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Prepared By: Andrea Yankelevich

Approved By: Chase Mcgrath

Report Highlights:

The Government of Argentina (GOA) approved five new genetically engineered (GE) events in late 2023 and 2024, including one cotton, two soybean, and two corn events. In 2024, the first three applications were submitted for joint assessment by the agricultural regulatory agencies of Argentina and Brazil under the Cooperation Agreement on Biosafety of Modern Biotechnology Products, signed in 2022. In the first week of September 2024, an edited potato developed in Argentina was reported as “non-GE.” In June 2024, Argentina, Brazil, Paraguay, and Uruguay established the International Biosafety Network of Products derived from Modern Biotechnology.

EXECUTIVE SUMMARY

Argentina is the third largest grower of GE crops in the world, with roughly 25 million hectares (HA) planted with GE soybean, corn, cotton, and wheat. The commercial adoption of GE crops began in 1996 with the introduction of herbicide-tolerant soybeans and has seen unprecedented growth in the area planted since. Currently, 100 percent of the soybean, 99 percent of the corn, and 100 percent of the cotton planted in Argentina are genetically engineered.

The seed royalty system remains an unresolved issue. Argentine law allows farmers to save and replant seed and does not enforce intellectual property protections for GE seed. Despite intense debate, Congress did not pass a new seed law before elections in October 2019 and has not discussed the proposal since the beginning of the COVID-19 pandemic. Argentina's adherence to the UPOV 91 Act was debated earlier this year and included in the first draft of the Framework Law prepared by the Executive. Still, it was excluded from the final text by the Argentine Congress.

China's approval of GE events continues to be a top trade priority for Argentina as China is a key export market for Argentine biotech-derived agricultural products. Since 2015, the Government of Argentina (GOA) has required that any approval of a genetically engineered (GE) soybean event include a condition stating that China must approve the event before it can be traded in Argentina. China is the world's largest importer of soybeans and one of Argentina's most important trading partners.

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CHAPTER 1. PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

A. RESEARCH AND PRODUCT DEVELOPMENT

Several public research groups and biotechnology companies in Argentina are researching new potential plant products. The country's robust research ecosystem includes collaborations between universities, governmental research institutions, and private biotechnology companies. However, specific details on current developments are not publicly available, and the stage of development of the products is unknown. Also, the information concerning the confined field trials being conducted is confidential.

In 2024, the National Institute of Agricultural Technology (INTA) conducted confined field trials on GE lettuce designed to enhance resistance to fungal pathogens. This project aims to reduce the need for synthetic fungicides by improving the plant's natural defense mechanisms.

In addition, INTA researchers have developed *Cisne*, a new variety of lettuce, using CRISPR gene-editing to enhance the *Grand Rapids* variety. This edited lettuce has more leaves, delayed flowering, and weighs nearly double, allowing for longer biomass accumulation and extended market availability. Currently, field trials are underway as the final step in the development process. These trials aim to evaluate the *Cisne*'s productivity and resilience to climate variations, pathogens, and insects. After completing these trials, the variety will be submitted to the National Seed Institute (INASE) for registration, which is the required step before commercialization.

Furthermore, INTA developed the first genome-edited non-oxidizing potatoes in Latin America, designed to delay enzymatic browning upon cutting. This innovation has the potential to significantly extend shelf life, reduce waste, and enhance value for the food processing industry.

In 2024, new field trials were conducted for a GE sugarcane variety developed by the Obispo Colombres Agroindustrial Experimental Station (EEAOC). The sugarcane is enhanced for increased drought tolerance by introducing genes from other plant species to boost resilience and productivity under water scarcity. Previous lab and greenhouse trials yielded positive results, and an EEAOC-CONICET research team evaluated the variety's field performance under confined conditions.

Among the local developers applying innovative technologies is the Argentine start-up *Bioheuris*. The company develops sustainable weed management systems for growers based on low-use-rate herbicides. Through its HEURIK™ synthetic biology and SWAP™ genome-- editing platforms, *Bioheuris* seeks to accelerate plant breeding without introducing GE elements. The HEURIK™ platform employs targeted protein evolution strategies and rational target site design to identify mutations that confer herbicide resistance in crops, allowing gene variant selection and comparing their efficiency in microbial systems in anticipation of crops. SWAP™ combines *in vitro* culture protocols with genome-editing techniques to introduce precise changes into the plant genome to confer herbicide resistance to plants. In neither case would the developments generate GE plants.

