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Report Highlights:

In 2019, Argentina granted conditional approval for a record nine biotech events including the first Chinese-developed soybean event developed and field-tested under a joint venture with an Argentine company which may be approved for export to China as early as 2020. Argentina also updated its biotechnology regulatory framework to improve harmonization with international institutions, in particular with the Cartagena Protocol on Biosafety. The seed royalty system continues to be an unresolved issue.

EXECUTIVE SUMMARY

Biotech Production & Regulation: Argentina continues to be the third largest producer of biotech crops by area, after the United States and Brazil, farming 12 percent of the world´s total biotech crop acreage on an estimated 24 million hectares.

In 2019, the Government of Argentina (GOA) updated the biotechnology regulatory framework to improve harmonization with international instruments and, in particular, the Cartagena Protocol on Biosafety. In general terms, the update covers new technologies including gene editing and simplification based on familiarity criteria. This, along with the recent renewal of Argentine National Advisory Committee on Agricultural Biotechnology (CONABIA) as an FAO Biosafety Reference Center, provides the country with a significant comparative advantage for the development and establishment of biotechnological ventures.

The seed royalty system continues to be an unresolved issue in the country. Argentine law allows farmers to save and replant seed and does not offer intellectual property protections for genetically engineered seed. Consequently, seed companies are hesitant to release newer varieties, limiting farmer access to new technology. Despite intensive debate, Congress did not pass a new seed law before elections in October 2019.

China: China's approval of GE events continues to be a top trade priority for Argentina due to its importance as an export market for Argentine biotech-derived agricultural products. Since 2015, the Government of Argentina (GOA) has included a conditional statement in every approval of a GE event that the event must be approved in China before domestic commercialization. Among the events approved in 2019 is a soybean event, DBN 09004-6, the first Chinese-developed soybean event developed and field-tested under a joint venture with an Argentine company. Industry contacts expect China to approve the event in 2020.

Bio-based Production: In 2019, the Ministry of Agriculture created and launched a bio-based products program and published regulations for companies to use the official "BioProducto Argentino" seal. The goal of this program is to increase the use of renewable agricultural resources, develop new value-added products, and encourage coordination among government agencies to increase the production and use of bio-based products. The program is modeled in part after USDA's BioPreferred program.

Animal genome editing: The U.S. Recombinectics and the Argentine Kheiron signed an agreement in June 2019 focused on precision breeding to introduce new commercial traits in cattle derived from elite genetic lines. The goal is to obtain livestock with different characteristics such as higher protein content

in meat, animal welfare, resistance to disease, and adaptability to adverse climatic conditions. This partnership was made possible, in part, by the GOA's modernized approach to regulation of gene-edited animals.

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PART A: TRADE AND PRODUCTION

A) PRODUCT DEVELOPMENT

All biotech events in Argentina must receive technical approval for safe use in the environment, for human, animal, and crop health, then receive commercial approval that their use will not disrupt Argentina's major export markets. The Ministry of Agriculture publishes a list of events that are approved, both technically and commercially. However, since 2015 all approvals have been additionally conditioned on Chinese approval prior to these events being planted commercially in Argentina. Thus even fully approved events cannot be planted until Chinese approval is granted.

In 2019, the Argentine National Advisory Committee on Agricultural Biotechnology (CONABIA) granted a record nine event approvals in 2019 - five corn, three cotton, and one soybean. A wheat event (containing the HB4 gene that confers drought resistance) received full technical approval but awaits commercial approval by the National Direction of Agricultural Food Markets (DNMA) under the Ministry of Agro-Industry.

In addition to the four major international technology developers: Bayer, Corteva, Syngenta, and BASF, Argentina's domestic biotechnology industry continues to innovate and seek regulatory approvals. One of the most important domestic traits is the *Instituto Agrobiotecnológico Rosario* (INDEAR) HB4, a drought resistance event developed by local researchers that, during field trials increased yield by 30 percent under extremely dry conditions, according to contacts. The HB4 gene was originally isolated from sunflower but has been introduced to wheat, soybeans, and corn. Soybeans with the HB4 gene are currently being field-tested in both Argentina and the United States. In the United States, this testing is being conducted as part of a joint venture between INDEAR and Arcadia AgroSciences.

First Chinese soybean event approved in Argentina

Since 2013, BIOCERES, 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.

In February 2019, DBN's soybean event DBN 09004-6, a trait to confer tolerance to glyphosate and glufosinate-ammonium herbicides in soybeans, received technical and commercial approval in Argentina, but has not yet been approved in China. It is the first Chinese-developed soybean event

approved in Argentina. This event has been field-tested in Argentina and private contacts from the industry expect China's approval by mid-year in 2020.

