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Report Highlights:
The Government of Argentina set a new record of seven biotech approvals in 2018, after a low level in 2017. Due to a severe drought, and in order to maintain soybean processing at normal levels, Argentina is importing U.S. soybeans for the first time in over two decades. The Ministry of Agro-Industry authorized the import of genetically engineered (GE) soybeans for industrial use only. Despite the intense dialog between the government, the industry and the farmers' associations, the seed royalty system continues to be an unresolved issue; a new Seed Law proposal is ready to be reviewed by Congress.

EXECUTIVE SUMMARY

Biotech Production: Argentina continues to be the third largest producer of biotech crops, after the United States and Brazil, producing 12 percent of the world´s total biotech crops on an estimated 25 million hectares. Among the events approved in 2018, there is one Safflower event – Argentina is the first country in the world to grant approval for a safflower event - one alfalfa, one potato and several soybean and corn events. China's approval of GE events continues to be a top priority for Argentine foreign trade, since China is one of the most important export markets for Argentine biotech-derived agricultural products. The Argentine Ministry of Agriculture recently updated the regulation applicable to animal biotechnology in order to frame the new technical advances that are taking place in this field.

A severe drought during the peak summer months in 2018 reduced Argentine soybean production and resulted in the import of U.S. soybeans to Argentina for the first time in decades.

The seed royalty system continues to be an unresolved issue in the country, and it is imminent that the Seed Law will be discussed at Congress. The United States and Argentina have some differences in approved events but, among those, most are not commercialized in the United States. However, one event, MON87708-9, *Genuity Roundup Ready 2 Xtend,* is commercialized in the United States and was not yet approved in Argentina. With the potential arrival of U.S. soybeans, on May 18, 2018 the Ministry of Agro-Industry released Resolution 26/2018. The resolution created a four-year authorization for the importation of biotech products for use as raw material in agro-industrial processing for human food and animal feed ("FFP" Food, Feed and Processing), but excluded its use for planting and seed commercialization.

Bio-based Production: The Ministry of Agribusiness created and launched the Program "Argentine bio-based products". The goal is to increase the use and value added of renewable agricultural resources, as well as encourage the coordination of joint actions with other Ministries and Agencies to increase the production and use of bio-based products.

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

New Technology Development: The Argentine Ministry of Agriculture recently updated the regulation applicable to animal biotechnology in order to frame the new technical advances that are taking place in this field. Several evaluations are currently in process, although information cannot be reported yet as they are in a confidential stage. Argentina is active in the development of genetically engineered animals for production of pharmaceutical products but has not approved any genetically engineered animals for food consumption. During 2017, the Ministry of Agriculture received requests for evaluation of GE animals focused on improving production. As for cloned animals, there are three companies and two public institutions in Argentina able to provide commercial cloning services, mostly for breeding animals. Argentina continues to be very proactive on the issue of somatic cell nuclear transfer (SCNT). The GOA is still in the process of determining its own policy on the technology.

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CHAPTER 1. PLANT BIOTECHNOLOGY

PART A: TRADE AND PRODUCTION

A) PRODUCT DEVELOPMENT

The Argentine National Advisory Committee on Agricultural Biotechnology (CONABIA) granted a record eight approvals in 2018 with seven for full approval and one soybean event for feed, food and processing only. A wheat event received technical approval but awaits commercial approval by the National Direction of Agricultural Food Markets (DNMA) under the Ministry of Agro-Industry.

Several soybean events received technical approval from CONABIA but final approval is still pending until the product is approved by China, Argentina's primary agriculture market. Because China is such a vital market for Argentina, the Ministry of Agro-Industry tends to deliver final approval for new biotech events only if they have already been approved in China in order to avoid potential trade disruptions. One of them is the INDEAR HB4, a drought resistant event, developed by local researchers from INDEAR that, contacts report, during field trials increased yield by 30 percent under extremely dry conditions.

First Chinese soybean event under public consultation process in Argentina

Since 2013, BIOCERES, a partner at the *Instituto Agrobiotecnológico Rosario* (INDEAR), the flagship of the local biotech industry and Beijing Da-Bei-Nong Technology Group (DBN) have partnered to facilitate regulatory approval of DBN's biotech events in Argentina and Bioceres' biotech events in China.

DBN's soybean event DBN 09004-6, a trait to confer soybean tolerance to glyphosate and glufosinate-ammonium herbicides, is expected to receive final approval in late 2018. This would be the first Chinese-developed soybean event approved in Argentina. This event is currently being tested in Argentina; private contacts expect China will approve the event once the trials are completed.

New GE safflower approval

In December 2017, the Ministry of Agriculture approved the safflower events IND-10003-4, IND-10015-7, IND-10003-4 x IND-10015-7 from INDEAR which produce the enzyme chymosin for use in cheese production. This was the first approval of a safflower in the world improved by modern biotechnology (molecular pharming) and the first incorporation of a crop that generates an enzyme for agri-food use.