Bioheuris affirms to be currently working on:

1. Expanding collaborations with Santa Rosa Semillas, Grupo Don Mario, and ACA to develop management systems for high-yield soybean varieties;
2. Advancing work on genome-edited sorghum and rice, in partnership with Tobin, to bring new hybrids to global markets;
3. Optimizing integrated rice management through gene editing of elite varieties and hybrids, in alliance with Adecoagro's Itá Caabó;
4. Continuing their partnership with Gensus to develop herbicide-resistant cotton;
5. Generating integrated weed management systems in high-productivity cultivars of alfalfa;
6. A new initiative for peanut and maize, focusing on improving weed control for these crops; and
7. Recently, *Bioheuris* has also expanded its efforts to sunflower cultivation in collaboration with Argenetics, developing integrated weed management systems for this oil crop.

Argentina does not use GE plants to produce antibiotics or pharmaceuticals for human or animal diseases.

B. COMMERCIAL PRODUCTION

Argentina is the world's third largest producer of biotech crops, after the United States and Brazil, with 82 biotech crop events approved for production and commercialization, including 24 soybean events, 44 maize events, eighth cotton events, two alfalfa events, one safflower event, two potato events, and one wheat event.

With the arrival of U.S. soybeans in 2018, entry protocols for GE events became a point of discussion. On May 18, 2018, the former Ministry of Agro-Industry released Resolution 26/2018. This resolution permits the import of GE soybeans with events that have not been approved in Argentina but that have been approved in other countries. These events may be used for food, feed, and processing, but not cultivation or seed commercialization. Under this resolution, the event MON-87751-7 from Monsanto/Bayer Argentina was approved in 2022 only for industrial processing.

The resolution was authorized to be in effect for four years after publication. Currently, the procedure is included in the new regulations (See Part B.a).

Soybean

Released in 1996, glyphosate-tolerant soybeans have been adopted at a very high rate in Argentina and encompass almost all the estimated 16.3 million hectares of soybeans harvested for the marketing year 2023/2024 season, while conventional seed accounted for 1.5 percent intended for human consumption. Furthermore, the new technology facilitated double-crop soybeans (allowing soybeans to be planted following wheat) in many areas where only one crop was planted before the availability of GE varieties.

After the introduction of glyphosate-tolerant soybeans, one of the most essential technological leaps in soybean production occurred in 2012 with the authorization to commercialize soybean seeds, products, and by-products with stacked insect resistance (IR) and herbicide tolerance (HT) events. Farmers in the northeastern region of Argentina, where there is a high incidence of Lepidoptera, have the highest

adoption levels of stacked soybean varieties. Adoption rates decrease incrementally going from northern to southern Argentina.

The Argentine soybean industry is almost entirely oriented towards exports. In MY 2023/24, 6.5 MMT were exported as whole beans, 27 MMT were crushed and exported as meal, and 5.1 MMT were exported as oil. Soybean exports are forecast at 27 MMT in MY 2024/25 as Argentina retakes its place as the largest soybean exporter in the world. Soy oil exports are forecast to grow as well to 5.3 MMT.

Two new soybean events were authorized in 2024:

- MON-87751-7 x MON-877Ø1-2 x MON- 877Ø8-9 x MON-89788-1 (MONSANTO ARGENTINA S.R.L), intended solely as raw material for agro-industrial processing and for human and animal food use.
- BCS-GM151-6 (BASF Argentina S.A.)

For more detailed information on soybean production, please see the Argentina Oilseeds Report:

<https://fas.usda.gov/data/argentina-oilseeds-and-products-annual-8>

Corn

Production in MY 2024/2025 is projected at 49 million tons, 2 million tons lower than USDA official estimates. Post forecasted an area of 6.2 million hectares, 200,000 hectares lower than USDA's official estimate.

Argentine farmers have been using stacked corn events for ten years across all regions of the country. These stacked events reduce the number of treatments and the amount of crop protection products applied and consequently their associated costs. The use of stacked events also allows for better crop health, higher yield potential, and an easier drying process.