First wheat event receives technical approval

A wheat event developed by INDEAR, containing the HB4 drought resistance gene, received technical approval in 2019 and awaits commercial approval from the DNMA. There is debate within the government about whether this event should be commercially approved in the near future since no other wheat exporting country has commercialized genetically engineered (GE) wheat varieties, and if approved, the presence of this wheat may lead to shipment rejections in Argentina's main markets. In recent years, Argentina has rebuilt its wheat production to more than 18 million tons per year, of which a third is consumed domestically and the rest exported. While eager for innovation, Argentina's wheat industry is concerned about risk to its export markets from being the first country to commercialize a GE wheat variety. Argentina is in a unique position to potentially commercialize GE wheat because Brazil, a country generally supportive of biotechnology, accounted for 66% of Argentina's wheat exports from 2014 to 2018.

1.) COMMERCIAL PRODUCTION

Argentina is the world's third largest producer of biotech crops, after the United States and Brazil, with sixty biotech crop varieties approved for production and commercialization: fifteen soybean, thirty five corn, six cotton, two potato, one alfalfa, and one safflower.

Introduction of biotech soybeans in the late 1990s sparked a rapid expansion of soybean production, which now surpasses 18 million hectares. A study (Eduardo Trigo & ArgenBio) published in November 2016 estimates the total benefit generated by biotechnology to the Argentine economy has been $ 127 billion 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).

China's approval of GE events

China's approval of GE events continues to be a top trade priority for 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 tolerance (Roundup Ready) soybeans have been adopted at a very high rate in Argentina and encompass all of the estimated 18 million hectares of soybeans planted for the 2018/2019 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 February 2019, Argentina approved DBN-ODBN-O9OO4-6, tolerance to glyphosate and gluphosinate.

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.

Corn

Argentine farmers have been using stacked corn events for ten years. In 2019, Argentina approved five new corn events:

1) DOW Argentina, MON-89O34-3 x DAS-O15O7 x MON OO603 x 6 x DAS-4O278-9 tolerance to herbicides formulated based on products of the family of ariloxifenoxi an 2,4,-D, ammonium gluphosinate and glyphosate, and resistance to lepidoptera.
2) MONSANATO + DOW +PIONEER Argentina, MON-89O34-3 x DAS-O1507-1 x MON-88O17-3 x DAS-59122-7 tolerance to glyphosate and gluphosinate. resistance to lepidoptera
3) MONSANTO ARGENTINA MON-87427 x MON-89º34-3 x DASO15O7-1 x MON-88017-3 x DAS- 59122-7 tolerance to ammonium gluphosinate, glyphosate and resistance to lepidoptera
4) MONSANTO ARGENTINA.MON-87427-7 x MON-89º34-3 Xmon-oo6o3-6 tolerance to ammonium gluphosinate, glyphosate and resistance to Lepidoptera
5) MONSANTO ARGENTINA. MON-87427-7 x MON 89O34-3 x SYN-IR162-4 x MON-OO603-6 tolerance to ammonium gluphosinate, glyphosate and resistance to lepidoptera

Cotton

In the 2018/19 crop season, the total cotton area was planted with the stacked event (Bt x TH). As there is new investment in cotton production after several years without any approvals in cotton, two new traits were approved during 2019:

1) BASF. BCS-GH811-4 Glyphosate tolerance and herbicides inhibitors of HPPD
2) BASF. SYN-IR1O2-7 and BCS-GHOO2-5 x BCS-GHOO4-7 x BCS-GHOO5-8 x SYN-IR1O2-7 the stacked BCS-GHOO4-7 and BCS-GHOO5-8 tolerance to ammonium gluphosinate, glyphosate and resistance to lepidoptera.

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

With the exception of biotech soybeans imported from Paraguay for use in the Argentine soy crushing industry, Argentina is not a major importer of GE-crops. 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. The Argentine soybean crushing industry needed to source beans to maintain its processing levels and imported soybeans in large quantities from the U.S. for the first time since 1997.

Import Policy

With the arrival of U.S. soybeans in 2018, the status of entry protocols became a point of discussion, especially relative to biotech events. On May 18, 2018, the Ministry of Agro-Industry released Resolution 26/2018 (https://www.boletinoficial.gob.ar/#!DetalleNorma/183969/20180518). This initiative permits the potential importation of biotech soybeans with events not authorized locally. It established 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 to supplement domestic soybean stocks due to the year's drought. Local reports indicate that this resolution resolved all pending issues regarding the importation of U.S. soybeans and shipments should continue to be able to enter with no interruptions for the course of the authorization. Contacts report the government viewed this as a transitory measure necessary to maintain crush levels until domestic production levels could normalize.