New alfalfa approval

In July 2018 CONABIA approved its first alfalfa event. The MON-ØØ179-5, MON-ØØ1Ø1-8 y MON-ØØ179-5 x MON-ØØ1Ø1-8 crop is the product of local research – INDEAR laboratories, and it is tolerant to glyphosate with a lower content of lignin.

Artic apples

In 2018, The Intrexon company's non-browning apples – an effect caused by the silencing of the gene polyphenol oxidase (PPO) – started field trials in Argentina.

1.) COMMERCIAL PRODUCTION

Argentina is the world's third largest producer of biotech crops, after the United States and Brazil, with fifty-one biotech crop varieties approved for production and commercialization: fourteen soybean, twenty-nine corn, four cotton, one potato, one alfalfa, and one safflower.

Introduction of biotech soybeans in the late 1990s sparked a rapid expansion of soybean production, which now surpasses 19 million hectares. The country´s total area cultivated with biotech varieties (soybeans, corn and cotton) in MY 2017/18 is estimated 25.3 million hectares.

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

China's approval of GE events

China's approval of GE events continues to be a top priority for the Argentina, due to its importance as an export market. Argentina requires that biotech events be approved in China prior to any domestic commercialization. The industry and government consistently stress to Chinese authorities the importance of timely, science-based safety reviews for new events to avoid asynchronous approvals that lead to trade disruptions.

In recent years, the rate of Chinese approvals has lagged behind other importing countries, such as Mexico, Japan, and South Korea, hampering producers' access to new seed technologies. An analysis of the agricultural and broader economic impacts of the delays in Chinese biotech approvals can be found at: https://croplife.org/?s=The+Impact+of+Delays+in+Chinese+Approvals+of+Biotech+Crops

Soybeans

Released in 1996, glyphosate tolerant (Roundup Ready) soybeans have been adopted at a very high rate in Argentina and encompass all of the estimated 19.5 million hectares of soybeans planted for the 2017/2018 season. Furthermore, the new technology facilitated 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. In March 2018, Argentina approved Bayer's MST-FG072-2 and MST-FG072-2xACS-GM006-4 tolerant to isoxaflutole Glyphosate and Glufosinate herbicides.

The Argentine soybean economy is geared almost entirely towards exports. Twenty percent of soybeans are exported as whole beans while eighty percent is crushed and exported as meal or oil. The great majority of soybean oil and meal is exported with a small remainder (7 percent of total meal and oil

supplies) directed to local feed operations. For more detailed information on soybean production, please see the Argentina Oilseeds and Products Annual Report in the Global Agricultural Information Network (GAIN) system (http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Oilseeds%20and%20Products%20Annual_Buenos%20Aires_Argentina_5-24-2018.pdf).

Corn

Argentine farmers have been using stacked corn events for ten years. In 2018, Argentina approved four new corn events:

1) Dow AgroSciences, DAS-40278-9 MON-89034-3 x DAS-01507-1 x MON-00603-6 x DAS-40278-9 and all the stacks. Tolerance to herbicides base of 2,4 D and herbicides of the family ariloxypheonoxypropionate, ammonium glufosinate and glyphosate. Resistance to lepidopteran.
2) Bayer S.A., SYN-05307-1 and SYN-BT011-1xSYN-IR162-4xSYN-IR604-5xDAS-01507-1xSYN-05307-1xMON-00021-9 and all the stacks. Tolerance to glyphosate and to amonium glufosinate and resistance to lepidopteran and coleoptera.
3) Monsanto, MON-87427-7, MON-87411-9, MON-87427-7 × MON-89Ø34-3 × SYN-IR162-4 × MON-87411-9 and all the stacks. Tolerance to glyphosate and resistance to lepidopteran and coleoptera.
4) MONSANTO, MON-87427-7 x MON-89Ø34-3 x MON-88Ø17-3. Tolerance to glyphosate and resistance to lepidopteran and coleoptera.

For more detailed information on corn production, please see the Argentina Grain & Feed Annual Report in the Global Agricultural Information Network (GAIN) system (http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Grain%20and%20Feed%20Annual_Buenos%20Aires_Argentina_4-30-2018.pdf).

Cotton

In the 2017/18 crop season, the total cotton area was planted with the stacked event (Bt x TH). Since the 2011/12 crop season, Argentine farmers have discontinued the used of the Bt cotton variety.

2.) EXPORTS

Argentina is a net exporter of GE commodities to numerous markets in the world, including the United States. Export documentation declares the content of GE seeds.