Stacked events for insect and weed control become important in late-planted corn crop production systems. While a later planting date can permit more flexibility in choosing the date of sowing and harvesting and in selecting the best conditions of temperature, soil moisture, etc., it exposes crops to higher pressure from insect pests, such as stem borer, armyworm, and bollworm. For this, hybrids with pest control technologies are particularly important for late corn during phenological stages of greater susceptibility. Until MY 21/22, 50% of growers who adopted the Bt technology also used the refuge system. However, refuge use was around 30% in the last two seasons. This decrease is due to the extreme drought during the 2022/23 season and the damage caused by the presence of the pest known as the 'leafhopper' (*Dalbulus sp*) during the 2023/24 season. It is worth noting that the Province of Córdoba incorporated refuge in Bt corn cultivation as an indicator in its Good Agricultural Practices Program.

Post projects corn production in MY 2023/2024 at 51 million tons, 1 million tons below USDA official estimates. Post forecasts corn exports in MY 2024/2025 at 35.5 million tons, practically the same as USDA official estimates. However, MY 2023/2024 exports are expected at 34 million tons, 3 million tons lower than USDA official estimates.

Two new corn events were authorized in 2024:

- DP2Ø2216-6 (CORTEVA SEEDS ARGENTINA S.R.L.).

- DP-202216-6 x MON-00603-6 x DAS-40278-9 (CORTEVA SEEDS ARGENTINA S.R.L.)

For more detailed information on corn production, please see the Argentina Grain and Feed Report: <https://fas.usda.gov/data/argentina-grain-and-feed-update-24>

Cotton

For the 2023/2024 Argentine cotton season, the estimated planted area increased to 610,000 hectares. According to INASE, 100% of the planted cotton was genetically engineered (GE), with 75% being stacked herbicide-tolerant (HT) and insect-resistant (IR) events, and 25% corresponding to HT cotton only. No new events were approved in 2022 or 2023. For the 2024/2025 season, projections estimate a slight decrease in the planted area to 525,000 hectares, while similar adoption of GE cotton is expected. A new cotton event was authorized in late 2023: BCS-GH004-7 x BCS-GH005-8 x BCS-GH811-4 x SYN-IR102-7 (BASF Argentina S.A.).

For more detailed information on cotton production please see: <https://ipad.fas.usda.gov/countrysummary/Default.aspx?id=AR&crop=Cotton>

Wheat

Production in MY 2024/25 is forecast up at 18.6 million tons because of an increase in area to 6.2 million hectares, 200,000 hectares higher than USDA's official area. Post projects harvested area at 6.0 million hectares (HA) and an average yield at 3.0 MT/HA. Argentina is a top global wheat exporter. Wheat exports in MY 2024/2025 are forecast up at 12.4 million tons, 900,000 tons higher than USDA because of expected higher production and lower ending stocks.

Bioceres sowed HB4 wheat under a system of special contracts of preserved identity under the strict control of the National Seed Institute (INASE) to avoid the possible escape of GE material that could impact the production chain or exports (as per Resolution 535/2021, see below). According to the national agency, during the 2022/23 season, almost 50,000 hectares were planted. The company has seeds for the multiplication and production of flour in mills exclusively for this grain, maintaining the segregation of conventional flour. However, the company states its commitment to keep the HB4 seed close-loop management system and, eventually, flour without modifications. This means that HB4 seeds or flour will not be openly commercialized.

The 2023 sales plan included 45 seed multiplier firms, a significant expansion from last season when only three companies were authorized to work with HB4 seeds.

Through the "HB4 Generation" program, *Bioceres* offers an identity-preserved production program through an associative scheme with farmers to test HB4 technology before its commercial stage. The farmer provides the land, tillage, monitoring, and storage. HB4 Generation provides the *Ecoseed*, *Rizobacter* nutrition and protection inputs, logistics, and a digital platform. The program offers benefits for farmers, who act as company providers. The farmer invoices a production service and is paid for the harvested crop with a 100% freight discount. The target areas for this wheat are Entre Ríos, Santa Fe Center, South of Córdoba, La Pampa, West of Buenos Aires, and Southwest of Buenos Aires.

