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**Report Highlights:**

In 2020, Argentina became the first country to grant conditional approval for cultivation of Genetically Engineered (GE) wheat. In addition, a soybean event jointly developed between Argentine and Chinese developers was approved in Argentina and China. Recent regulatory framework updates eliminated the requirement to request permission to commercialize stacked GE events in Argentina. Ongoing issues relating to the lack of a perpetual royalty system for GE seeds remains largely unresolved.

## EXECUTIVE SUMMARY

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

On October 7, 2020, the Argentine company *Bioceres Crop Solutions* received final regulatory approval for its HB4 Eco Wheat, bred for drought tolerance, making Argentina the first country to approve GE wheat. The approval, however, is contingent upon approval in Brazil (Argentina's main market for wheat). Developed by a joint venture between *Bioceres* and the French company *Florimond Desprez*, the HB4 Eco Wheat's enhanced drought resistance comes via the HB4 event derived from sunflowers. The approval has raised concerns within the wheat industry, due to concerns over risk to wheat exports.

The Government of Argentina (GOA) has continued to update its biotechnology regulatory framework to improve harmonization with international instruments, particularly the Cartagena Protocol on Biosafety. In general terms, the updates cover new breeding techniques (NBTs), including gene editing, and eliminate the requirement for separate approvals of stacked GE events. This provides the country with a significant comparative advantage for the development and establishment of biotechnological ventures.

The seed royalty payment system issue continues to be unresolved. Argentine law allows farmers to save seed, resulting in unsecured intellectual property protections for GE seed. Despite intense debate, legislative attempts to create a payment scheme have all failed. Consequently, seed companies have been cautious in recent years in releasing new varieties, thus limiting farmer access to the latest technology. One exception to this trend occurred in late 2019 when BASF and Syngenta re-activated the approval process for several GE cotton lines.

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 has granted only conditional approvals for GE soybean products, mandating that events must be approved in China before domestic commercialization.

GE soybean events approved in 2019 included DBN 09004-6, the first Chinese developed soybean event approved anywhere in the world. The initial approval by a third country, in this case Argentina, is a prerequisite for approvals of GE events for import into China. As a result, the Argentine approval allowed this event to be approved by the Chinese Government in June 2020.

**Animal genome editing:** An Argentine company made a formal consultation to Argentine regulators regarding the regulatory status of three breeds of genome-edited cattle, which are being developed under a joint venture with the U.S. company *Recombinetics/Acceligen*. Two animal breeds are being developed to incorporate heat tolerance and hornless traits. In 2020, Argentine regulators ruled that these animals would not be considered GE.

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## CHAPTER 1. PLANT BIOTECHNOLOGY

### PART A: TRADE AND PRODUCTION

#### A) PRODUCT DEVELOPMENT

All GE events in Argentina must pass a three-pronged approval process with considerations for environmental safety; human, animal, and crop health; and export approval in foreign markets. Since 2015, Argentina has also required that all soybean approvals secure approval by China prior to being planted commercially in Argentina.

**First approval of a wheat event in the world** After a historic record of nine GE event approvals in 2019, Argentina approved only one GE crop in 2020, the HB4 wheat developed by the Argentine company [Bioceres Crop Solutions](#), under a joint venture with the French company [Florimond-Desprez](#). The incorporated traits are tolerance to drought and ammonium glufosinate. The company reports that the crop can sustain yields even in cases of severe drought, displaying a 40% higher yield compared to non-GE wheat grown under similar conditions. The effective entry into force of the commercial approval is conditional on the Brazilian approval of the crop. Brazil, a country generally supportive of biotechnology, accounted for 33 % of Argentina's wheat exports in 2019. Sources indicate that Brazil's approval could be granted by the end of 2020; however, its domestic wheat industry has already expressed resistance to Brazil's approval.

The HB4 gene, originally isolated from the sunflower, has been introduced to wheat, soybeans, and corn. Soybeans with the HB4 gene are currently under field trials in both Argentina and the United States, with commercial release expected in the near future. In the United States, this business is being conducted as part of a joint venture between [INDEAR](#) and [Arcadia BioSciences](#)

#### **First Chinese soybean event approved in Argentina**

Since 2013, *Bioceres Crop Solutions*, the flagship of the local biotech industry, has partnered with [Beijing Da-Bei-Nong Technology Group \(DBN\)](#) 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 received regulatory approval, and is the first Chinese-developed soybean event approved in Argentina. This event trait confers tolerance to glyphosate and glufosinate-ammonium herbicides in soybeans. Initial approval by a third country is a requisite for considering approvals of GE events for import to China; the 2019 Argentine approval allowed this event to be approved by the Chinese Government in June 2020.

#### B.) COMMERCIAL PRODUCTION

Argentina is the world's third largest producer of biotech crops, after the United States and Brazil, with 61 biotech crop varieties approved for production and commercialization: 16 soybean

varieties, 34 corn varieties, seven cotton varieties, two potato variety, one alfalfa variety, and one safflower variety.

## **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:

[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 99.8 percent of the estimated 18 million hectares of soybeans planted for the 2019/2020 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.

The Argentine soybean economy is targeted toward exports. 20 percent of soybeans are exported as whole beans while 80 percent are crushed and exported as meal or oil. The majority of soy oil and soy 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 Foreign Agricultural Service Report [Argentina Oilseeds and Products Report](#) .

## **Corn**

Argentine farmers have been using stacked corn events for ten years. No new corn events were approved in 2020.