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

In order to improve harmonization with international institutions and in particular with the Cartagena Protocol on Biosafety, the GOA updated in 2019 the regulatory framework in biotechnology thru Resolutions No. 36/2019 and No. 44/2019. In general terms, the update covers new technologies including gene editing, and simplification based on familiarity criteria. Full text of Resolutions 36 and 44 (in Spanish) may be found at:

https://www.boletinoficial.gob.ar/detalleAviso/primera/210280/20190701?busqueda=1

https://www.boletinoficial.gob.ar/detalleAviso/primera/210398/20190702?busqueda=1

Since 2012, the evaluation of new events takes place on a case-by-case basis, taking into consideration the breeding method 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 Directorate. This office coordinates three technical areas: biosafety (the head is a member of the 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 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. 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.

CONABIA is a multi-sectorial organization made up of representatives from the public sector, academia and private sector organizations related to agricultural biotechnology. Its 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. CONABIA ensures compliance with

Resolutions 701/2011 and 661/2011 (please see links below). These new resolutions supersede Resolution 39/2003.

Under the regulatory framework, CONABIA is directed to complete its evaluations in 180 days. The use of electronic forms has been added, allowing all agencies to access documents at the same time, further speeding up the approval process. CONABIA has reviewed over 2,100 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 CONABIA's 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 Directorate of Agricultural Food Markets (DNMA)*

Role: Evaluate commercial impact on export markets by preparing a technical report to avoid a negative impact on Argentine exports. DNMA mainly analyzes the approval status of the event under study in key destination markets to determine if the addition of this event to Argentina's export supplies might restrict access to these markets. Under the framework, the DNMA evaluates 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 Tolerance	40-3-2	Nidera S. A.	SAPyA N° 167 (25-3-96)
Soybean	Resistance to Glufosinate Ammonium	A2704-12	Bayer S.A.	(2011)
Soybean	Resistance to Glufosinate Ammonium	A5447-127	Bayer S.A.	(2011)
Cotton	Resistance to Lepidoptera	MON 531	Monsanto Argentina S.A.I.C.	SAGPyA N°428 (16-7-98).
Cotton	Glypohosate Herbicide Tolerance	MON 1445	Monsanto Argentina S.A.I.C.	SAGPyA N° 32 (25-4-01).
Cotton	Resistance to Lepidoptera and Glyphosate Tolerance	MON 1445 x MON 531	Monsanto	(2009
Corn	Resistance to Lepidoptera	176	Ciba-Geigy	SAPyA N° 19 (16-1-98).
Corn	Glufosinate Ammonium Tolerance	T25	AgrEvo S. A.	SAGPyA N° 372

				(23-6-98)
Corn	Resistance to Lepidoptera	MON 810	Monsanto Argentina S.A.I.C.	SAGPyA N° 429 (16-7-98).
Corn	Resistance to Lepidoptera	Bt 11	Novartis Agrosem S.A.	SAGPyA N° 392 (27-7-01).
Corn	Glyphosate Herbicide Tolerance	NK 603	Monsanto Argentina S.A.I.C.	SAGPyA N° 640 (13-7-04).
Corn	Resistance to Lepidoptera and Glufosinate Ammonium Tolerance	TC 1507	Dow AgroSciences S.A. and Pioneer Argentina S.A	SAGPyA N° 143
Corn	Glyphosate Herbicide Tolerance	GA 21	Syngenta Seeds S.A.	SAGPyA N° 640 (22-08-05)
Corn	Glyphosate Herbicide Tolerance **and** Resistance to Lepidoptera	**NK603x MON810**	**Monsanto**	SAGPyA Nº 78 (28/08/07)
Corn	Resistance to Lepidoptera and Glufosinate Ammonium and Glyphosate Tolerance	1507 x NK603	Dow AgroSciences S.A. y Pioneer Argentina S.R.L.	SAGPyA Nº 434 (28/05/08
Corn	Glyphosate Herbicide Tolerance **and** Resistance to Lepidoptera	Bt11 x GA21	Syngenta Seeds S.A.	(2009)

Corn	Resistance to Lepidoptera	MON89034"	Monsanto	(2010)
Corn	Glyphosate Herbicide Tolerance **and** Resistance to Lepidoptera	MON 88017	Monsanto	(2010)
Corn	Glyphosate Herbicide Tolerance **and** Resistance to Lepidoptera and Coleoptera	"MON89034x88017"	Syngenta Agro S.A.	(2010)
Corn	Resistance to Lepidoptera	MIR 162	Syngenta Agro S.A.	(2011)
Corn	Resistance to Lepidoptera and Glyphosate and Glufosinate Herbicide Tolerance	Bt11xGA21xMIR162	Syngenta Agro S.A.	(2011)
Corn	Glyphosate Tolerance and herbicides that inhibit ALS	DP-098140-6	Pionneer Arg. S.R.L.	(2011)
Corn	Resistance to Coleoptera	MIR 604	Syngenta Agro S.A.	(2012)
Corn	Resistance to Lepidoptera and Coleoptera, and Glyphosate and Glufosinate	Bt11xMIR162xMIR604xGA21	Syngenta Agro S.A.	(2012)