For more detailed information on wheat production, please see the Argentina Grain and Feed Report: <https://fas.usda.gov/data/argentina-grain-and-feed-update-24>

C. EXPORTS

Argentina is a net exporter of GE commodities to numerous markets worldwide, including the United States. Export documentation for grains declares the GE content. The country does not regard non-DNA-containing products derived from GE plants to be genetically engineered. Argentina requires that biotech events be approved in main importing countries before granting authorization for domestic commercialization, to prevent possible trade disruptions.

D. IMPORTS

With the exception of GE soybeans imported from Paraguay for use in the Argentine soy-crushing industry, Argentina is not a major importer of GE crops. In 2024, Argentina is expected to import approximately 4.3 million metric tons (MMT) of soybeans. This is a reduction from the record 11 MMT imported during the previous marketing year (2023), which was necessary to fill the gap created by the severe drought that heavily impacted domestic production. The lower import volume for 2024 reflects a recovery in local production, which is projected to reach around 49.5 MMT.

Import Policy

During a major drought in 2018, the Argentine regulatory agencies allowed the possibility of granting approvals for food, feed, and processing (FFP) only to facilitate imports destined for industrialization. Resolution 26/2018 allows for a fast-track commercial authorization of GE crops destined to for food, feed, and processing (FFP), excluding seed cultivation and commercialization. As a result, in 2018, Argentina imported soybean varieties from the United States and Brazil, which contained events approved for FFP but not for cultivation.

Developers of these soybeans did not seek approval for cultivation due to Argentina's lack of Intellectual Property Rights (IPR) protection for plant varieties.

E. FOOD AID

Argentina is not a food aid recipient or donor and is not likely to be one.

F. TRADE BARRIERS

Post is unaware of any current trade barriers.

PART B. POLICY

A) REGULATORY FRAMEWORK

<i>Legal term (in official language)</i>	Legal Term (in English)	Laws and Regulations where term is used	Legal Definition (in English)
<i>Acumulación de eventos</i>	Stacked events	<ul style="list-style-type: none"> • Resolution 32/21 • Resolution 45/22 	Accumulation by sexual crossing of transformation events that were obtained separately, as well as retransformation or cotransformation resulting in separate and independently segregating inserts.
<i>Agroecosistema</i>	Agroecosystem	<ul style="list-style-type: none"> • Resolution 32/21 • Resolution 45/22 	Ecosystem managed and/or adapted for agriculture, livestock, aquaculture, fisheries, forestry, and agro-industrial production.
<i>Biotecnología moderna</i>	Modern biotechnology	<ul style="list-style-type: none"> • Resolution 32/21 • Resolution 45/22 	Application of: (a) In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or (b) Fusion of cells beyond the taxonomic family, which overcome natural physiological barriers to reproduction or recombination and which are not techniques used in traditional breeding and selection.
<i>Construcción</i>	Construct	<ul style="list-style-type: none"> • Resolution 32/21 • Resolution 412/2 • Resolution 45/22 • Resolution 21/21 	A nucleic acid segment consisting of TWO (2) or more contiguous nucleotide sequences that have been combined by in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA).
<i>Evento</i>	Event	<ul style="list-style-type: none"> • Resolution 32/21 	Individual transformation event, consisting of the insertion of a defined genetic construct into the genome. Multiple copies