## **Cotton**

In the 2018/19 crop season, total cotton planted area used stacked pest resistance and herbicide tolerance events.. Three new traits were approved in 2019:

- 1) BASF. BCS-GH811-4: Glyphosate tolerance and herbicides inhibitors of HPPD
- 2) BASF. SYN-IR102-7 and BCS-GH002-5 x BCS-GH004-7 x BCS-GH005-8 x SYN-IR102-7: the stacked BCS-GH004-7 and BCS-GH005-8 events provide tolerance to ammonium glufosinate and glyphosate, and resistance to lepidoptera.

3) Syngenta SYN-IR1Ø2-7: resistance to lepidoptera.

### **C.) EXPORTS**

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

### **D.) IMPORTS**

With the exception of GE soybeans imported from Paraguay for blending use by the Argentine soy crush industry, Argentina is not a major importer of GE crops. However, a severe drought during the peak summer months in 2018 forced Argentine crushers to seek additional sources of soybeans to maintain its processing levels. As a result, Argentina imported soybeans in large quantities from the U.S. for the first time since 1997. Therefore, the Argentine regulatory system enabled the possibility of granting approvals for food, feed and processing (FFP) without granting approval for planting. This allowed the import of soybeans as grains (not allowed to be used as seed) from the US and Brazil containing GE events that were assessed to be safe in Argentina. Owner companies of these GE soybeans did not want to obtain planting permission because of Intellectual Property Rights (IPR) issues regarding seed trade (see next).

#### ***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. On May 18, 2018, the Ministry of Agro-Industry released [Resolution 26/2018](#) (link available only in Spanish). This initiative permits the potential importation of GE soybeans, even if they contain events that have not been authorized locally. It established a four-year authorization for the importation of all GE products 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.

### **E.) FOOD AID**

Argentina is not a food aid recipient or donor and is not likely to be one in the near future.

### **F. TRADE Barriers**

There are no significant biotechnology-related trade barriers that negatively affect U.S. exports.

## **PART B. POLICY**

### **A) REGULATORY FRAMEWORK**

In order to improve harmonization with international institutions, particularly the Cartagena Protocol on Biosafety, the GOA updated in 2019 the regulatory framework in biotechnology through the following Resolutions (all links in Spanish):

[Resolution 44/19](#) (field trials of GE Plants)

<http://servicios.infoleg.gob.ar/infolegInternet/verNorma.do?resaltar=true&id=324699>

Resolution 36/19 (commercialization of GE Plants)

<http://servicios.infoleg.gob.ar/infolegInternet/verNorma.do?resaltar=true&id=324647>

Disposition 1/19 (New breeding techniques)

<http://servicios.infoleg.gob.ar/infolegInternet/verNorma.do?resaltar=true&id=328693>

Disposition 2/19 (Isolation measures)

<http://servicios.infoleg.gob.ar/infolegInternet/verNorma.do?resaltar=true&id=329788>

Disposition 3/19 (Synergy of stacks)

<http://servicios.infoleg.gob.ar/infolegInternet/verNorma.do?resaltar=true&id=331335>

Disposition 4/19 (Management of insect resistance)

<http://servicios.infoleg.gob.ar/infolegInternet/verNorma.do?resaltar=true&id=331336>

Since 2012, the GOA has conducted the evaluation of new events 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. Argentine regulations are based upon the characteristics and behaviors of the GE event. Aspects of the GE product that may differ from those of its conventional counterpart are taken into consideration, with consideration for potential impacts to the agroecosystem as well as for its safety as food for human and animal consumption.

Events in Argentina must pass a three-pronged approval process with considerations for environmental safety; human, animal, and crop health; and export approval in foreign markets. Approvals within the first two categories are considered to be “technical approvals” and the final category is “commercial approval.” Without commercial approval, the event cannot be either commercialized or exported.

The Biotechnology Directorate within the Ministry of Agriculture centralizes all biotech activities and information, and coordinates the three technical areas: biosafety, policy analysis and formulation, and regulatory design.

The approval process for commercialization of GE 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 GE crops to 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 related regulatory processes.

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 concurrently, speeding the approval process. CONABIA has reviewed over 2,100 permit applications since its creation.. CONABIA is an advisory agency that operates pursuant to a resolution by the Argentine Ministry of Agriculture. Due to 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.

*-National Service of Agricultural and Food Health and Quality (SENASA)*

Role: Evaluate the safety of food products derived from GE crops for human and animal consumption.

*-National Directorate of Agricultural Food Markets (DNMA)*

Role: Evaluate commercial impact of GE approvals on export markets. 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)*