	Herbicide Tolerance			
Corn	Resistance to Lepidoptera and Coleoptera, and Glyphosate and Glufosinate Herbicide Tolerance	MON 89034 x TC 1507 x NK603	Dow Agro Sciences	(2012)
Corn	Resistance to Lepidoptera and Glyphosate	MON 89034 x NK603	Monsanto	(2012)
Soybean	Resistance to Lepidoptera Glyphosate	MON 87701 x MON 89788	Monsanto	(2012)
Soybean	Resistance to Imidazolinones	CV 127	Basf	(2013)
Corn	Resistance to Lepidoptera, Glyphosate and Glufosinate Herbicide Tolerance	TC1507xMON810xNK603 y TC1507xMON810	Pioneer Argentina	(2013)
Corn	Resistance to Lepidoptera, Glyphosate and Glufosinate Herbicide Tolerance	Bt11xMIR162xTC1507xGA21 and all the intermediate stacked	Syngenta Agro S.A.	(2014)
Soybean	Resistance to 2, 4D, Glyphosate and Glufosinate	DAS-44406-6	Dow AgroSciences S.A.	(2015)
Potato	Virus Resistance	SY233	Tecnoplant S.A.	(2015)

Soybean	High oleic content and glyphosate Tolerance	DP-305423 x MON-04032-6	Pioneer Argentina S.R.L.	(2015)
Soybean	Drought Resistance	IND410(Hb4)	INDEAR S.A.	(2015)
Cotton	Resistance to Glyphosate and Ammonium Glufosinate	BCS-GHØØ2-5 x ACS-GHØØ1-3 GHB614xLLCotton25	Bayer S.A.	(2015)
Corn	Resistance to Lepidoptera, Glyphosate and Glufosinate	TC1507xMON810xMIR162xNK603	Pioneer Argentina S.R.L.	(2016)
Soybean	Resistance to Glyphosate	MON-89788-1	Monsanto Argentina	(2016)
Soybean	Resistance to Lepidoptera	MON-87701-2	Monsanto Argentina	(2016)
Corn	Resistance 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	Resistance to Lepidoptera, Glyphosate and Glufosinate	DAS-81419-2 x DAS-444Ø6-6 and DAS-81419-2	Dow AgroSciences Argentina S.R.L	(2016)

Corn	Resistance to Lepidoptera, Glyphosate and Glufosinate	SYN-BT011-1 x SYN-IR162-4 x MON-89034-3 x MON-00021-9	Syngenta Agrosciences	(2016)
Soybean	Tolerance 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	MON-87427-7, MON-87411-9, MON-87427-7 × MON-89Ø34-3 × SYN-IR162-4 × MON-87411-9 and all the	Monsanto Argentina S.R.L.	May, 2018

	Lepidoptera y Coleoptera	stacked in between		
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
Soybean	Tolerance to glyphosate and gluphosinate. Drought Resistance.	IND-ØØ41Ø-5 x MON-Ø4Ø32-6 (OCDE)	INDEAR	October 2018
Cotton	Glyphosate Tolerance and herbicides inhibitors of HPPD	BCS-GH811-4	BASF	February 2019
Soybean	Tolerance to glyphosate and gluphosinate	DBN-Ø9ØØ4-6	INDEAR	February 2019
Corn	Tolerance to herbicides formulated based on products of the family of ariloxifenoxi an 2,4,-D, ammonium	MON-89O34x DAS-O1507 x MON -OO603 x SYN-IR162-4 x DAS-40278-9	DOW Argentina	April 2019

	gluphosinate and glyphosate, and Resistance to lepidoptera.			
Cotton	Tolerance to ammonium gluphosinate, glyphosate and Resistance to lepidoptera	SYN-IR1Ø2-7 y BCS-GHØØ2-5 x BCS-GHØØ4-7 x BCS-GHØØ5-8 x SYN-IR1Ø2-7, the intermediate stacked and the events BCS-GHØØ4-7 y BCS-GHØØ5-8	BASF	June 2019
Corn	Tolerance to glyphosate and gluphosinate. Resistance to lepidoptera	MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-88Ø17-3 x DAS-59122-7	MONSANATO + DOW +PIONEER Argentina	August 2019
Corn	Tolerance to ammonium gluphosinate, glyphosate and Resistance to lepidoptera	MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7	MONSANTO ARGENTINA	August 2019
Corn	Tolerance to ammonium gluphosinate, glyphosate and Resistance to lepidoptera	MON-87427-7 × MON-89Ø34-3 × MON-ØØ6Ø3-6	MONSANTO ARGENTINA	August 2019
Corn	Tolerance to ammonium gluphosinate, glyphosate and Resistance to lepidoptera	MON-87427-7 x MON-89Ø34-3 x SYN-IR162-4 x MON-ØØ603-6	MONSANTO ARGENTINA	September 2019
Cotton	Resistance to insects and lepidoptera	SYN-IR1Ø2-7	Syngenta	October 2019