		<ul style="list-style-type: none"> Resolution 45/22 	tandem insertion of the same construct or of different constructs shall be considered the same event.
<i>Organismo Genéticamente Modificado (OGM)</i>	Genetically Modified Organism (OGM)	<ul style="list-style-type: none"> Resolution 32/21 Resolution 45/22 	Any biological entity capable of transferring or replicating genetic material that possesses a novel combination of genetic material obtained through the application of modern biotechnology.
<i>Actividades confinadas</i>	Confined activities	<ul style="list-style-type: none"> Resolution 45/22 	Activities that take place either in a plot or in a conventional greenhouse, called release sites, whose design and management characteristics of the materials that are developed in them prevent the generation of propagative material flows outside the delimited area.
<i>Condiciones de Aislamiento</i>	Insulation Conditions	<ul style="list-style-type: none"> Resolution 19/21 and Annex 	Set of measures or processes aimed at insulation conditions for tests with regulated GM materials and reference parameters for confined activities with GMOs vegetables. Isolation distances and duration of the control period postharvest and purging material tolerances.
<i>Bioseguridad</i>	Biosafety	<ul style="list-style-type: none"> Resolution 45/22 	Set of measures or processes aimed at minimizing the potential risks associated with carrying out activities involving a GMO plant and preventing the escape of the latter from the regulated area.
<i>Escape</i>	Scape	<ul style="list-style-type: none"> Resolution 45/22 	Unintentional dissemination of pollen and/or viable propagating material of a regulated plant GMO that occurs by any means.
<i>Liberación (del OGM vegetal)</i>	Plant GMO release	<ul style="list-style-type: none"> Resolution 45/22 	The controlled introduction of a regulated plant GMO into the agroecosystem.
<i>Material Regulado</i>	Regulated Material	<ul style="list-style-type: none"> Resolution 45/22 	Seed and/or biomass of a regulated GMO plant, including materials presumed to contain them, and those non-GMO or

			commercial GMOs present in the regulated area that are sexually compatible with a regulated GMO.
<i>OGM vegetal regulado</i>	Regulated plant GMO	<ul style="list-style-type: none"> Resolution 45/22 	GMO plants belonging to species for agro-industrial use, and/or modified for agro-industrial use, and/or that could be released into the agroecosystem, containing events that do not have authorization for commercial use.
<i>PLAN DE MANEJO DE RESISTENCIA DE INSECTOS (PMRI)</i>	INSECT RESISTANCE MANAGEMENT PLAN (PMRI)	<ul style="list-style-type: none"> Resolution 49/21 	The objective of the “INSECT RESISTANCE MANAGEMENT PLAN (PMRI)” is to ensure the sustainability of agricultural production, maximize the useful life of the technology and delay the evolution of resistance in target insect pests. All events that contain proteins that confer protection against insect pests must have an approved PMRI before the commercial scale planting of the cultivars that contain them.
<i>Nueva técnica de mejoramiento genético</i>	New breeding technique	<ul style="list-style-type: none"> Resolution 21/21 	Change produced in the genome of the organism by the incorporation, in a stable and joint form, of ONE (1) or more genes or nucleic acid sequences that form part of a defined genetic construction.

Argentine biotechnology regulations are based upon the final characteristics of GE products and their potential risks to human health, animals, or to the environment, as compared to risks posed by their conventional counterparts.

The approval process (commercial authorization) for a GE organism takes approximately 6 months. Commercial authorizations are granted by the Undersecretary for Agricultural and Forestal Production, upon completion of three independent assessments by the following agencies of the Secretariat of Agriculture, Livestock and Fisheries of the Ministry of Economy:

- The *Coordination of Innovation and Biotechnology* reports to the National Directorate for Agriculture of the Undersecretariat for Agricultural and Forestal Production of the Secretariat of Agriculture, Livestock and Fisheries of the Ministry of Economy.

The office of the focal point for agrobiotechnology issues in the country and is responsible for conducting the environmental-risk assessment of the applications for confined use (Resolution 45/22) and for commercial authorization of GE organisms destined for agricultural use (Resolution 32/2021).

The office is also responsible for drafting and updating regulations related to GE organisms. Regulators assess GE organism applications and share their findings with CONABIA to jointly assess whether to authorize the commercial release of a GE organism.

- The *National Advisory Committee on Agricultural Biotechnology (CONABIA)* is a multi-sectoral panel integrated by agrobiotechnology experts from academia and the public and private sectors.

CONABIA's responsibility is to conduct the environmental impact assessment of releasing biotech crops into Argentina's agroecosystem. Under Argentina's regulatory framework, CONABIA must complete the GE product assessment in 180 days.

The Food and Agriculture Organization of the United Nations (FAO) recognized CONABIA as the Unique Center of Reference for the Biosafety of GE events. The agreement was renewed for the third time in 2023 and is valid until 2027.

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

SENASA is responsible for the food and feed safety assessment of the products derived from GE crops under the proceedings and criteria established in Resolution 412/02 (in Spanish).