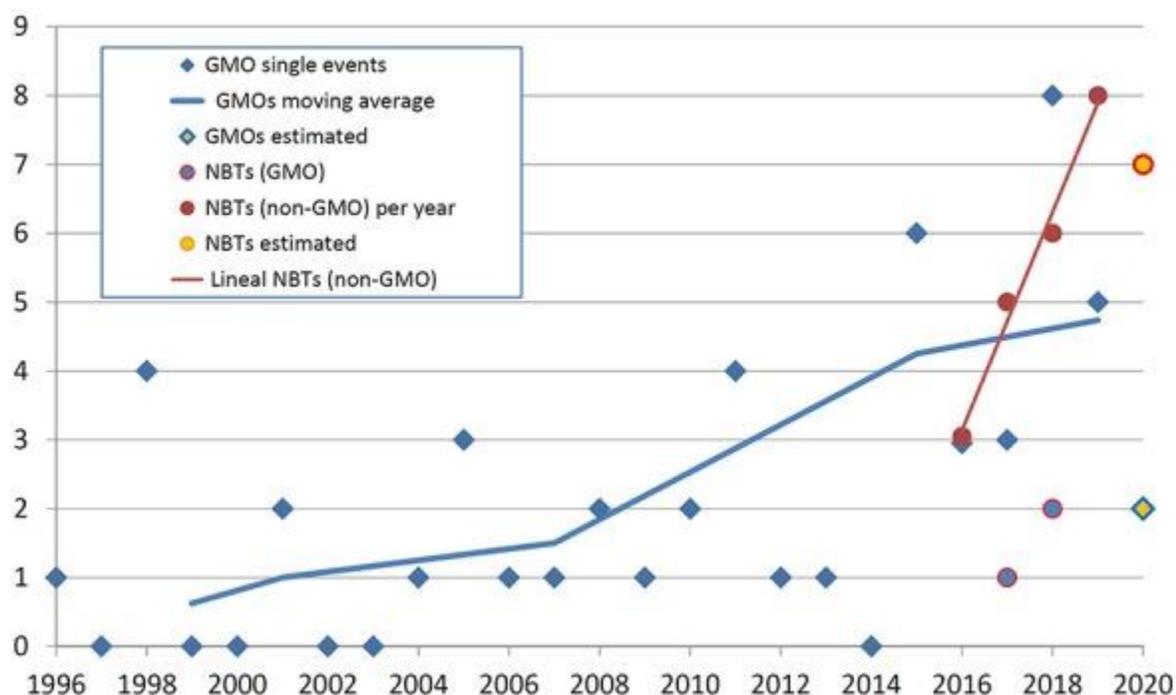
Role: Establish requirements for registration in the National Registry of Cultivars.

Upon completion of the steps mentioned above, the Biotechnology Directorate compiles all pertinent information and prepares a final report to the Secretary of Bioeconomy, Food and Land Development for a final decision.

## **B. APPROVALS**

The chart below shows a timeline of GE approvals in Argentina. See Part B, section A for more information on the approval process. See the end of this report for a full list of GE crops approved in Argentina.

### **Timeline of GE approvals in Argentina and the determination of conventional or GE status for products obtained using different NBTs**



The horizontal axis represents the year of the regulatory decision, while the vertical axis represents the number of products.

Source: Whelan, A. I., Gutti, P., & Lema, M. A. (2020). Gene editing regulation and innovation economics.

### C) STACKED EVENTS

Historically, 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 (Argentina’s National Food Safety and Quality Service) 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. The evaluation also considers possible effects of the stacked event in the ecosystem and potential risks to food safety. CONABIA and SENASA sometimes require additional information from applicants.

A new regulation approved in late 2019 changes the way stacked events are assessed and approved, and eliminates the need to assess or approve stacks of events that have been approved previously and were considered to represent a low possibility of synergy with other events. With this approach Argentine policy is aligned with that in the US, where most stacks do not require additional approval (unless they combine insecticidal proteins).

## **D) FIELD TESTING**

In Argentina intense field-testing activity for GE crops is performed by many local and international developers, with an average of 60 field testing applications per year. Each application includes requests dozens of release sites and for permission to test hundreds of different events. Argentina uses a permit-based system in which developers must present an application for evaluation and approval on a case by case basis. The list of field trial applications currently under assessment is not public information. Local field trials are necessary for the approval of new transformation events, but not for varieties that stack previously approved individual events. The number of local field trials can be reduced by combining information from field trials performed overseas.

## **E) INNOVATIVE BIOTECHNOLOGIES**

In the second semester of 2019, Argentina presented a declaration in the plenary of the WTO SPS committee (WTO document code G/SPS/GEN/1699) WTO document Code G/SPS/GEN/1699 The declaration was issued by the Ministers of Agriculture of Argentina, Brazil, Chile, Paraguay and Uruguay, all of whom are members of the Agricultural Council of the South (CAS). This declaration provided strong support for genome editing and other innovative breeding techniques and is in line with a similar declaration that Argentina had presented to the WTO on behalf of the “like minded” group.

### **Argentina’s Regulatory System for Products Derived from New Breeding Techniques**

Argentina was the first country with a “GMO-trigger” (Cartagena Protocol compliant) regulatory system that adopted explicit criteria for establishing whether products obtained with gene editing techniques are “Genetically Modified Organisms” (GMOs) To date, seven Latin-American countries (Chile, Brazil, Colombia, Paraguay, Ecuador, Honduras, and Guatemala) have enacted equivalent regulations.

Argentine policymakers and regulators debated for more than 3 years to clarify the status of products derived from New Breeding Techniques (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 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 considered to be a “GMO”. 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 are considered to be 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. Argentine policy makers have found it difficult to create technically clear 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 widely applicable criterion regarding the regulatory status of end products since these can differ significantly.

Argentina determined that the analysis to establish whether a certain NBT-derived crop is subject to regulations for “GMOs” 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 “GMO” regulations and deemed applicable for review under conventional processes.

