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Argentina

Agricultural Biotechnology Annual

Argentina Biotechnology Annual Report

Approved By:

Melinda D. Sallyards

Prepared By:

Andrea Yankelevich

Report Highlights:

Argentina continues to be the third largest producer of biotech crops after the United States and Brazil, producing 15 percent of the world's total biotech crops.

On March 16, 2012, The Government of Argentina announced the implementation of the new regulatory framework for agricultural biotechnology. The goal with this revamped regulatory system is to reduce the approval time for new events to 24 months.

Argentina is willing to take the lead in the region in the development and use of new technologies. This has been demonstrated this current year by the approval of Syngenta's quadruple corn event which was approved before Brazil, and the development of new genetically engineered (GE) seeds with drought resistance created by Argentine researchers. This focus on biotechnology was further highlighted by a recent trade mission to Brazil to explore a joint venture of GE drought resistant sugar cane variety. Furthermore within the last month the industry has announced substantial investment in the country.

Even when intellectual property rights (IPR) continues to be an unresolved issue in Argentina, the private agreement developed by Monsanto in 2011, continues to be a successful model.

Section I. Executive Summary:

Argentina continues to be the third largest producer of biotech crops after the United States and Brazil, producing 15 percent of the world's total biotech crops. The country's area cultivated with biotech varieties in MY2011/12 is 23.6 million hectares, 800,000 more hectares from the previous year (an increase of 3.2 percent). Almost all soybean area is planted with biotech seed varieties, while 92 percent of corn area and 100 percent of cotton area are biotech varieties.

On March 16, 2012, the Government of Argentina (GOA) announced the implementation of the new regulatory framework for agricultural biotechnology. The goal with this revamped regulatory system is to reduce the approval time for new events to 24 months, while before the average was 42 months.

Argentina has a clear intention to be in the forefront in the introduction of innovative technologies to farmers and this has been demonstrated in several ways: the approval of Syngenta's quadruple corn event which was approved before Brazil; a trade mission to Brazil to explore a joint venture of a GE drought resistant sugar cane variety; new GE seeds with drought resistance created by Argentine researchers; and the announcement of industry's substantial investment in the country.

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.

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

Although intellectual property rights (IPR) continues to be an unresolved issue in Argentina. However, in an effort to move forward in finding a mechanism to recognize IPR in order to allow the country to obtain the new soybean varieties, in 2011 Monsanto (supported by the seed industry) developed a private agreement with farmers. The agreement is based on an "intention letter" where the farmers express their willingness to have access to the Round Up Ready 2Y and the Round Up Ready 2YBt soybeans, and commit to pay royalties if they use any of those varieties. The system does not apply to the first generation of the Roundup Ready technology (known as the 40-3-2 event). Monsanto reports that 8000 farmers have already signed the agreement, proving to be a successful alternative in allowing new varieties in Argentina.

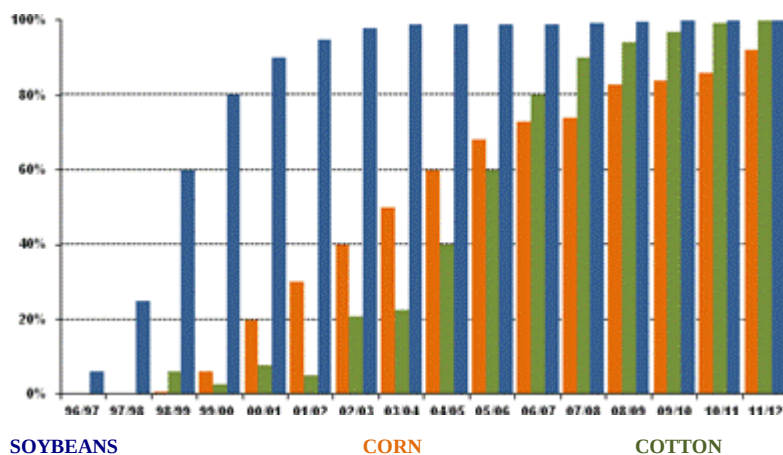
Argentina is active in development of genetically engineered animals for production of pharmaceutical products, but has not approved any genetically modified animals for food consumption (see Section VI Animal Biotechnology).

