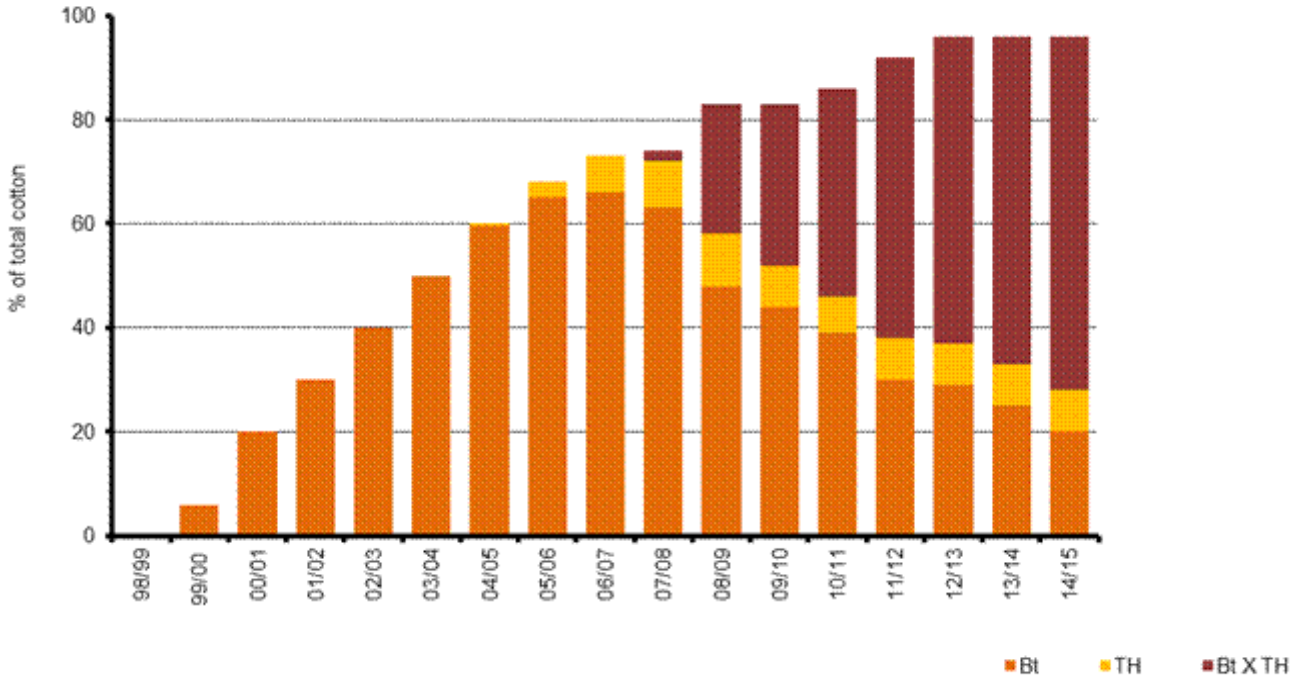
Source: ArgenBio

Cotton

Biotech cotton adoption represents 100 percent of total cotton planted area (450,000 hectares). In the 2014/15 crop season 88 percent (396,000 hectares) was planted with the stacked event (Bt x TH), and 12 percent (54,000 hectares) 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). The graphics below show the high rate of adoption of this event by the Argentine farmers.

Evolution of Area Planted with GE Cotton Varieties



Source: Argenbio

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) 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

New Regulatory Framework for Agricultural Biotechnology in Argentina –Third Year of Implementation

On March 16, 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.

This new framework was a result of a two year long coordinated effort by many sectors in Argentina. In December 2010 Argentine Secretary of Agriculture Lorenzo Basso signed an agreement with the Argentine Seed Association (ASA) to develop a working plan to identify the problems in the Argentine regulatory system. To comply with this goal they created five working groups where each group analyzed a different phase of the approval process, and developed proposals to improve its efficiency.

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	SAGPyA N° 143

			Pioneer Argentina S.A	
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)

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.

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, but was not successful in the legal action.