## **Regulatory Process**

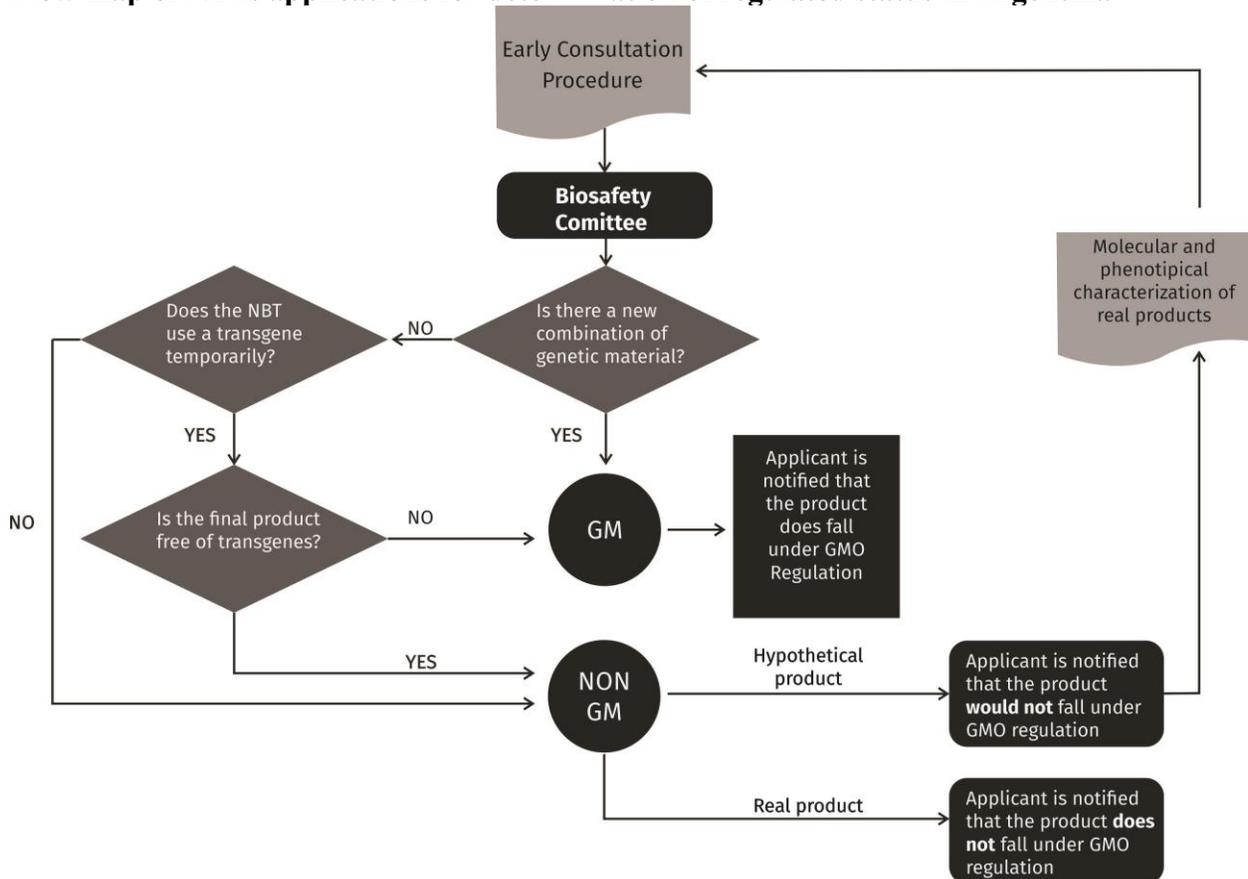
[Resolution no. 173/15](#) of the Secretariat of Agriculture, Livestock and Fisheries (In Spanish) established procedures to determine the criteria under which crops obtained by breeding techniques involving modern biotechnology do not fall under “GMO” regulations. To receive a determination, applicants submit an application for each product (NBT-derived crop) to establish whether the result of the breeding process is a “new combination of genetic material.”

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. 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 “GMO” regulation. If the product is not regulated as a “GMO” event, but its features 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.