3.) IMPORTS

Generally, biotech-derived imports to Argentina are negligible. However, a severe drought during the peak summer months in 2018 reduced Argentine soybean production to 36 million tons, down from 54 million tons from projected estimates. In addition, Argentine producers that can afford it are holding a significant inventory of beans on speculation of higher prices, thus further reducing available inventory. Therefore, the local crushing industry needed to source beans to maintain its processing levels.

In April 2018, U.S. private exporters reported to the U.S. Department of Agriculture (USDA) contracts for shipments totaling 490,000 tons of soybeans to Argentina for delivery in the 2017/18 and 2018/19 marketing years with import sales possible in the near future of up to 1 million tons, depending on market conditions. USDA estimates Argentina will import almost 3.9 million tons of soybeans in 2017/18, an increase of 50 percent over the previous year. The main suppliers of these soybeans are Paraguay, the United States, and Brazil.

Import Policy

With the arrival of U.S. soybeans, an important event not seen in Argentina in several decades, the status of entry protocols became a point of discussion, especially relative to biotech events. One event, MON87708-9, Genuity Roundup Ready 2 Xtend, is commercialized in the United States and not yet approved in Argentina.

On May 18, 2018, the Ministry of Agro-Industry released Resolution 26/2018 (https://www.boletinoficial.gob.ar/#!DetalleNorma/183969/20180518). It establishes a four-year authorization for the importation of biotech products (regardless of its originating biotech event) for use as raw material in agro-industrial processing for human food and animal feed ("FFP" Food, Feed and Processing), but excludes use for planting and seed commercialization. The Argentine government granted this temporary authorization because there was a vital need for foreign soybeans due to this year's drought. Contacts report the government the views this as a transitory measure necessary to maintain crush levels until domestic production levels normalize.

This initiative permits the potential importation of biotech soybeans with events not authorized locally, from the United States. Local reports indicate that this resolution resolves all pending issues regarding the importation of U.S. soybeans and shipments should be able to enter with no interruptions. This initiative was especially geared towards the United States as it became a significant supplier of soybeans to the Argentine soybean-processing sector.

4.) FOOD AID

Argentina is not a food aid recipient nor likely to be one in the near future.

PART B. POLICY

A) REGULATORY FRAMEWORK

The regulatory framework for Agricultural Biotechnology, implemented in 2012, has reduced approval times and bureaucracy. The evaluation of new events takes place on a case-by-case basis, taking into consideration the process only in those instances where the environment, agricultural production or 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. This office coordinates three technical areas: biosafety (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 of 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 any sector. 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 regulatory framework, the evaluation time for CONABIA is 180 days. In addition, the use of electronic forms has been included, allowing all agencies to access documents at the same time, further speeding up the approval process.

CONABIA has reviewed over 2000 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 the 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.gob.ar/normativas/resolucion-701-2011-senasa-servicio-nacional-de-sanidad-y-calidad-agroalimentaria

http://www.minagri.gob.ar/sitio/areas/d_recursos_humanos/concurso/normativa/_archivos//000001_Resoluciones/000000_RESOLUCI%C3%93N%20661-2011%20Semillas.pdf

-*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 access these markets. Under the framework, the DNMA will evaluate the commercial impact on export markets within 45 days.

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

Upon completion 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	Glyphosate Herbicide Tolerant	"40-3-2"	Nidera S. A.	SAPyA N° 167 (25-3-96)
Soybean	Resistant to Glufosinate Ammonium	A2704-12	Bayer S.A.	(2011)
Soybean	Resistant to Glufosinate Ammonium	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 Ammonium 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 Ammonium Tolerant	"TC 1507"	Dow AgroSciences S.A. and Pioneer Argentina S.A	SAGPyA N° 143
Corn	Glyphosate Herbicide Tolerant	"GA 21"	Syngenta Seeds S.A.	SAGPyA N° 640 (22-08-05)
Corn	Glyphosate Herbicide Tolerant **and** Resistant to Lepidoptera	NK603x MON810	Monsanto	SAGPyA Nº 78 (28/08/07)
Corn	Resistant to Lepidoptera and Glufosinate Ammonium and Glyphosate Tolerant	1507 x NK603	Dow AgroSciences S.A. y Pioneer Argentina S.R.L.	SAGPyA Nº 434 (28/05/08
Corn	Glyphosate Herbicide Tolerant **and** Resistant to Lepidoptera	Bt11 x GA21	Syngenta Seeds S.A.	(2009)
Corn	Resistant to Lepidoptera	"Mon89034"	Monsanto	(2010)

Corn	Glyphosate Herbicide Tolerant **and** Resistant to Lepidoptera	"Mon 88017	Monsanto	(2010)
Corn	Glyphosate 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 Glyphosate and Glufosinate Herbicide Tolerant	Bt11xGA21xMIR162	Syngenta Agro S.A.	(2011)
Corn	Glyphosate 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 Glyphosate and Glufosinate Herbicide Tolerant	Bt11xMIR162xMIR604xGA21	Syngenta Agro S.A.	(2012)
Corn	Resistant to Lepidoptera and Coleoptera, and Glyphosate and Glufosinate Herbicide Tolerant	Mon 89034 x TC 1507 x NK603	Dow Agro Sciences	(2012)