Section II. Plant Biotechnology Trade and Production:

Argentina is the world's third largest producer of biotech crops after the United States and Brazil, with twenty four biotech crop varieties approved for production and commercialization: three for soybeans, eighteen for corn, and three for cotton (please see complete list of biotech crops approved in Argentina at the end of this section).

Introduction of biotech soybeans in the late 1990s sparked a rapid expansion of soybean production, which now surpasses 18.8 million hectares. The country's area cultivated with biotech varieties in MY 2011/12 is 23.6 million hectares, 800,000 more hectares from the previous year (an increase of 3.2 percent).

Argentina, Evolution of GE Area



SOYBEANS

Source: Argenbio 2012

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 18.8 million hectares of soybeans planted for the 2011/2012 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.

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.

Monsanto announced that they expect their Bt x RR2 event (resistant to herbicide and insects) to be commercially approved for the next crop season (2012/2013). The company already holds the local patent for this event. In the past, the company failed to obtain a local patent for the RR event introduced in Argentina 15 years ago and its efforts to collect royalties have been frustrated by local regulations. However, Monsanto says it is making progress in reaching an agreement with farmers to pay royalties before introducing the new, improved variety of soybean seeds. The company plans to launch the new variety in the Northern provinces of Argentina first, and later in the rest of the country. (Please see details of the agreement signed by Monsanto & farmers under “Royalties”, Section III, Biotechnology Policy of this report).

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

This will be the fifth season where Argentine farmers used stacked corn events. In February 2007, the government simplified the approval process for stacked events allowing applications for a transgenic crop combining two already approved events without a full analysis of the new crop. On August 31, 2007 Argentina approved the first stacked gene, Monsanto’s NK603x810.

The most recent approval is Syngenta’s Bt11 x MIR162 x GA21 x MIR 604 quadruple stack corn. Previously, Syngenta’s triple stack corn seed with herbicide tolerance and above-ground insect control was approved in November 2011. The addition of the MIR604 trait will represent an important tool for growers to combat the increasing presence of corn rootworm in Argentina increases.

Biotech corn adoption represents 92 percent of total corn planted area, 4.2 million hectares. In the 2011/2012 crop season the

area planted with stacked events (Bt x TH) accounted for 57 percent of the total area (approx 2.4 million hectares). The rest of the biotech corn planted corresponded to Bt, estimated in 1.4 million hectares, representing approx 33 percent, and glyphosate tolerant variety (GA 21) with 400,000 hectares planted, corresponding to 10 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.

Cotton

Biotech cotton adoption represents 100 percent of total cotton planted area (575,000 hectares). In the 2011/12 crop season 88 percent (506,000 hectares) was planted with the stacked event (Bt x TH), and 12 percent (69,000 hectares) was planted with the glyphosate resistant event (TH).

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.

News – New Initiatives

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 approval of Syngenta's quadruple corn event which was approved before Brazil, a trade mission to Brazil to explore a joint venture of a GE drought resistant sugar cane variety, new GE seeds with drought resistance created by Argentine researchers, and industry's recent announcement of projected large investment in the country.

Approval of Syngenta's quadruple stacked corn event

Argentine Secretary of Agriculture Lorenzo Basso announced on March 22, 2012, the official approval for Syngenta's MIR604 corn rootworm trait, and for its Bt11 x MIR162 x GA21 x MIR 604 quadruple stack corn. The approval of this quadruple stack event, not yet approved in Brazil, shows that Argentina is anxious to again take the lead in the region in the development and use of new technologies.

GE Sugar variety- Argentine Mission to Brazil

The Argentine mission led by high level officials from the Argentine Ministry of Agriculture and accompanied by industry representatives and researchers, evaluated the possibility of a private joint venture with Brazilian industry in developing a GE drought resistant sugar cane variety. Brazilian researchers are already working on the development of this variety, and with the input of Argentine researchers they might have it ready by the beginning of 2013. 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.