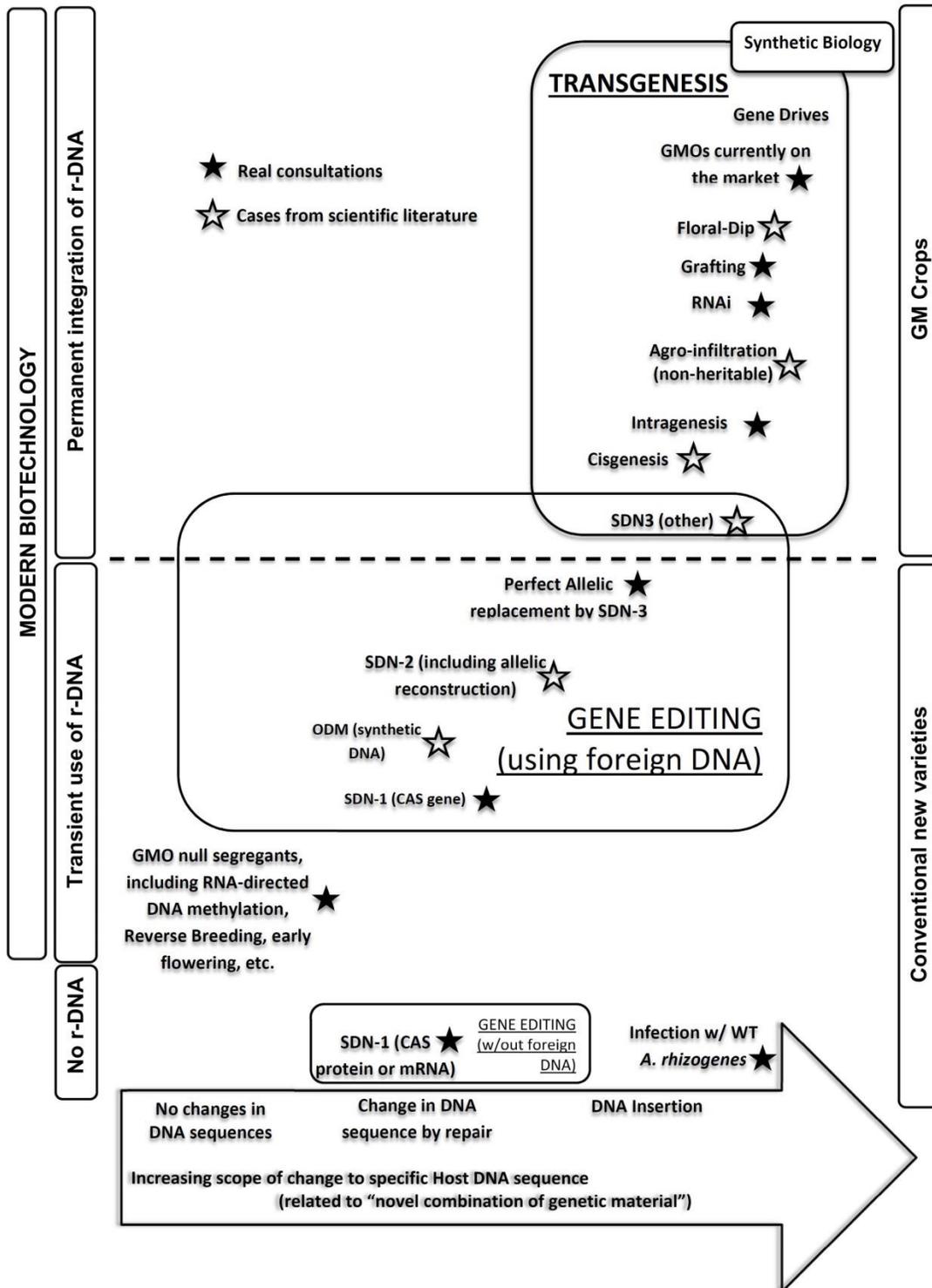
For projects in the design stage, applicants may file inquiries aimed at a preliminary assessment of whether the expected product might be regulated as a GE event. When the new crops are finally generated, the applicant must still submit factual determinations about the genetic modification. In the event 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



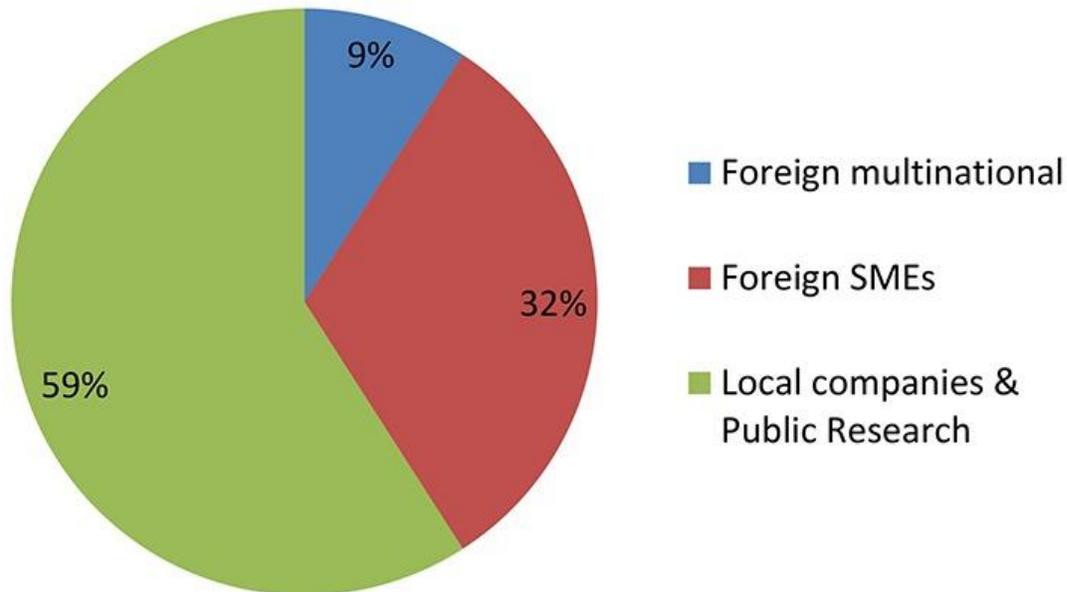
Source: Whelan, A. I., & Lema, M. A. (2019). Regulation of genome editing in plant biotechnology: Argentina. In *Regulation of Genome Editing in Plant Biotechnology* (pp. 19-62). Springer, Cham.