Corn	Resistant to Lepidoptera and Glyphosate	Mon 89034 x NK603	Monsanto	(2012)
Soybean	Resistant to Lepidoptera Glyphosate	Mon 87701 x Mon 89788	Monsanto	(2012)
Soybean	Resistant to Imidazolinones	CV 127	Basf	(2013)
Corn	Resistant to Lepidoptera, Glyphosate and Glufosinate Herbicide Tolerant	TC1507xMON810xNK603 y TC1507xMON810	Pioneer Argentina	(2013)
Corn	Resistant to Lepidoptera, Glyphosate and Glufosinate Herbicide Tolerant	Bt11xMIR162xTC1507xGA21 and all the intermediate stacked	Syngenta Agro S.A.	(2014)
Soybean	Resistant to 2, 4D, Glyphosate and Glufosinate	DAS-44406-6	Dow AgroSciences S.A.	(2015)
Potato	Virus Resistant	SY233	Tecnoplant S.A.	(2015)
Soybean	High oleic content and glyphosate tolerant	DP-305423 x MON-04032-6	Pioneer Argentina S.R.L.	(2015)
Soybean	Drought resistant	IND410 (Hb4)	INDEAR S.A.	(2015)

Cotton	Resistant to Glyphosate and Ammonium Glufosinate	BCS-GHØØ2-5 x ACS-GHØØ1-3 GHB614xLLCotton25	Bayer S.A.	(2015)
Corn	Resistant to Lepidoptera, Glyphosate and Glufosinate	TC1507xMON810xMIR162xNK603	Pioneer Argentina S.R.L.	(2016)
Soybean	Resistant to Glyphosate	MON-89788-1	Monsanto Argentina	(2016)
Soybean	Resistant to Lepidoptera	MON-87701-2	Monsanto Argentina	(2016)
Corn	Resistant to Lepidoptera, Glyphosate and Glufosinate	MON-89034-3 x DAS-01507-1 x MON-00603-6 x SYN-IR162-5	Dow Agro Sciences Argentina	(2016)
Soybean	Resistant to Lepidoptera, Glyphosate and Glufosinate	DAS-81419-2 x DAS-444Ø6-6 y DAS-81419-2	Dow AgroSciences Argentina S.R.L	(2016)
Corn	Resistant to Lepidoptera, Glyphosate and Glufosinate	SYN-BT011-1 x SYN-IR162-4 x MON-89034-3 x MON-00021-9	Syngenta Agrosciences	(2016)
Soybean	Tolerant to glufosinate and enzyme HPPD inhibitors	SYN-000H2-5	Syngenta Agrosciences & Bayer S.A.	2017

Safflower	Expression of bovine pro-quimosin in seeds	IND-10003-4, IND-10015-7, IND-10003-4 x IND-10015-7	INDEAR	Dec7, 2017
Corn	Tolerance to a herbicides base de 2,4 D and herbicides of the family ariloxifenoxi, ammonium glufosinate and glyphosate. Resistance to Lepidoptera	DAS-40278-9 MON-89034-3 x DAS-01507-1 x MON-00603-6 x DAS-40278-9 and all the stacked in between	Dow AgroSciences Argentina S.R.L.	March, 2018
Soybean	Tolerance to herbicides isoxaflutole, glfosate and amonium glufosinato.	MST-FG072-2 y MST-FG072-2xACS-GM006-4	Bayer S.A.	March, 2018
Corn	Tolerance to glyphosate and to ammonium glufosinate and Resistance to Lepidoptera and Coleoptera	SYN-05307-1 y SYN-BT011-1xSYN-IR162-4xSYN-IR604-5xDAS-01507- 1xSYN-05307-1xMON-00021-9 and all the stacked in between	Syngenta Agro S.A.	March, 2018
Corn	Tolerance to glyphosate and Resistance to Lepidoptera y Coleoptera	MON-87427-7, MON-87411-9, MON-87427-7 × MON-89Ø34-3 × SYN-IR162-4 × MON-87411-9 and all the stacked in between	Monsanto Argentina S.R.L.	May, 2018
Alfalfa	Tolerance to glyphosate and decrease in the content of lignin	MON-ØØ179-5, MON-ØØ1Ø1-8 y MON-ØØ179-5 x MON-ØØ1Ø1-8	INDEAR	July 2018
Soybean	Only for processing (Food, Feed and Processing)	MON-877Ø8-9 x MON-89788-1	MONSANTO	July, 2018

Potato	Resistance to viruses	TIC-AR233-5	Tecnoplant S.A.	August, 2018
Corn	Tolerance to glyphosate and Resistance to Lepidoptera y Coleoptera	MON-87427-7 x MON-89Ø34-3 x MON-88Ø17-3	MONSANTO ARGENTINA S.R.L.	August 2018

Source: CONABIA

C) STACKED EVENTS

Approval of stacked events is based on a case by case evaluation under which the applicant must submit a letter simultaneously to the Ministry of Agriculture (Direction of Biotechnology) and 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, 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 additional information from the applicants required.