Source: CONABIA

C) STACKED EVENTS

Approvals of stacked events are decided on a case by case evaluation under which the applicant must submit a letter simultaneously to the Ministry of Agriculture (Directorate of

Biotechnology) and SENASA requesting technical and commercial approval 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 is required.

D) FIELD TESTING

Argentina's regulation does not require field testing of GE crops. However, for most events it is necessary to provide the scientific information generated from doing field testing in Argentina. 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. In March 2019, the Ministers of Agriculture of Argentina, Brazil, Chile, Paraguay and Uruguay, members of the (CAS), met in Buenos Aires, Argentina and issued a declaration on gene editing (see Related Issues).

Argentina's Regulatory System for Products Derived from NBTs

In accordance with Argentina's status as one of the most sophisticated regulatory systems in the world, Argentine 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**

There is no unified reference list of techniques that generate NBTs due to the emerging pace of these technologies. For instance, in many of the initial lists of NBTs created in the mid-2000s, the CRISPR-Cas9 system was not included, since that technology was not in widespread use, 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. Therefore, 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 technological terms such as “Cisgenesis," “Reverse Breeding," “Site Directed Nucleases” may be satisfactory for a scientific discussion, when comparing different uses of an NBT by different research groups, differences from one case to another made it difficult for Argentina to adopt definitions for 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.

Argentina determined that the analysis to establish whether a certain NBTs-derived crop is subject to regulations for “Genetically Modified Organisms” (GMO) could only be made on a product by product basis. So far, Argentina has evaluated six plants produced by NBTs, and all were excluded from the “GMO” regulation and deemed applicable for review under 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 crops obtained by breeding techniques involving modern biotechnology do not fall under "GE" regulation.

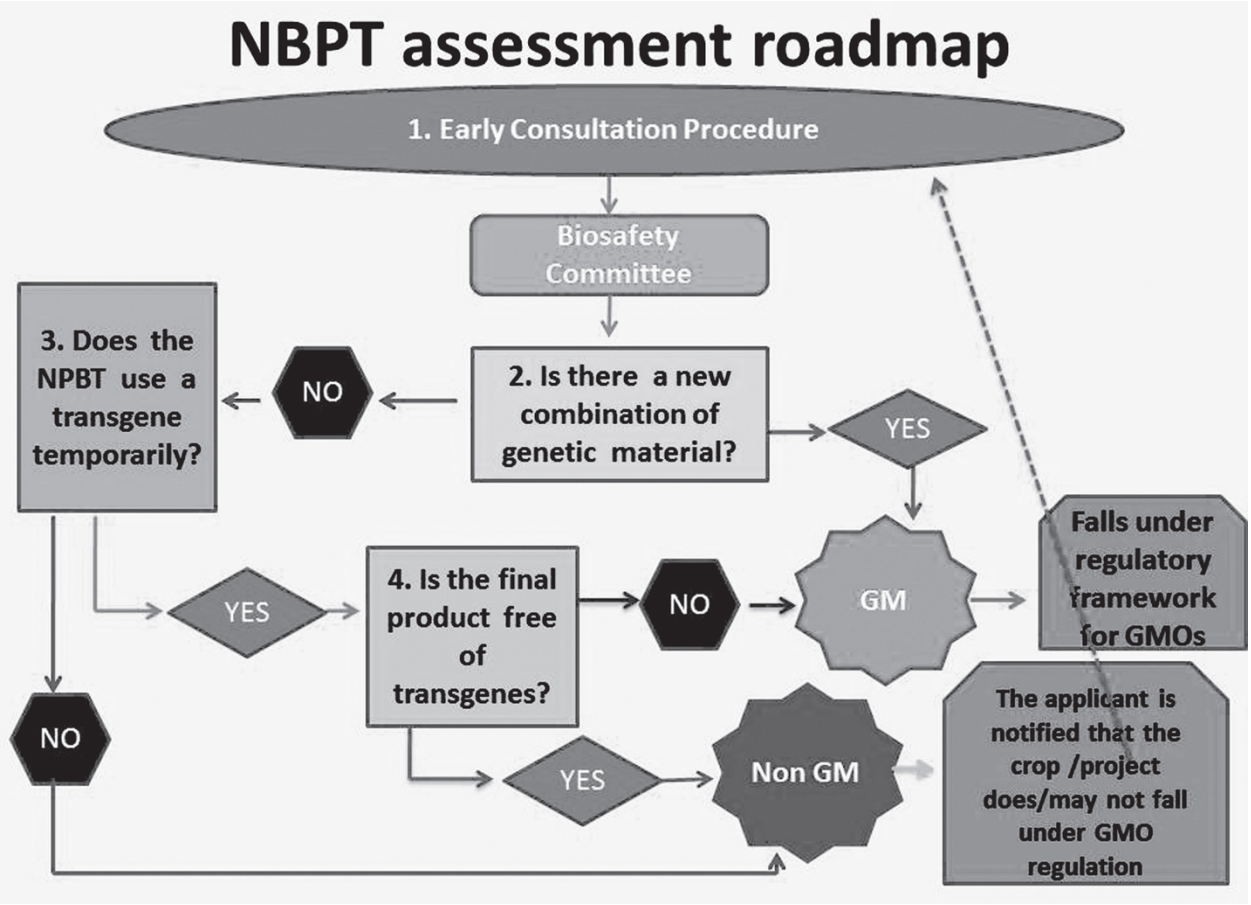
To this end, applicants submit each product (NBT-derived crop) to establish whether the result of the breeding process is a new combination of genetic material or not.