# Map of GMO and non-GMO techniques developed by Argentine regulators



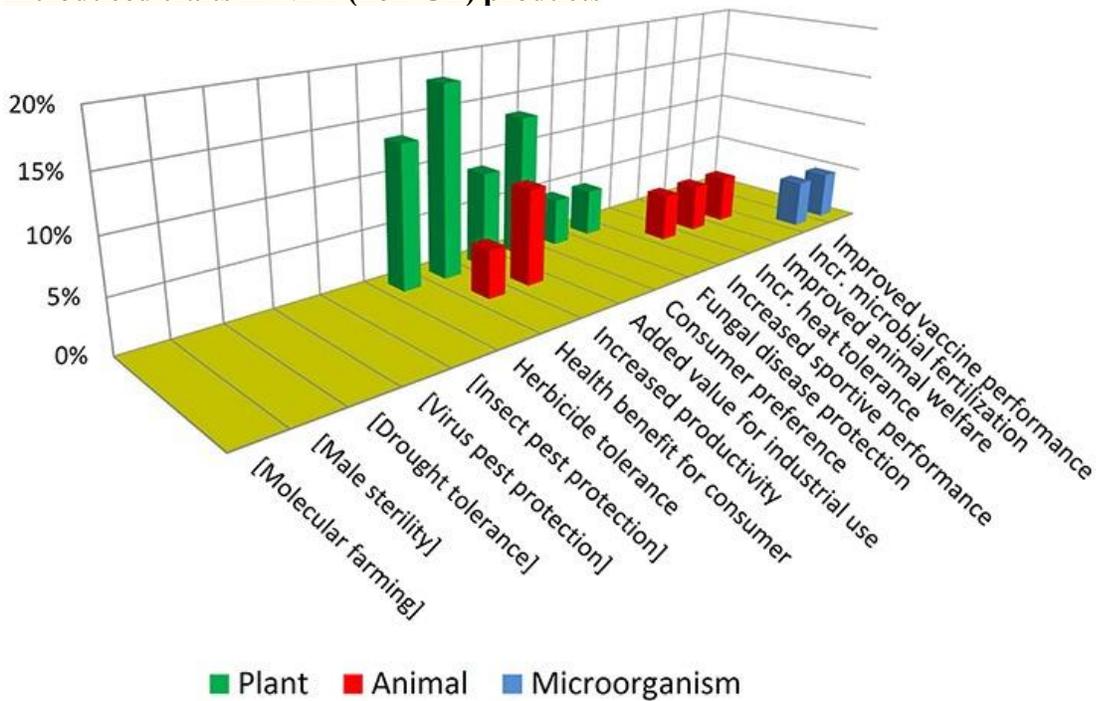
Source: Whelan, A. I., & Lema, M. A. (2019). Regulation of genome editing in plant biotechnology: Argentina. In *Regulation of Genome Editing in Plant Biotechnology* (pp. 19-62). Springer, Cham.

### NBT (non-GE) products by developer profiles



Source: Whelan, A. I., Gutti, P., & Lema, M. A. (2020). Gene editing regulation and innovation economics. *Frontiers in Bioengineering and Biotechnology*, 8, 303.

### Introduced traits in NBT (non-GE) products



Source: Whelan, A. I., Gutti, P., & Lema, M. A. (2020). Gene editing regulation and innovation economics. *Frontiers in Bioengineering and Biotechnology*.

## **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 the following into account:

- 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**

Argentina does not maintain a traceability system. Exporters provide an affidavit stating the GE content of the shipment. Private companies (authorized labs) have the capability to perform required tests and the National Institute of Agricultural Technology (INTA) provides analysis on a private basis. To date, there have been no provisions for gene-edited products in this respect.

## **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.

Nevertheless, industry has established a testing system to identify end users of GE soybean seeds. The program, called *Bolsatech*, is not intended to identify unapproved events but is a voluntary system implemented by the Grain Board of Trade with technology providers to confirm all seed technology users are identified for royalty collection at point of sale. Farmers can pay in advance or at the point of delivery. Farmers that are found to be with selling certified seed without permission must pay royalties at the point of delivery. Under this situation, the payment is automatically deducted or the sale is rejected under agreements between technology companies and exporters.

### **Seed Law**

The system for perpetual seed royalties continues to be an unresolved issue. 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 a 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 or seed multiplication.

Indigenous people and producers registered under the National Family Farming registry (low-income producers) would not be obligated to pay royalties. Another exception would be allowed for the use of seed for research and development purposes. The proposal strengthens the authority of the National Seed Institute, allowing it access to any crop or product for the purpose of implementing this law and 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 the 2019 elections, it is unclear when the new Congress will begin debating a seed law, or what legislative draft will serve as the basis for future discussions.

### **Biosafety Law**

The abovementioned regulations constitute the specific regulations for biosafety, and they are based on general laws on food safety and animal and plant health; this scheme is similar to the US regulatory framework. For this reason, there is no biosafety law in Argentina.

## **J) CARTAGENA BIOSAFETY PROTOCOL**

GOA officials are very active in working with regional neighbours towards regulatory harmonization. Argentina signed the Biosafety Protocol in May 2000 in Nairobi, Kenya, but has not ratified it. Argentina is still undergoing a consultation process, analyzing and debating with the involved sectors regarding the country's position. However, sources indicate that Argentina is working toward ratification of the Protocol in the near future, on the basis of a project proposed by the Biotechnology Directorate in 2019.

## **K) INTERNATIONAL TREATIES/FORA**

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

As GE corn producers and global suppliers, Argentina, Brazil, and the United States face similar trade barriers in export markets. 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***

Representatives of exporting countries met in Argentina in 2010 to set the scope, aim, and priority of 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 increase substantially 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. For instance, there are periodic exchanges between agricultural attachés of Like-Minded Group countries in Brussels and China.

### ***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 support both 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 the transfer of technologies developed by national agricultural research institutes.
4. Any arbitrary and unjustified distinctions between agricultural products obtained by gene editing and those obtained through other breeding techniques must be avoided.