D) FIELD TESTING

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

E) INNOVATIVE BIOTECHNOLOGIES

In 2015, the Ministry of Agriculture announced a new regulatory framework for Innovative Biotechnology/New Breeding Techniques in Plants (NBT). The new regulation did not alter the regulatory framework applicable to traditional GE events. Rather, it sets forth proceedings to determine the cases in which an organism obtained by NBT's are subject to GE rules and regulations.

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

Argentina's Regulatory System for Products Derived from NBTs

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

As one of the top regulatory systems in the world, policymakers and regulators debated for over 3 years to clarify the status of products derived from NBTs under the current GE events regulation. During the debate, policymakers and regulators noted that no difficulties emerged with interpreting the term

"organism" or "modern biotechnology" (which in practice means the use of recombinant DNA at some step of the breeding process). Only the term "novel combination of genetic material" was a matter of debate regarding its interpretation.

As a conclusion, "novel combination of genetic material" is the critical factor for Argentina in deciding whether a product derived from NBTs (where NBTs are new techniques that use DNA manipulation as an aid during the breeding process) is a GE event. The following are the main foundational criteria under the new Argentine regulation:

- **Cartagena Protocol Definition**

For transboundary movements of GE and NBT crops, Argentina currently bases its regulation on language similar to that in the Cartagena Protocol on Biosafety.

- **Flexibility for Future Technologies**

As mentioned before, there is no unified reference list of techniques that generate NBTs due to the emerging pace of these technologies. For instance, in the seminal list, CRISPR-Cas9 was not included, since that technology was invented later, however, it is currently one of the most promising NBTs. In addition, although in scientific papers a technology name may be perceived as a clear denomination, discussion with policymakers in Argentina revealed that it was not easy to produce "satisfactory" (technically clear, fit to purpose) legal definitions of the various technologies.

As a conclusion, Argentina decided that a new regulation on NBTs should not be based on a closed list or description of particular technologies, but instead should be framed to be flexible and applicable to existing or forthcoming technologies as much as possible.

- **Case by Case Analysis**

Although certain technology names such as "Cisgenesis," "Reverse Breeding," "Site Directed Nucleases" may be satisfactory for a scientific discussion, when comparing different implementations of an NBT by different research groups, differences from one case to another made it difficult for Argentina to adopt a definition of one of these technologies for regulatory purposes. For similar reasons, Argentina found it difficult to arrive at a "technology-broad" criterion regarding the regulatory status of end products since these can differ significantly.

As a conclusion, Argentina determined that the analysis to establish if a certain NBTs-derived crop is subject to regulations for "Genetically Modified Organisms" (GMO) or not could only be made product by product. So far, Argentina has evaluated six plants produced by NBTs, and all of them were excluded from the "GMO" regulation as conventional processes.