In the meantime, the Argentine National Advisory Committee on Agricultural Biotechnology (CONABIA) is already evaluating applications for the Round-Up Ready (RR) and the Bt sugar cane varieties. 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 in 2014. The GE sugar cane has not been approved yet in any country; therefore, if approved in 2014, Argentina would be the first country in the world.

Industry's investments in Argentina

On June 15th, 2012, Monsanto announced an investment of US\$ 355 million to build a new corn-seed-production plant in Argentina. The plant will be in Cordoba province and it is expected to be finalized in December 2013. As reported by Monsanto representatives, this investment will increase the company's capacity in Argentina by 80 percent. Less than a month later, On July 5th, the Swiss company Syngenta announced they will invest US\$ 175 million to boost their seed-

production capacity in Argentina by building a new plant. The new facility will be built in Cordoba province as well, and will produce annually one million bags of corn and sunflower seeds.

New GE seeds with drought tolerance

Argentine researchers have isolated the drought tolerance gene 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. The Argentine firm Bioceres, who has been granted a license for the use and exploitation of this gene, signed a joint venture agreement with the U.S. Company Arcadia Biosciences. When consulted, representatives of the this new partnership named Verdeca, expressed that they expect to have the new seeds in the market by 2015 or 2016, as two or three more years of environmental and nutritional testing will be required before the new seeds obtain the commercial approval. These new varieties will be an important milestone for the Argentine agricultural sector since they will help confront the effects of the climate change.

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 that are under CONABIA's evaluation at the moment, might be commercially approved in 2013. 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.

Biotech Crops Approved in Argentina

Crop	Trait Category	Event	Applicant	Resolution
Soybean	Glyphosate Herbicide Tolerant	"40-3-2"	Nidera S. A.	SAPyA N° 167 (25-3-96)
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	Glyphosate 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	Glyphosate 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

				 (15-03-05)
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 N° 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 N° 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	Bt11xMIR162xMIR604xGA21	Syngenta	(2012)

	Glyphosate and Glufosinate Herbicide Tolerant		Agro S.A.	

Source: CONABIA

For a complete list of evaluations, please visit: <http://www.minagri.gob.ar/SAGPyA/areas/biotecnologia/>

Section III. Plant Biotechnology Policy:

New Regulatory Framework for Agricultural Biotechnology in Argentina

On March 16, 2012, Argentine Secretary of Agriculture Lorenzo Basso announced the implementation of the new regulatory framework for agricultural biotechnology in Argentina. The goal with this revamped regulatory system is 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 trials and commercial release.

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 groups conducted about 50 meetings and 2 workshops during 2011, and they focused on three main points: reduction of the administrative process, easy access to the evaluation process, and coordination of the different agencies regarding the information required on each stage. The outcome of this coordinated effort is the new regulatory framework announced by Secretary Basso on March 2012.

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 agroecosystem 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 1200 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 final decision.

Traceability

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

Labeling

There is no specific regulation in Argentina in reference to labeling biotech products. The current regulatory system is based on the characteristics and identified risks of the product and not in the production process of that product.

The policy of the Ministry of Agriculture on labeling 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 labeled according to its characteristics as food product, not according to aspects concerning the environment or production process.

- Differential labeling 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 labeling would end up being paid by the consumers, without assuring that this would represent better information or increased food security.

Stacked events

Approval of stacked events is based in a case by case evaluation under which the applicant needs to submit a letter simultaneously to the Ministry of Agriculture (Direction of Biotechnology) 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.

Intellectual Property Rights – Royalties

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

Argentine Intellectual Property (IP) laws are based on UPOV-78, which provides strong protection for the right of farmers to save and replant seeds, and exempts them from providing explanations on how selected seeds were used. The lack of effective enforcement options for plant variety rights, combined with the absence of patent protection for a significant range of biotech inventions, renders Argentina's intellectual property system inadequate from the perspective of the biotechnology industry.