### **M) LOW LEVEL PRESENCE POLICY**

#### ***Intra Mercosur Regulation on setting a mechanism to decrease occurrence of trade disruptions caused by Low Level Presence (LLP) of GE organisms***

Based on a proposal from Argentina, Mercosur members signed resolution [MERCOSUR/GMC/RES. N° 23/19](#) in order to decrease trade disruptions caused by LLP situations. This resolution establishes an operating mechanism that member countries must implement to avoid LLP situations with GE organisms.

When there is commercial authorization of GE products for use in human or animal feed in any member country, that country 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 following the date of authorization.

When sharing aforementioned authorization, the member country must send 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.

In summary, the objective of this process is to speed up the coordinated approval of an event in the four countries of the MERCOSUR following the event's approval in any one country. This process does not entail sharing information on LLP incidents with third parties or for other purposes.

## **N) RELATED ISSUES**

None

## **PART C. MARKETING**

### **A) PUBLIC/PRIVATE OPINIONS**

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. 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.

### **B) MARKET ACCEPTANCE/STUDIES:**

Argentine consumers accept the economic benefits of biotech products but remain cautious about supporting the technology for food production. Although there are no rejections or controversies around the safety of GE crops, there is increasing activism against the use of glyphosate, which represents a growing concern to consumers.

Post is unaware of any relevant country specific studies on the marketing of GE plants and plant products. A study has been made on the prospective impact on innovation economy of gene-edited organisms of agricultural use: Whelan, A. I., Gutti, P., & Lema, M. A. (2020). Gene editing regulation and innovation economics. *Frontiers in Bioengineering and Biotechnology*, 8, 303.

## **CHAPTER 2. ANIMAL BIOTECHNOLOGY**

### **PART D: PRODUCTION AND TRADE**

#### **A) Product Development:**

Argentina produces both Gene Edited and cloned animals.

## **GE animals**

### **Gene edited Cattle: Joint venture between Recombinetics and Kheiron**

The U.S. company *Recombinetics/Acceligen* and Argentine company *Kheiron* signed an agreement in June 2019 focused on precision breeding in Argentina. Through the agreement, they will work introduce new commercial traits in cattle derived from elite genetic lines. The intended end goal of this strategic alignment is the commercialization of 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 genetic diversity and estimated breeding values for performance. The companies are working together on a series of projects in Argentina that intend to produce multiple animal product lines and address existing concerns in the cattle industry.

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.

Their first product would be animal breeds that are hornless and have improved heat tolerance. These products were presented to the Argentine Biosafety Commission CONABIA for revision in 2019. In May 2020, the Commission recommended that these animals should be considered as non-GE.

## **Gene edited Fish**

In 2017, The U.S. company *AquaBounty*, received a non-GE designation from Argentine regulators for its genome-edited tilapia fish. The AquaBounty fish grows more efficiently as compared to other tilapia varieties.

## **Cloned Animals: Research and Development Activity**

Although more than 400 cloned cattle have been generated in Argentina, ongoing activity has stalled, mostly due to concerns regarding trade barriers in the European Union. Cloning activity of polo horses remains robust, and to date almost cloned 300 animals have been produced. There are several ongoing research projects to clone different species, specially endangered species. In Sept 2020 a group from the University of Buenos Aires reported that they for the first time they had been successful in cloning a zebra,

**B) COMMERCIAL PRODUCTION:** Argentina's commercial production is limited to

polo horses (about 300 hundred clones have been already produced). No other cloned animals are currently produced. No biotech animals have been approved yet, therefore there is no commercial production.

C) **EXPORTS:** Argentina exports polo horses to several destinations, including the United States. No biotech animals are currently exported.

D) **IMPORTS:** None

#### E) **TRADE BARRIERS**

There are no trade barriers at this time that would affect U.S. exports for GE animals, cloned animals, or the offspring of cloned animals to Argentina.

### **PART E: POLICY**

#### **A) REGULATORY FRAMEWORK**

Argentina now has procedures in place for requesting the commercial approval of GE animals, as well as for excluding gene-edited animals from the GE regulations. This was enabled by [Resolution 63/19 \(link is in Spanish\)](#).

B) **INNOVATIVE BIOTECHNOLOGIES:** the regulation for Gene Edited animals in Argentina perfectly mirrors the regulation for GE crops, having the same provisions for field trial and commercial release applications and genome-edited or stacked products.**APPROVALS:** No biotech animals have been approved yet, although there is extensive research performed by several groups.

#### **C) 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.

In 2014, The Rural society also organized a workshop among top breeders to discuss the implications of adopting and/or tracing gene-edited animals. A mix of concerns and expectations was shared by participants.

#### **E) INTELLECTUAL PROPERTY RIGHTS**

Argentina does not have any specific IPR regulations for animal biotechnology.

#### **F) 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.

**G) RELATED ISSUES:** None

### **PART F. MARKETING**

#### **A) 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 expressed concern about the possible production of polo horses that have been genetically manipulated, mutated, or edited for both sport and breeding. Genetic doping is of particular concern to the association, as is the misuse of genetic therapies to improve performance. They requested that an efficient and accurate detection method be developed to deter those who seek to use genetic doping in horses in order to maintain the integrity of the sport.

#### **B) MARKET ACCEPTANCE/STUDIES**

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

## **CHAPTER 3: MICROBIAL BIOTECHNOLOGY**

### **PART G: PRODUCTION AND TRADE**

#### **a) COMMERCIAL PRODUCTION**

There are currently no commercial production projects working on GE microbes in the Argentine food industry.