How Regulation Works

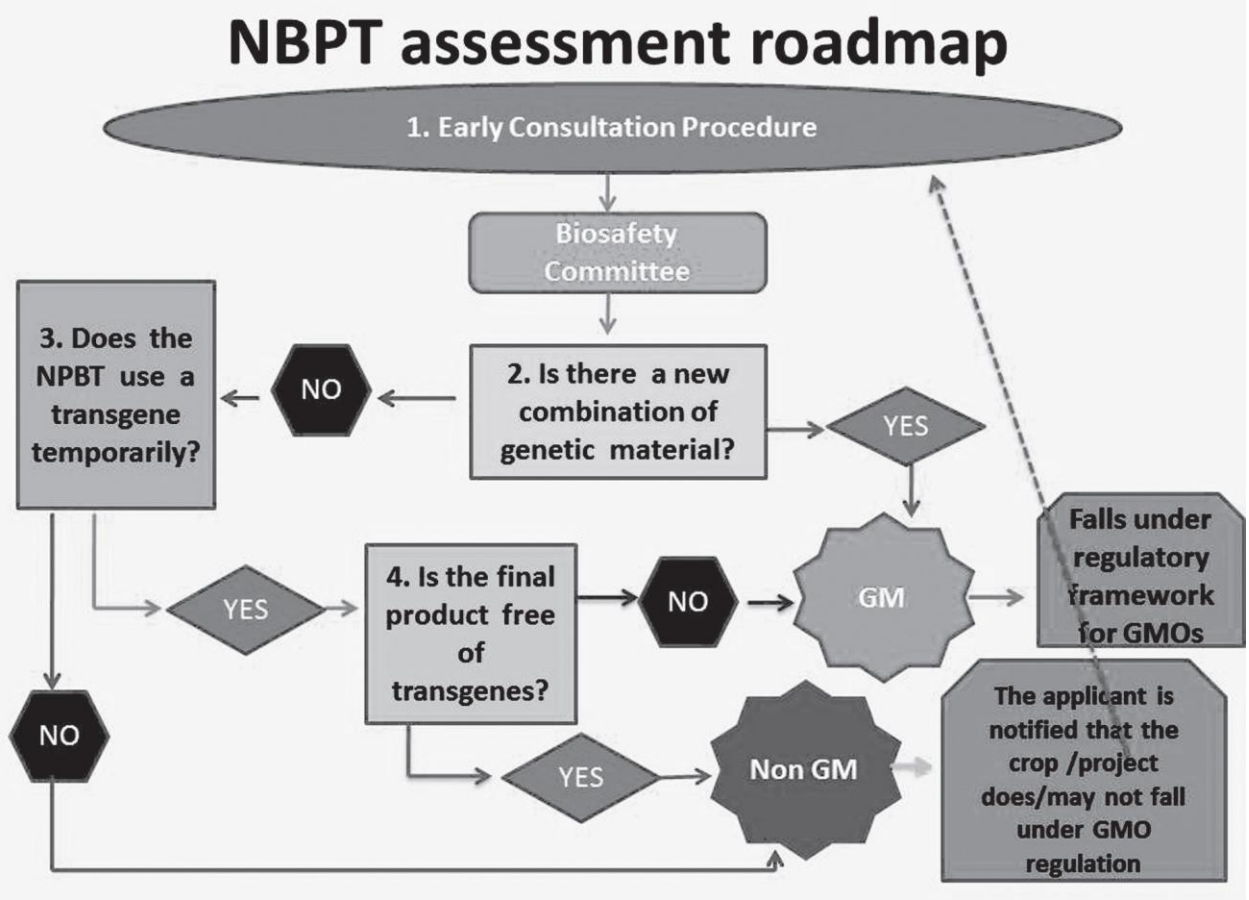
Resolution no. 173/15 of the Secretariat of Agriculture, Livestock and Fisheries (attached as an Appendix) established procedures to determine the criteria under which a crop obtained by breeding techniques involving modern biotechnology does not fall under "GMO" regulation.
To this end, applicants submit each product (NBT-derived crop) to establish whether the result of the breeding process is a new combination of genetic material or not.

A genetic change is regarded as a new combination of genetic material when a stable and joint insertion of one or more genes or DNA sequences that are a part of a defined genetic construct are introduced permanently into the plant genome. Also, if appropriate, the existence of sufficient scientific evidence must support the absence of transgenes that may have been used transiently during the crop breeding process.

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

For projects: In the design stage, applicants may file preliminary inquiries aimed at a preliminary assessment of whether the expected product might be regulated as a GE event. When the new crops are finally generated, the applicant must still submit factual determinations about the genetic modification. In the event that the product possesses the features anticipated in the preliminary inquiry, the earlier assessment regarding its regulatory status would remain.

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



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

F) COEXISTENCE

Argentina has no regulations governing coexistence.

G) LABELING

Argentina has no regulations regarding the labeling of biotech products. The current regulatory system is based on the characteristics and identified risks of the product and not on the production process.

The Ministry of Agriculture's position on labelling in international fora is that it should be based on the type of food product derived from a specific biotech event 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, of which the majority are commodities, the identification process would be complicated and expensive. The increased production costs due to labelling would be paid by consumers without necessarily providing better information or increased food security.

H) 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.

There is no official traceability 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.

I) INTELLECTUAL PROPERTY RIGHTS

Argentine Intellectual Property (IP) laws are based on UPOV-78 which provides strong protection for the right to save and replant seeds. 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.

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

Seed Law – New proposal

The latest seed proposal, sponsored by seed manufactures (via the Argentine Seed Association) and some of the major farmer groups, appears to provide clearer rules in the marketing of seed technologies and IPR protections. The proposed law facilitates producer's own use of seed by mandating that that the price paid by producer for seed will cover the intellectual property rights of that product for a minimum period of three years. That is to say that when the producer purchases a bag of seed he/she will pay for the rights to utilize the biotechnology, germplasm and products obtained from the seed for the three-year period or longer. Although the law does not limit the final use or transfer of seed technologies, it grants the right to the owner of the protected seed technology to require payment for the own use of seed in each subsequent propagation and/or seed multiplication. Indigenous people and producers registered under the National Family Farming registry (low-income producers) are not obligated to pay for the seed technology. Another exception is allocated for the use of seed for research and development purposes.