Agreement between Monsanto and the farmers

In 2011, and before bringing the new soybean RR2Y and/or RR2YBt technologies varieties to Argentina, Monsanto developed a private agreement that is signed between the company and the farmers. The system does not apply to the first generation of the Roundup Ready technology (known as the 40-3-2 event).

In case the RR2Y and/or RR2YBt technologies are available in the country and if the farmers decide to use such technologies they commit to:

- Purchase soybeans containing Monsanto's RR2Y and/or RR2YBt technologies from Monsanto or Licensees authorized by Monsanto
- Plant such seeds within the Argentine territory.
- Commercialize grains obtained with those exporters or grain elevators participating in the system,
- Pay the corresponding royalties for each use of such technologies upon the purchase of seed bags of certified soybeans, or upon statement and planting of seeds for own use, or upon the delivery of such grains to the exporter or grain elevator participating in the system,
- Use the RR2Y and/or RR2YBt technologies pursuant to the commercialization system established by Monsanto, which will be in line with the good agricultural practices system as defined by the Argentine Seed Association.
- Locate geographically, along with Monsanto, the farmer's plots during the planting of soybeans containing the RR2Y and/or RR2YBt technologies.

Other considerations of the agreement:

- Payment of royalties shall entitle the farmer to plant soybean seeds containing the RR2Y and/or RR2YBt technologies in the country and commercialize a definite number of tons of grains harvested.

- Exporters and grain elevators participating in the system shall evaluate the presence of the RR2Y and/or RR2YBt technologies in the grain they receive.
- Monsanto shall be entitled to evaluate the presence of the RR2Y and/or RR2YBt technologies in the farmer's fields through inspections and sample taking.
- In the event that royalties have not been paid before delivering the grains to the exporter/grain elevator participating in the system, the amount due for royalties shall be received by such participant and sent to the supplier of the technology on behalf of the farmer. That could lead to an adjustment in the grain transaction in order to reflect such payment.

This agreement does not represent a license or authorization to use of the RR2Y and/or RR2YBt technologies. The use of such technologies shall be subject to the terms of the agreement and the corresponding license for commercial use.

Monsanto obtained a high rate of acceptance of this agreement among farmers since 2004. However, a dispute aroused after farmers conclude their first growing season using Monsanto's *Intacta* soy. The Argentine Rural Confederation (CRA), one of the main Argentine farmers Associations representing over 100,000 farmers, advised its members to reject the "abusive" option of paying royalties for future output when buying seeds. After other farmer associations adhered to CRA, the government decided to step in the middle of the battle between Monsanto and farmers over royalties the U.S. companies want to collect for GM seeds. The government first announced a Decree of Urgent Necessity "DNU" (akin to an executive order) to resolve the matter with Monsanto, but then changed its approach and decided that a targeted law, to be addressed in Congress, would be the appropriate legal mechanism for establishing

a system that meets the needs of everyone: the producers, the associations, the exporters, the seed companies, and the GOA.

Seed Law – New proposal

The current Argentine Seed Law allows producers to retain seeds for future use 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. According to official numbers, 15 percent of the total area planted with soybeans in Argentina is sown with seeds purchased from authorized dealers; 35 percent with seeds saved by farmers for their own use, and the remaining 50 percent with seeds selected and sold illegally.

Contacts within the GOA stated that a new law is necessary, since lawyers currently dispute whether seed royalty collection falls under the seed law or intellectual property rights law. The draft law is at President's Office at the moment and it is estimated that it would be sent to Congress as soon as practicable.

There are three pillars in the proposed draft law:

1. Seed companies set their own royalty prices and contracts directly with producers. Producers pay the royalty fees when purchasing seed. Other than at point of sale, seed companies will have no other opportunity to collect royalty fees from producers. No GOA involvement in this phase.

1. All sales are recorded in a registry, under the control of the Federal Administration of Public Income (AFIP). The registry will give the GOA knowledge of the seed companies' market share.