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 described product 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 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: Directorate 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 a 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 official traceability system in place. Exporters provide an affidavit stating the content of the shipment. There are private companies (authorized labs) which have the capability to perform the required tests, and the National Institute of Agricultural Technology (INTA) does analysis on a private basis.

Since 2016, biotech testing of some export shipments has been conducted under the *Bolsatech* program. This is not intended to identify unapproved events but is meant to help recuperate costs for technology providers since IPR rights for biotech seed in Argentina are difficult to enforce. *Bolsatech* is a voluntary system implemented by the Grain Board of Trade that assures that seed companies will be able to collect royalties and provides farmers different options to pay for the technology. Farmers can choose either advance payment or at the point of delivery. Payment for the technology at point of delivery is used by those farmers that did not purchase certified seed but have used it without permission. If detected, they have the option of paying at port and *Bolsatech* provides additional testing and arbitration. For those farmers who do not join the *Bolsatech* system and test positive at port, the payment is automatically deducted (or the shipment is rejected) under agreements between the seed companies and the exporters.

I) INTELLECTUAL PROPERTY RIGHTS

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. Argentine Intellectual Property (IP) laws are based on UPOV-78 which provides strong protection for the right to save and replant seeds. Seed companies can register new varieties, but penalties for unauthorized use of protected seed varieties are negligible. Seed companies have tried to use contracts to ensure that seeds containing biotech events are only used by authorized purchasers. However, judicial enforcement of such contracts has proved ineffective as a mechanism to prevent the unauthorized commercial use of GE varieties in Argentina.

Seed Law

The seed royalty system continues to be an unresolved issue in the country. Despite intensive debate, Congress did not pass a new seed law before elections in October 2019. 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 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, 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 it to have access to any crop or its product to implement this law, sanctioning anyone who limits this effort or provides false information. However, this was not the only proposal that was submitted to Congress. There have been other drafts submitted, which do not have the consensus of the seed industry nor the farmer organizations. After the failure to pass a new seed law before elections in October, it is unclear when the new Congress will begin debating the seed law, or what legislative draft will serve as the basis for discussion in the future.

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 unlikely to be considered in the short term.

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

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 trade barriers when exporting 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 sectors 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

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 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 2019, the Like-Minded Group continues to be very active.

Declaration of the Ministers of Agricultural Council of the South (CAS) on Gene Editing

The Ministers of Agriculture of Argentina, Brazil, Chile, Paraguay and Uruguay, members of the (CAS), met in Buenos Aires, Argentina in March 2019 and agreed that**:**

1. Crops improved by genome editing have the potential to play a fundamental role in addressing the challenges of the agricultural production, contributing to increase the food supply in a sustainable manner.
2. Gene editing can generate crops analogous to those obtained through other conventional breeding methods.
3. CAS countries present public and private investment in the development of improved crops by Genome Editing. This is because it can accelerate the access of the agricultural producer to new characteristics of agricultural interest, while representing an opportunity for technology transfer developed by national agricultural research institutions and small and medium biotech companies.
4. Arbitrary and non-justified distinctions between products obtained by genome editing and other breeding methods should be avoided.

In consideration of the above mentioned, Ministers declared that**:**

1. They will exchange information on product development and existing regulatory frameworks that apply to them, exploring opportunities with scientific basis for regional and international regulatory harmonization

2. They will seek to work together and with third countries to avoid obstacles without scientific basis to trade in improved agricultural products by gene edition.