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. Up until now, 8000 farmers have signed the "letter of intention" which represents an area of 11 million hectares (60.7 percent of the total area). 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.

Any controversy and/or dispute arising from or related to this agreement shall be resolved, at the discretion of any of the parties, by the *Grain Arbitration Chamber of the Rosario Board of Trade* (Cámara Arbitral de Cereales de la Bolsa de Comercio de Rosario) or by the *Buenos Aires Grain Arbitration Chamber* (Cámara Arbitral de Cereales de Buenos Aires).

Biosafety Law

Argentina does not have a biosafety law in place. Initial discussions on developing a biosafety law took place in 2001, but due to the institutional and economic crisis that broke out in December 2001, the draft was never discussed in Congress and there is no evidence that it will be in the near future. Private sources have indicated that due to the current conditions at Congress, a Biosafety Law is considered a long term objective.

International Negotiation Fora

Cartagena Biosafety Protocol

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

Codex Alimentarius and Other Agreements

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.

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.

InterAmerican Institute for Agricultural Cooperation (IICA) Workshop on Low Level Presence (LLP)

In an effort to review the status of the LLP situation in the different countries, IICA invited government representatives of the IICA member countries, Canada and the United States to attend a two-day seminar to assess the potential impact of LLP for parties involved in GE crops trade.

The objectives of the workshop were to develop a common understanding among IICA member countries on the issue of LLP for food, feed and processing, to exchange views on how to internationally move the issue forward, and to support ongoing LLP work on the Americas. Another issue of high importance discussed, was asynchronic approval of GE events in the different countries. Relevant topics of discussion were:

Definition of LLP: All countries agreed that the initial step is to establish a common definition of LLP that sets thresholds, as it is not yet defined by Codex Alimentarius.

Different levels of knowledge and implementation: it was clear that the level of knowledge on these issues varies significantly from one country to another. A growing number of countries have established risk assessment procedures for approving the import of GE crops. However, most of these countries have not, as yet, adapted these processes to address the potential LLP in their imports of GE material already authorized and being produced in other countries, but not yet approved (and therefore not intended to be present) in the importing country. This gap has the potential to cause significant trade disruptions.

Zero tolerance policy: Agricultural commodities inevitably mix to a small extent, therefore it is not possible to comply with a zero tolerance policy. Industry can implement different strategies and adopt various operational changes to reduce, but not eliminate, the likelihood of LLP. However, it must be noticed that lower thresholds incur higher additional costs as development, production, and distribution expenditures rise.

Sharing information: the representatives recognized the common need to share information and to develop capacity building. Knowing what the other countries are working on will not only help to improve synchronized approvals but also to harmonize procedures internationally.

Global policy: the representatives support the need to have a global policy on the issue that will allow having a common message.

The conclusions of the workshop were that LLP and asynchronic approvals are becoming of high importance for all the represented countries due to the increasing level of regional and international trade of GE commodities. In order to comply with the objectives, the governments intend to work together to promote the development of a global policy, and to make the initial steps to create a system that would allow sharing of information.

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.

Argentine Biotech Chamber

In December 2011, a group of private companies with support of the Ministry of Science and Technology, and several Argentine Universities, announced the creation of the Argentine Chamber of Biotechnology. Argentina has a strong institutional platform, both in the public and private sectors, and the objective of the newly launched chamber is to promote the development of a public-private synergy in the area of biotechnology, where Argentina has strong competitive advantages due to its natural, human and scientific resources. It is a multi-sectorial organization made up by representatives of the food industry, animal and plant health, diagnosis, agricultural and forestry industry and biofuels. As its first initiative, the chamber will conduct a survey among all the companies that have some biotech related activity with the intention of developing a comprehensive “map” of the scientific, commercial and technological availability in the country.

Section IV. Plant Biotechnology Marketing Issues:

Public Perception – Consumer’s Attitude

Most Argentine scientists and farmers are optimistic and enthusiastic about the prospects of using biotechnology to improve yields and nutritional value of crops while decreasing the input of chemical pesticides. 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.