1. For those farmers who hold over some grain from their harvest to use as seed to plant for the next year, a practiced known as "*uso propio*," (self use in Spanish) the GOA will demand that farmers pay a fixed fee, on a per hectare basis, to the Ministry of Agriculture. The collection of this fixed fee will go into a trust fund, from which 80% will go back to the seed companies, proportionately to their market share and seed variety sold, and 20% will go into a research fund administered by the Ministry of Agriculture.
    a. The Ministry of Agriculture will determine the fixed fee, based on what it believes is just and taking into account input from both the farmers and the seed companies.
    b. The objective is to set a fixed fee high enough to disincentive as much as possible the practice of "*uso propio*."
    c. The Ministry will administer the research fund by setting research objectives and public calls for proposals. The seed companies who win the contracts will receive the research funds respectively.

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. 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.

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 Agreement between 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, it is proposed that an international maize alliance with these and other likeminded countries 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

1. Argentina announced policy on New Breeding Techniques (NBT)

On May 12, 2015, the Ministry of Agriculture announced the official regulation that applies to New Breeding Techniques in Plants (NBT). This decision does not alter the regulatory framework applicable to Genetically Modified Organisms (GMOs) 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.

In Argentina, as in the rest of the world, major advances are being produced in the development of NBT. 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 GE-plants or, on the contrary, are not subject to such regulations. The National Advisory Committee on Agricultural Biotechnology (CONABIA) has agreed on this regulation after extensive debate in several of its meeting during 2013 and 2014.

2. 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

First Meeting of the Like-Minded Group on Innovative Agricultural Technologies with a focus on GE crops

A group of representatives of exporting countries met in Argentina in 2012 with the intention of setting the scope, aim and priority issues of a like-minded group on innovative agricultural technologies with a focus on 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.

PART C. MARKETING

A & B) MARKET ACCEPTANCE AND PUBLIC PRIVATE OPINIONS

Monsanto Seed Plant construction halted in Cordoba Province

After Monsanto's announcement of its new plant in Cordoba province in 2012, several NGOs and consumer associations expressed deep concern and published several articles about possible negative impacts on human health and the environment. But in 2014 opposition grew to the point that activists of local environmental organizations blockade the construction site for over three months preventing workers from completing work on the plant. It is claimed that there were violations of environmental laws that occurred in the provincial Ministry of Environment, the authority that granted the authorizations. A labor appeals court ruled that the construction of the plant is unconstitutional and halted work on the site, until a new environmental assessment is completed to determine the plant's future impact on the area.

As the Monsanto Plant issue gained publicity on TV and newspapers, there were other environmental groups that organized demonstrations both in the capital city and in the other provinces. They mainly question the potential for contamination, toxicity and allergenicity of biotech products.

Despite the above mentioned, 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.

PART D. CAPACITY BUILDING AND OUTREACH

A) ACTIVITIES

2015

Three Argentine Scientists will participate of a Biotechnology Program sponsored by Cochran Program.

FAS Buenos Aires along with FAS Washington will sponsor one Argentine Scientist to participate of

the “2015 Animal Biotechnology Conference in California”.

FAS Buenos Aires will coordinate and sponsor the First Cloning Seminar in Paraguay and will support participation of an Argentine scientist as main speaker of the Seminar.

2014

Two Argentine Scientists participated of the Michigan State University Biotechnology Short Course.

FAS Buenos Aires will participate of the Second International Workshop for Regulation of Animal Biotechnology to be held in Brasilia, Brazil on August 2014.

2013

FAS Buenos Aires participated of the Institute of Life Sciences (ILSI) “International Workshop on Compared Food Safety Evaluation Practices for GM crops” in Buenos Aires

Two Argentine Scientists participated of the Michigan State University Biotechnology Short Course.

2012

FAS Buenos Aires participated in the First Meeting of Low Level Presence (LLP) organized by the Ministry of Agriculture.

The Argentine Ministry of Agriculture and FAS Buenos Aires coordinated the First Meeting of the Like-Minded Group on Innovative Agricultural Technologies with a focus on GE crops.