**b) EXPORTS** Argentina is a net exporter of food products and wine, but the Government as well as the industry, do not have any records of the use of GE microbes in the food or wine industry.

**c) IMPORTS** Argentina does not currently require an import notification of GE microbes for use in the food industry, such as ingredients. Therefore, there are no-records of GE microbes.

**d) TRADE BARRIERS** Currently there are no trade barriers that would affect U.S. exports for GE microbes to Argentina.

**PART H: POLICY**

**a) REGULATORY FRAMEWORK** Argentina has not developed specific regulations for GE microbes.

**b) APPROVALS** No approvals for GE microbes have been granted, as there as been no request for GE microbes’ for research, development, or commercialization in Argentina.

**c) LABELING and TRACEABILITY** There are currently no labeling requirements for GE microbes.

**d) MONITORING AND TESTING** No monitoring and/or testing system in place for GE Microbes in the country.

**e) ADDITIONAL REGULATORY REQUIREMENTS** None

**f) INTELLECTUAL PROPERTY RIGHTS (IPR)** Argentina is a party to international bodies related to Intellectual Property Rights, which addresses plant patents, copyright protection, registration requirements.

**g) ) RELATED ISSUES** None

**PART I: MARKETING**

**a) PUBLIC/PRIVATE OPINIONS** No public or private opinions has been published in any public media in Argentina, regarding GE microbes.

**b) MARKET ACCEPTANCE/STUDIES** The production or use of GE microbes for agricultural use or for the food industry is unknown by local consumers. There are no market studies regarding GE microbe’s acceptance.

**GE Crops Approved in Argentina**

Crop	Trait Category	Event	Applicant	Resolution
Soybean	Glyphosate Herbicide Tolerance	40-3-2	Nidera S. A.	SAPyA N° <u>167</u> (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.	<u>SAGPyA N°428</u> (16-7-98).
Cotton	Glyphosate Herbicide Tolerance	MON 1445	Monsanto Argentina S.A.I.C.	<u>SAGPyA N° 32</u> (25-4-01).
Cotton	Resistance to Lepidoptera and Glyphosate Tolerance	MON 1445 x MON 531	Monsanto	(2009)
Corn	Resistance to Lepidoptera	176	Ciba-Geigy	<u>SAPyA N° 19</u> (16-1-98).
Corn	Glufosinate Ammonium Tolerance	T25	AgrEvo S. A.	<u>SAGPyA N° 372</u> (23-6-98)
Corn	Resistance to Lepidoptera	MON 810	Monsanto Argentina S.A.I.C.	<u>SAGPyA N° 429</u> (16-7-98).
Corn	Resistance to Lepidoptera	Bt 11	Novartis Agrosem S.A.	<u>SAGPyA N° 392</u> (27-7-01).
Corn	Glyphosate Herbicide Tolerance	NK 603	Monsanto Argentina S.A.I.C.	<u>SAGPyA N° 640</u> (13-7-04).
Corn	Resistance to Lepidoptera and Glufosinate Ammonium Tolerance	TC 1507	Dow AgroSciences S.A. and Pioneer Argentina S.A.	<u>SAGPyA N° 143</u> 

Corn	Glyphosate Herbicide Tolerance	GA 21	Syngenta Seeds S.A.	<u>SAGPyA N° 640</u>  (22-08-05)
Corn	Glyphosate Herbicide Tolerance and Resistance to Lepidoptera	NK603x MON810	Monsanto	<u>SAGPyA N° 78</u>  (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.	<u>SAGPyA N° 434</u>  (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	Pioneer 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 Herbicide Tolerance	Bt11xMIR162xMIR604xGA21	Syngenta Agro S.A.	(2012)
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-GH002-5 x ACS-GH001-3 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-44406-6 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 Agrosiences	(2016)
Soybean	Tolerance to glufosinate and enzyme HPPD inhibitors	SYN-000H2-5	Syngenta Agrosiences & 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.	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

	Resistance to Lepidoptera			
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 x MON-89034-3 x SYN-IR162-4 x 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-00179-5, MON-00101-8 y MON-00179-5 x MON-00101-8	INDEAR	July 2018
Soybean	Only for processing (Food, Feed and Processing)	MON-87708-9 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-89034-3 x MON-88017-3	MONSANTO ARGENTINA S.R.L.	August 2018
Soybean	Tolerance to glyphosate and glufosinate.	IND-00410-5 x MON-04032-6 (OCDE)	INDEAR	October 2018

	Drought Resistance.			
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 gluphosinate and glyphosate, and Resistance to lepidoptera.	MON-89034x DAS-O1507 x MON - OO603 x SYN-IR162-4 x DAS-40278-9	DOW Argentina	April 2019
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 glufosinate, glyphosate and Resistance to lepidoptera	MON-87427-7 × MON-89034-3 × MON-00603-6	MONSANTO ARGENTINA	August 2019
Corn	Tolerance to ammonium glufosinate, glyphosate and Resistance to lepidoptera	MON-87427-7 x MON-89034-3 x SYN-IR162-4 x MON-00603-6	MONSANTO ARGENTINA	September 2019
Cotton	Resistance to insects and lepidoptera	SYN-IR102-7	Syngenta	October 2019
Wheat	Tolerance to drought and ammonium glufosinate	IND-00412-7	Indear-Bioceres	October 2020

*Source: Webpage of the Argentine Government*

**Attachments:**

No Attachments