<http://servicios.infoleg.gob.ar/infolegInternet/verNorma.do?id=74376>

- The *National Directorate of Agricultural Food Markets (DNMA) (Dirección Nacional de Mercados Agroalimentarios)*

DNMA evaluates the potential trade impacts of GE product approvals in Argentine export markets under Resolution 510/11. DNMA analyzes the approval status of new events in the main destination markets (those with up to 1 percent of total exports of that crop, such as China for soybeans and Brazil for wheat and corn) and alerts on possible trade disruption risks. In those cases where an event was not approved in a relevant exporting country, the DNMA recommends its approval but on a conditional basis. According to the regulatory framework, DNMA must deliver its assessment within 45 days.

<http://servicios.infoleg.gob.ar/infolegInternet/verNorma.do?id=185853> (in Spanish)

Upon completion of the new event's environmental risk, food and feed safety, and trade impact assessments, the governmental agencies elaborate independent decision documents recommending the approval or not of the event under evaluation. The Coordination of Innovation and Biotechnology submits a final report with the three recommendations to the Undersecretary for Agricultural and Forestal Production, who delivers the final decision on the authorization of GE products.

The full text of Resolution 763/11 (general guidelines of the regulatory framework, in Spanish) can be found at:

<http://servicios.infoleg.gob.ar/infolegInternet/anexos/185000-189999/185806/norma.htm>

The approval process for an event takes approximately six months. The authorization is valid for the entire Argentine territory and does not have an expiration time, i.e., once the event has been authorized, it does not have to be re-registered. As mentioned above, if the event has not yet been authorized in a relevant importing country, the Government of Argentina may issue an approval that is contingent upon obtaining that authorization.

The National Seed Institute (INASE) establishes requirements for seed registration in the National Registry of Cultivars. Only once an event has been authorized, the variety or hybrid carrying it can be registered, and the farmer can proceed to the GE seeds commercialization.

Also, the Coordination of Innovation and Biotechnology and CONABIA conduct the environmental assessment for confined field trials and other activities (import, export, processing) with non-commercial GE events and recommend to the Undersecretariat the issuance of the permit (see Part D, Field Testing).

Under Argentine regulations, no distinction is made between transgenic plant products that contain DNA in the final product form and those transgenic plant products that do not. Non-commercial GE plant products must be handled under a permit that contemplates different containment conditions according to the characteristics of each product (live or not) and its associated risks.

In 2021 and 2022 the GOA updated its regulatory framework for agricultural biotechnology through the following resolutions (all links in Spanish):

Resolution 19/2021 (Isolation Conditions for confined activities with GE plants)

<https://www.argentina.gob.ar/normativa/nacional/resoluci%C3%B3n-19-2021-346692>

Resolution 32/2021 (Environmental risk assessment for the approval of GE plants, including regulation for stacks) https://magyp.gob.ar/sitio/areas/biotecnologia/conabia/_pdf/RES_032-2021_3%20anexos.pdf

Resolution 49/2021 (Management of insect resistance)

<http://servicios.infoleg.gob.ar/infolegInternet/anexos/345000-349999/349663/norma.htm>

Resolution 45/22 (field trials with GE Plants)

https://www.magyp.gob.ar/normativa/_pdf/20220704094400.pdf

Resolution 83/2022 (Conditions for the multiplication of GE crops with conditioned approvals).

<http://servicios.infoleg.gob.ar/infolegInternet/anexos/360000-364999/363410/norma.htm>

B) APPROVALS/ AUTHORIZATIONS

All biotech events in Argentina must receive technical authorization for safe use in the environment, for human, animal, and crop health, and the commercial assessment approval establishing that their adoption will not disrupt Argentina's major export markets or domestic production. The Secretariat of Agriculture publishes a list of the events that are approved.

For detailed information on approvals please visit:

<https://www.argentina.gob.ar/agricultura/alimentos-y-bioeconomia/ogm-vegetal-eventos-con-autorizacion-comercial>

C.) STACKED OR PYRAMIDED EVENT APPROVALS

As per Resolution 32/2021, a stacked event is obtained by sexual crossing or by the retransformation or co-transformation of individual events resulting in separate inserts. For the environmental risk assessment of a stacked event, the applicant must submit a prior consultation request (ICP) to CONABIA and the Coordination of Innovation and Biotechnology with relevant information. This assessment is conducted on a case-by-case basis and follows the Problem Formulation methodology.