M) LOW LEVEL PRESENCE POLICY

Intra Mercosur Regulation on setting a mechanism to decrease occurrence of presence in Low Level Presence of GE organisms between states parties

Based on a proposal from Argentina Mercosur members signed resolution MERCOSUR/GMC/RES. Nº 23/19 in order *to set a mechanism to decrease occurrence of presence in Low Level Presence of GE organisms between states parties. Members took into consideration*:

- That there is currently a great development of genetically engineered organisms planted in a large number of hectares in the member countries.

- That there is an increase in the number of events present in agricultural products that circulate internally and / or that are exported by the member countries.

- That there is no effective mechanism for coordination between the member countries, there being a continuous increase in the asynchrony of event approvals, increasing the risk of trade disruptions arising from the presence at low levels of events not yet approved in at least one member country.

- That it is necessary to consolidate the internal trade of MERCOSUR in regard to trade in agricultural products

Scope and description of the resolution

This Resolution establishes an operating mechanism that member countries must implement in those situations of LLP of GE Organisms.

This Resolution applies to GE organisms authorized in any member country for use in human and/or animal feed in accordance with the risk assessment procedure of the guidelines established by Codex Alimentarius (CAC / GL 45/2003), but which It has not yet been approved in at least one MERCOSUR member country.

Implementation of the resolution

When there is commercial authorization that includes use in human and/or animal feed of GE organism in any member country, the latter must inform the other member countries of said authorization, within the scope of the Committee on Agriculture Biotechnology (CBA) of the Working Subgroup N 8 "Agriculture (SGT N 8), within 30 calendar days from the date of authorization.

When communicating on the aforementioned authorization, the member country must send to the CBA, the appropriate risk assessment carried out by the national body responsible for GE biosafety, the

information on the status of approval of the event in the main markets of export, and the information submitted by the applicant, excluding information classified as “confidential”

For the implementation of this mechanism, the developers of the authorized event must have previously submitted the request for commercial evaluation of the product in the other member countries.

Having all aforementioned information, the CBA in each case must:

-Analyze possible LLP situations of the GE event that may occur in the region.

-Recognize the risk assessment of the member country as input for a decision making.

-Prepare a report to recommend exclusive approval for GE LLP situations. In that report, each member country may define maximum tolerance limits according to its convenience, as well as other technical recommendation it deems relevant. That report must be recorded as an annex to the CBA minutes.

-Submit the report to SGT N 8, so that the highest corresponding authorities of the member countries become aware of it.

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

Post is unaware of any 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

During 2019 CONABIA received two applications to evaluate GE animals, one for bovines that carry a gene that produces human growth hormone in milk and milk with proteins against rotavirus, and one for sheep which is still at a confidential stage.

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.

Center for Animal Reproduction and Biotechnology

In 2017, the Ministry of Agriculture, together with INTA and 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.

Improved Brangus breed

Kheiron, a leader in cloning and animal genome editing, used CRISPR to silence the myostatin gene to improve the productivity of Brangus breeds. The expected result of silencing the myostatin gene is to obtain greater muscle mass and thus greater protein production per animal.

Joint venture between Recombinetics and Kheiron

The American Recombinectics and the Argentine Kheiron signed an agreement in June 2019 focused on precision breeding in Argentina, to introduce new commercial traits in cattle derived from elite genetic lines. The intended end goal of this strategic alignment will be commercializing precision-bred animals that generate highly valued germplasm products for the global market with an initial emphasis on adaptability traits for climate change. The use of Recombinetic's gene-editing platform, combined with Kheiron's in-vitro embryo production, cloning, and gene-editing platform and infrastructure, will allow

single generation production of market-ready animals without sacrificing diversity and estimated breeding values for performance. The companies signed an alliance on a series of projects in Argentina that intend to produce multiple animal product lines to solve existing concerns in the cattle industries.

Part of the challenge in using gene editing and cloning methods for genetic improvement is commercial acceptance of innovative breeding. In Argentina, this is made possible, in part, by the GOA's modernized approach to regulation of gene-edited animals.

Cloned Animals: Research and Development Activity

Three companies and one public institution in Argentina provide commercial cloning services, mostly for breeding animals. There are more than 400 cloned animals in Argentina and to facilitate control (mainly of the ownership of the animals and germplasm) 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 Agriculture simplified and updated 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 animals created via biotechnology is the same used to evaluate plant events, that is, the evaluation takes place on a case-by-case basis. 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 a Genealogic Registry for cloned animals to assist owners and prospective owners of cloned animals. However, this is not an official traceability system adopted by the GOA. At present, there is no official traceability system managed by the government.