The proposal strengthens the authority of the National Seed Institute, allowing them to have access to any crop or its product to implement this law, sanctioning anyone who limits this effort or provides false information. This proposal is still pending for revision at the National Congress.

Biosafety Law

Argentina does not currently have a biosafety law. Private sources indicate that due to the current conditions in Congress, a Biosafety Law is considered a long-term objective.

J) CARTAGENA BIOSAFETY PROTOCOL

GOA officials are very active in working with the other countries of the region towards harmonization. Argentina signed the Biosafety Protocol in May 2000 in Nairobi, Kenya, but has not yet ratified it. Argentina is still undergoing a consultation process, analyzing and debating with all the involved sectors the position the country will take in this respect. However, it has become public that Argentina is firmly working toward ratification of the Protocol in the near future.

K) INTERNATIONAL TREATIES/FORA

Codex Alimentarius and Other Agreements

Argentina is working to reach consensus on biotech labelling in an effort to avoid potential trade disruptions and unnecessary cost increases. Numerous proposals have been presented over the past decade, but nothing has been implemented. Contacts believe the Argentine Congress will first focus on the Seed Law before addressing biotech labelling.

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

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

1. **Global asynchronous and asymmetric approvals:** The governments and industry of Argentina, Brazil, and the United States 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 United States 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.

Note: These are the positions of MaizALL.

L) RELATED ISSUES

Intra Mercosur Regulation on Low Level Presence (LLP)

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

A group of representatives of exporting countries met in Argentina in 2010 with the intention of setting the scope, aim and priority issues of a like-minded group on innovative agricultural technologies with a focus on cloning and GE crops. Recognizing that agricultural production will need to substantially increase to meet global food demand; understanding that innovative agricultural technologies need to continue to play a critical role in addressing these challenges, and emphasizing that regulatory approaches should be science based, the group was successful in setting the basis for collaborative work especially in the areas of research and education, promotion of utilization of Codex regulations, and support of science based assessments of food, feed and environmental safety. As of 2018, the Like-Minded Group continues to be very active.

M) LOW LEVEL PRESENCE POLICY

Based on a proposal from Argentina, Mercosur is working on an ¨ Intra Mercosur¨ regulation on LLP. According to the proposal, when a country grants an approval it would notify the Mercosur Biotech Commission, who would decide whether to set a threshold. The intention is to have the proposal ready very soon and then sent to all Mercosur members. The proposal has to go to the SGP8 and to the¨ Common Market Group for review. The expectation is to have the system in force by June 2019.

PART C. MARKETING

A & B) PUBLIC PRIVATE OPINIONS AND MARKET ACCEPTANCE

Most Argentine scientists and farmers are optimistic and enthusiastic about the prospects of using biotechnology to improve the yield and nutritional value of crops while decreasing inputs. Argentine consumers accept the economic benefits of biotech products but remain cautious about supporting the technology for food production. 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 plant products.

CHAPTER 2. ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

Argentina produces both GE and cloned animals.

GE animals

Argentina was the first country in Latin America to develop two generations of genetically engineered cows capable of producing human growth hormone. The cloned (and 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, which is still pending, is approval by the Secretary of Public Health.

Scientists from the National Agricultural Research Institute (INTA), and from the University of San Martin presented the first genetically engineered calf in 2011 that had two human genes introduced in its sequence, which guide the production of two proteins (lactoferrin and lysozyme) contained in human milk. The presence of these proteins in milk offer infants better antibacterial and antiviral protection than normal cow's milk.

GE Salmon

In 2018, United States based company AquaBounty Technologies finalized field trials of its genetically engineered "AquAdvantage" salmon in Argentina. The company states that AquAdvantage will improve productivity and sustainability for an important food product and open the door for the application of similar and new approaches to global protein production.

New Center for Animal Reproduction and Biotechnology

In 2017, the Ministry of Agribusiness, together with INTA the Maimonides University, inaugurated the new Center for Animal Reproduction and Biotechnology to conduct research to generate "GMOs." This project allows the country to open a wider spectrum of intervention in Animal Health and Production, from animals that confer resistance to certain diseases to an improvement in feed conversion and even animals that can produce active ingredients in their by-products like milk.

In addition, the initiative will generate new knowledge in DNA biotechnologies to obtain animals with differentiated and genetically altered capacities, either by transgenesis or gene editing.

Cloned Animals: Research and Development Activity

Three companies and one public institution in Argentina provide commercial cloning services, mostly for breeding animals. There are over 400 cloned animals in the country and to facilitate control (mainly of the ownership of the animals) the Argentine Rural Society has created a Genealogic Registry.

It is unlikely that cloned animals will enter the food chain in the near future due to the expense of production.

PART E: POLICY

A) REGULATORY FRAMEWORK

In 2017, CONABIA updated the existing regulation applicable to animal biotechnology, which introduced improvements to the permit application form for field trials, among other measures.