B) STRATEGIES AND NEEDS

Proposed Activities

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

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

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

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

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

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

- Workshops especially directed to medical doctors and nutritionists, explaining the safety of biotech

products;

- Workshop in risk assessment that will be directed to Argentine, Paraguayan and Uruguayan experts.
- Technical workshop to discuss treatment and analysis of stacked biotech events.

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

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

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.

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/FORA

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.

PART H. CAPACITY BUILDING AND OUTREACH

A) ACTIVITIES

In December 2008, the Argentine Ministry of Agriculture and FAS Buenos Aires organized the first cloning seminar with the participation of researchers and experts from the U.S., Argentina and the European Union. Cloning was a standing agenda item in the U.S. – Argentina Consultative Committee on Agriculture (CCA) meeting in November 2009, when both countries agreed to maintain bilateral collaboration on the issue.

In December 2010 and March 2011, the Argentine Ministry of Agriculture with FAS Buenos Aires collaboration invited representatives from the governments of Australia, Brazil, New Zealand, Paraguay, United States, and South Africa to discuss trade regulation of cloning. As a result of those meetings, a *Joint Intergovernmental Statement on Animal Cloning for Livestock Production* was agreed (text included in this report).

More recently, on November 2011, the Argentine Foreign Affairs Ministry organized a workshop to debate novel agricultural technologies with representatives of the European Union (EU). During the debate on cloning, EU officials announced their work on a strict labeling scheme for the import of meat, dairy and other products from the descendents of cloned animals. Argentine officials stated the goal that

in five or six years, Argentina will be the world's largest exporter of cloned and transgenic products, but recognized the need to get past EU resistance.

The Second International Workshop for Regulation of Animal Biotechnology:
Preparing Markets for New Animal Product Opportunities was held in Brasilia, Brazil in August 2014, and Argentine representatives from the government and industry participated.

Animals that have been produced using biotechnologies and are intended for commercial production are approaching the market. As a result, international organizations and the national authorities of a number of countries are developing frameworks for the food and environmental safety assessment of products of animal biotechnology. As animal biotechnologies mature and grow, there is a consensus of the need to evaluate where things stand at the moment, and plan for where things need to be tomorrow.

Building on the 1st international animal biotechnology regulatory workshop in Argentina (2011), this workshop accomplished the revision of the emerging elements of regulatory frameworks for the food and environmental safety assessment of products from animals produced using animal biotechnologies, including cloning, genetic engineering, and gene editing. It was intended primarily for a global exchange among professionals working for regulatory agencies, biosafety specialists and animal biotechnology and production experts. The objectives of the workshop included: disseminating guidance and experiences, enhancing regulatory cooperation and promoting capacity building initiatives, as well as increasing engagement between regulatory, scientific and industry sectors on animal biotechnology regulatory and development challenges.

The targeted outcomes helped advance the international regulatory environment for the adoption of production animals produced using modern biotechnologies. These include, but were not necessarily limited to the following:

- Provide a forum for regulatory officials from around the world to engage in a dialog on the regulation of animal biotechnology with a goal to increase regulatory harmonization.
- Describe the opportunities and potential represented by animal biotechnology and encourage engagement between regulators, technology developers and animal production sectors.
- Describe the need for transparent, predictable, science-based regulatory frameworks and characterize the regulatory impacts on innovation, technology acceptance/adoption, and international trade.
- Assess the status of animal biotechnology regulations in different countries and identify challenges to the harmonization of animal biotechnology regulations with a goal to develop ideas for improving global harmonization across regulatory frameworks.
- Identify the regulatory issues and challenges posed by new animal technologies for food production and public/human health applications.
- Identify next steps and develop recommendations for measures necessary to ensure safety of products derived from animal biotechnologies, while encouraging innovation and development and acceptance of new animal technologies.

B) STRATEGIES AND NEEDS

Continue the scheme of work to enforce measures that avoid trade restrictions. Also, develop actions to ensure that once the public learns about GE and cloned animals there is enough science based information available for consumers.