C) TRADE BARRIERS

Post is unaware of any country specific trade barriers to the trade of GE or cloned animals from Argentina.

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 public comment 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 to the association is that genetic doping, and the misuse of genetic therapies to improve performance, will be 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

Post is not aware of any relevant market studies on animal biotechnology in the country.

APPENDIX I: Resolution 173

Innovative Biotechnology/NBTs

BUENOS AIRES,

Having reviewed file No. S05:0001472/2015 of the Registry of the Ministry of Agriculture,

Livestock and Fisheries, and Food

WHEREAS:

Decree No. 763 dated August 17, 2011 of the Ministry of Agriculture, Livestock and Fisheries

(MAGYP) sets forth the guidelines for the activities involving Genetically Modified Organisms

(GMO) in the Republic of Argentina.

Pursuant to article 3.A of the Resolution No. 763/11, risk assessment, design of biosafety measures and risk management during each stage of GMO assessment hereof shall be conducted by the National Advisory Commission on Agricultural Biotechnology (CONABIA), which Executive Secretariat is held by the Biotechnology Directorate of the National Directorate of Processes and Technologies of the Under secretariat of Added Value and New Technologies under the Secretariat of Agriculture, Livestock and Fisheries (SAGYP) under the MAGYP.

Article 3 of Resolution (SAGYP) No. 437 dated August 06, 2012 sets forth as actions pertaining to CONABIA, among others, to advise the Secretary of Agriculture, Livestock and Fisheries on “risk assessment, design of biosafety measures and risk management in the various stages of assessment, authorization and release into the agro-ecosystem of genetically modified organisms ”and “every issue to be submitted to its scientific evaluation”.

Resolution (SAGYP) No. 701 dated October 27, 2011 sets forth the requirements and proceedings that must be met by biosafety assessments for the release of GM-plants into the agro-ecosystem.

Resolution No. 701/11 defines GM-plant as a plant organism bearing a combination of genetic

material obtained through the application of modern biotechnology.

Such regulation defines event as “the combined and stable insertion into the plant genome of one

or more genes or DNA sequences that are part of a defined genetic construct”.

The development of agricultural biotechnology is a key tool for the addition of value in the agribusiness value chain in the Argentina Republic.

In the Argentina Republic, as in the rest of the world, mayor advances are being produced in the development of new breeding techniques in plants (NPBT).

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

This decision does not alter the regulatory framework applicable to GMO but rather sets forth proceedings to determine the cases in which a crop obtained by NBT that use modern biotechnology to generate genetic modifications are subject to GMO rules and regulations.

CONABIA, after extensive debate in several of its meeting during 2013 and 2014 has rendered its agreement to this regulation during its ninth meeting of the year 2014, which took place on November 25, 2014.

The General Directorate of Legal Affairs of the Ministry of Agriculture, Livestock and Fisheries has expressed its legal opinion.

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

Therefore,

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

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

Article 2.- In order to determine whether a specific case is subject to the proceedings herein, Applicants shall submit such case for the assessment of CONABIA through a Previous Consultation

Stage (“ICP”) pursuant to Resolution No. 701/11. During the ICP the Applicant shall submit data on the breeding methodology used to obtain and select the crop, on the new trait or characteristic

introduced, and on evidence of the genetic changes present in the final product.

Within the ICP, the applicant shall request CONABIA to establish whether the result of the

breeding process is a new combination of genetic material. A genetic change shall be regarded as a new combination of genetic material when the assessment establishes that a stable and joint

insertion of one or more genes or DNA sequences that are a part of a defined genetic construct

have been inserted into the plant genome.

Article 3.- GM-plant offspring shall be regarded as a GM-plant unless the scientific data allows to draw a different conclusion. Thus, in addition to the provisions contained in Article 2 herein,

applicants shall inform if any event that is no longer present in the crop to be introduced into the

agro-ecosystem was used during the breeding process and include evidence of the absence of the

event(s) under consideration during the in ICP.

Article 4.- The Biotechnology Directorate will conduct a preliminary assessment on the data

furnished by applicants in a period that shall not exceed sixty (60) calendar days, and proceed to

list the matter for debate in the following CONABIA meeting. On the basis of the information filed during the ICP, CONABIA will establish whether a new combination of genetic material has been created. Also, if appropriate, CONABIA will determine if there exists enough scientific evidence to support the absence of the event(s) used transiently during the crop breeding process. Both the Biotechnology Directorate and CONABIA may request the Applicants to file additional data and information in order to complete their assessments.

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

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

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

Article 7. - Applicants may file for a preliminary inquiry aiming at anticipating whether a

hypothetical expected product derived from new plant breeding techniques in projects still in the

design stage would fall under the scope of Resolution No. 763/11 and its complementary

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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.

Attachments:

No Attachments