If all the individual events included in the stack already have a favorable decision from CONABIA, the information on the ICP should focus on possible interactions (metabolic, epistasis) between the individual events contained in the stacked event and the resulting combined traits. In those event accumulations with protection against pests with synergistic effects between expression products, studies on non-target organisms or scientific evidence should be submitted to assess possible effects of the proteins in combination on non-target organisms.

Applicants must submit a complete application (Resolution 32/2021) for any individual events included in the stack not previously assessed by CONABIA. However, this application may be required to be evaluated jointly with the ICP corresponding to the maximum stack event within 260 working days.

At the end of the risk analysis, the Coordination of Innovation and Biotechnology, together with CONABIA, delivers its conclusions on the environmental safety of the maximum stack event, its intermediated stack events, and any other individual events not previously evaluated.

In the case of SENASA's food and feed safety assessment, applicants can submit a letter requesting approval of the particular stacked event, as described at the beginning of this section.

D.) FIELD TESTING

In Argentina, experimental field trials of non-commercial GE events for research and development activities or seed counter-season multiplication for export are regulated under a permit-based system described in Resolution 45/22 (<https://www.magyp.gob.ar/normativa/pdf/20220704094400.pdf>) (in Spanish).

When applying for a permit, local and international developers must submit information about the event, the confined activities intended, the locations, and the biosafety conditions to implement to avoid GE event release into the environment. The Coordination of Innovation and Biotechnology and CONABIA assess and decide on applications on a case-by-case basis, with an average of 60 applications per year, each including hundreds of events and dozens of release sites. Once the permit is granted, local and international developers must report to the regulatory agency all activities with GE seeds (planting,

harvesting, importing, exporting, processing, and storage). INASE and SENASA carry out periodic inspections to verify compliance with the required biosafety conditions and GE seed stocks.

CONABIA has reviewed over 2,100 permit applications since its creation. The list of field trial applications currently being assessed, and the trials conducted are not public information.

Local field trials are not necessary for the approval of new GE events. Following data transportability criteria, developers can provide information from field trials conducted in other countries with environmental conditions equivalent to those in Argentina.

E. INNOVATIVE BIOTECHNOLOGIES

In 2015, Argentina became the first country in the world with a regulatory system to adopt explicit criteria establishing that certain products obtained with genome editing techniques are not classified as “living modified organisms” subject to Argentine regulations for agricultural biotechnology. Since then, other Latin-American countries (Chile, Brazil, Ecuador, Colombia, Paraguay, Honduras, and Guatemala), African countries (Kenya), and Asian countries (The Philippines and Bangladesh) have followed this lead and enacted similar regulations.

Argentine policymakers and regulators debated for over three years to clarify the status of products derived from “new breeding techniques (NBTs)”, such as genome editing, under the existing biotechnology regulation. During the debate, policymakers and regulators noted that no disagreements emerged in interpreting the terms “living modified organism” or “modern biotechnology” (which in practice means the use and insertion of foreign recombinant DNA at some step of the breeding process, preserving the foreign DNA in the characteristics of the final product). However, the interpretation of the phrase “novel combination of genetic material,” was a matter of debate.

As a result, a “novel combination of genetic material” is the critical factor for Argentina in deciding whether a product derived from “NBTs” is regulated as a “living modified organism”. The following are the main foundational criteria under the Argentine regulation:

- **Case-by-Case Analysis**

In 2021 the GOA enforced Resolution 21/21 to improve the previous regulation on “NBT”-derived crops. This regulation established procedures to determine the criteria under which crops obtained by new breeding techniques fall under agricultural biotechnology regulations. To this end, applicants submit a prior consultation request (ICP) to the Coordination of Innovation and Biotechnology and CONABIA with relevant information on each product (“NBT”-derived crop). This information is assessed by regulators to establish whether the result of the breeding process is a new combination of genetic material still containing foreign DNA in the final product.