After Monsanto’s announcement of its new plant in Cordoba province (please see Section II Biotechnology Trade & Production in this report) several NGOs and consumer associations expressed deep concern and have published several articles about possible negative impacts on human health and the environment. They mainly question the potential for contamination, toxicity and allergenicity of biotech products.

Public Participation, Education and Awareness Activities

In 2004 the GOA included biotechnology as a mandatory subject in schools, but most teachers did not have any training or access to sources for information. At that time a panel of experts from Argenbio (the national nonprofit biotechnology association) designed a training course and educational materials that are now offered free of charge to schools around the country. As of today, more than 11,000 teachers have received the “Por qué Biotecnología” (Why Biotechnology) training.

Section V. Plant Biotechnology Capacity Building and Outreach:

2007

FAS Buenos Aires organized and accompanied a group of Argentine journalists to the United States to demonstrate how the United States uses and regulates agricultural biotechnology.

2008

FAS Buenos Aires selected and facilitated the trip of an Argentine expert who was key speaker of a biotech Conference held

in South Africa, Mozambique and Madagascar.

2009

- A. Ag Counselor participated as speaker of the Biotech Forum in Rosario, Santa Fe Province.
- B. FAS Buenos Aires sponsored a trip for Argentine biotech expert to participate in a hemispheric seminar organized by the US Codex Office in Lima, Peru.

2010

FAS Buenos Aires coordinated a trip for five Argentine biotech experts to participate in a hemispheric meeting organized by the US Codex Office in Panama City, Panama.

2011

FAS Buenos Aires coordinated a trip along with the United Soybean Board for 2 Argentine farmers to participate of the “Farmer to Farmer” workshop held in Asuncion, Paraguay.

2012

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.

Proposed Activities

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

- Workshops in different cities to target audiences around the country,
- A two-day conference directed mainly to Congressmen, but also to media, academia and government officials among others,
- Activities with local universities to demonstrate the benefits of Biotechnology in Argentina
- Continue Cooperator, Cochran, and International Visitor program activities,
- Special activities designed for consumer association leaders and consumers in general,
- Workshops especially directed to medical doctors and nutritionists, explaining the innocuousness of biotech products;
- Workshop in risk assessment that will be directed to Argentine, Paraguayan and Uruguayan experts.
- Technical workshop to discuss treatment and analysis of stacked biotech events.
- Work with Senators and Representatives on the regional forum created after the Southern Cone Reverse CODEL; and,
- Meetings to develop lines of communication between the GOA and the USG during the review process of biotech events.

Section VI. Animal Biotechnology:

I. Development and Use

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 and SENASA 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.

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In 2007, Biosidus Company developed another line of cloned calves, this time to produce insulin. After several years of research and 4 million dollars investment, "Patagonia" was the first calf born. In this case, the insulin produced by 25 cows like Patagonia will meet the annual demand of the entire country at a lower cost (30% less than the currently used insulin). The intention is to produce enough insulin to be able to export in the near future. And finally in late 2008 with the "Porteña" dynasty, Bio Sidus has accomplished the production of a hormone for bovine growth from cloned and transgenic calves, which will increase the production of cow milk up to 20%. The country will thus be the top world producer and exporter of this product. For this project the gene of the hormone for bovine growth was added to the bovine cells, so that this may be produced inside the udder and secreted to the milk of these animals. This Porteña dynasty is not focused on the pharmaceutical market but the rural sector, where the hormone for bovine growth is used to increase the production of milk. Thus, this new product has a totally exporting profile, since it is mainly used in the USA, Mexico and Brazil, among other countries. 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 lactation artificial induction the scientists confirmed that both proteins (lactoferrin and lysozyme) are present in its milk.

II. 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 agencies involved are CONABIA, SENASA, and the National Direction of Agricultural Food Markets. 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/>

III. Stakeholder/Public Opinion

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.

IV. Outreach, Needs and Strategies

No activities have been developed specifically on genetic engineered animals.