Resolution 79-E / 2017, published in the Official Gazette on November 2017, updated the following:
- Improvements to the permit application form for field trials, which were identified with the experience of their use and the improvement of the biosafety criteria.
- Include new technologies for animal breeding such as Gene Editing and new features that were unknown a decade ago.
- The possibility of including new types of animals besides mammals, including fish or insects.
- Diversification in the forms of management and containment of animals, such as pools.
- Greater clarity in the sphere of intervention of the evaluation and control bodies, such as the Directorate of Biotechnology of MINAGRO, CONABIA and SENASA.

The technical content of the regulation, which was developed within CONABIA, allows the regulation of cutting-edge developments in the field of animal biotechnology, which are promoted by different research institutes and national and foreign companies. For example, projects for livestock improvement, production of biopharmaceuticals and animals for xenotransplantation that will be carried out by the Animal Reproduction and Biotechnology Center.

With this improvement, the Ministry of Agribusiness simplified and updated the completion of procedures while promoting technological innovation in the agricultural sector and the safe adoption of new technologies.

Full text of the regulation may be found in the Official Bulletin (Spanish version)
https://www.google.com/search?q=google+translator&rlz=1C1GCEA_enUS771US771&oq=googl&aqs=chrome.1.69i57j69i59l2.2760j0j7&sourceid=chrome&ie=UTF-8.
The regulatory system applied to animal created via biotechnology 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, the National Administration of Medicines, Food and Medical Technology (ANMAT in Spanish), is also involved in the evaluation.

B) LABELLING AND TRACEABILITY

The Argentine Rural Society has created as a guide a Genealogic Registry for cloned animals. However, this is not the official traceability system adopted by the GOA. At present, there is no official traceability system managed by the government.

C) TRADE BARRIERS

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

D) INTELLECTUAL PROPERTY RIGHTS

The country does not have any IPR regulations for animal biotechnology.

E) INTERNATIONAL TREATIES/FORA

Argentina has been proactive on the issue of somatic cell nuclear transfer (SCNT) cloning, including collaboration between scientists of different Argentine research centers (mainly University of Buenos Aires, the University of San Martin, and INTA) with counterparts in the United States, Canada, Australia, New Zealand and the European Union, among others.

PART F. MARKETING

A&B) MARKET ACCEPTANCE & PUBLIC/PRIVATE OPINIONS

In general, the development of transgenic animals has not caused much backlash in Argentina.

However, with the development of new breeding techniques, the Argentine Polo Horse Association has expressed concern about the possible production of polo horses genetically manipulated, mutated or edited for both sport and breeding. Of particular concern, the association states that genetic doping, and the misuse of genetic therapies to improve performance, is the next phase of doping that will face equestrian sports. They requested that an efficient and accurate detection method be developed to deter those who seek to use genetic doping in horses and maintain the integrity of the sport.

C) MARKET STUDIES

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

APPENDIX I: Resolution 173

Innovative Biotechnology/NBTs

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

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

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

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

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

The General Directorate of Legal Affairs of the Ministry of Agriculture, Livestock and Fisheries has expressed its legal opinion.
The Secretary of Agriculture, Livestock and Fishery has the authority to render this resolution pursuant to Decree No. 357 dated February 21, 2002 as amended.

Therefore,

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

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

Article 2.- In order to determine whether a specific case is subject to the proceedings herein, Applicants shall submit such case for the assessment of CONABIA through a Previous Consultation Stage ("ICP") pursuant to Resolution No. 701/11. During the ICP the Applicant shall submit data on the breeding methodology used to obtain and select the crop, on the new trait or characteristic introduced, and on evidence of the genetic changes present in the final product.
Within the ICP, the applicant shall request CONABIA to establish whether the result of the breeding process is a new combination of genetic material. A genetic change shall be regarded as a new combination of genetic material when the assessment establishes that a stable and joint
"2015 - AÑO DEL BICENTENARIO DEL CONGRESO DE LOS PUEBLOS LIBRES"
insertion of one or more genes or DNA sequences that are a part of a defined genetic construct have been inserted into the plant genome.

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

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

Article 5.- Upon CONABIA finding that a new combination of genetic material has not been created and, if applicable, that no unauthorized events subsist in the crop, the SAGYP, through the Biotechnology Directorate shall notify the Applicant that the product does not fall under the scope of Resolution No. 763/11 and its complementary regulations.

Notwithstanding the aforementioned, CONABIA may still recommend the Secretary of Agriculture, Livestock and Fisheries, the adoption of follow-up measures for an individual crop taking into account its features and/or novelty on scientific and technical grounds.

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

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

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

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

RESOLUTION SAGYP No. 173

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

APPENDIX iI: JOINT STATEMENT ON ANIMAL CLONING FOR LIVESTOCK PRODUCTION – MARCH 2011

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.

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.