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 part of a genetic construct is introduced permanently into the plant genome. With this criteria, “NBT”-derived products containing INDELS, nucleotide substitutions, and ALLELE replacements have been excluded from the agricultural biotechnology regulations. 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 an 80 working day time limit, after which the applicant receives a reply stating if the described product falls under the agricultural biotechnology regulations or not. The regulatory commission must also report to the authorities if the product is not considered to be a “living modified organism”, but its features and/or novelty lead to a significant risk hypothesis. This report is channeled to regulators within the Coordination that assess the crop under agricultural biotechnology regulations.

An “NBT”-derived crop falls under agricultural biotechnology regulations until authorities decide that it is not regarded as “a “living modified organism”, therefore it must be handled as such (e.g. a field trial permit is required before planting).

For projects in the design stage, applicants may file inquiries aimed at a preliminary assessment of whether the expected product might be regulated. When the new crops are finally generated, the applicant must still submit factual determinations about its genetic makeup. If the product possesses the features anticipated in the preliminary inquiry, the earlier assessment regarding its regulatory status would remain unchanged. This preliminary assessment allows local developers to predict costs and development time and to present cases in a wide variety of crops, with diverse phenotypes even at the design stage.

- **Cartagena Protocol Definition**

For transboundary movements of GE and genome-edited crops, Argentina’s regulations adopt a wording similar to that of the Cartagena Protocol on Biosafety.

- **Flexibility for Future Technologies**

Argentina decided that a new regulation on “NBTs” should not be based on a closed list or description of particular technologies but should be flexible and applicable to existing or forthcoming technologies.

In summary, Resolution 21/2021 adopts the following characteristics:

- The procedure determines if a product obtained by an “NBT” is regulated as a “living modified organism”.
- The ICP should include information on the organism involved, the “NBT” used, the improved trait, evidence of the genetic changes generated, and, if a transient plasmid or an intermediate transgene was used during the product’s development, demonstrate its absence in the final product.
- The analysis is carried out on a case-by-case basis.
- It is not restricted to a specific list of techniques.
- Allows consultation during the design stage of products.
- The Commission must provide a response within 80 working days.
- Uses the definitions of “LMOs/GMOs” from the Cartagena Biosafety Protocol and the definition of “Novel Combination of Genetic Material”.

The full text of Resolution 21/21 (In Spanish) can be found at:

<https://www.argentina.gob.ar/normativa/nacional/resoluci%C3%B3n-21-2021-346839>

In the past nine years, Argentina has assessed several plants developed using genome editing. One hundred and twenty-two (twenty-nine actual cases, ninety-two hypothetical cases, and one case that was later withdrawn) were submitted for evaluation. All crops derived from “NBTs” were regarded as “non-GMO” and fell under conventional seed regulations. The list of plants derived from “NBTs” excluded from the “GMO” regulations and the applications currently under evaluation is not public information.

Of the total 124 cases evaluated during the 2015-2024 period:

- 67.5 percent were presented by mixed domestic/foreign entities, 8.7 percent by domestic entities, and 3.8 percent by foreign entities.
- 78.1 percent were presented by private entities, 20 percent by public entities, and 1.9 by mixed entities.
- 73.6 percent of the products presented were plants, 12.5 percent were animals, and 11.3 percent were microorganisms.

Assessments involved the following plant species: Alfalfa, cotton, rice, brassica, camelina, cannabis, barley, rapeseed, peach, lettuce, maize, Mercadonia, potato, soybean, sorghum, tomato, and triticale.

And the following traits: enhanced agronomic yield (higher biomass and quality), herbicide tolerance, pest resistance, ornamentals, increased seed oil content, early flowering, enhanced response against abiotic stress, sweetening and browning resistance, different response to vernalization, reduced carbohydrates, reduced THC, low raffinose, lower height.

- **The form: "Should my product be regulated?"**

"Should my product be regulated?" (<https://www.magyp.gob.ar/conabia/>) (in Spanish) is an online Form that allows developers who are interested in submitting applications for authorization of trials with GE and genome-edited products to find out the regulatory process required for each process or product.

The Coordination of Innovation and Biotechnology is in charge of the process. Since its creation in 2021, thirteen cases have been reviewed, (three in 2023 and six in 2024), and it is expected that cases will continue to increase in the future.

F. COEXISTENCE

Argentina has no regulations governing coexistence.

G. LABELING AND TRACEABILITY

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

The Secretariat of Agriculture’s position on labeling is that it should be based on the type of food product derived from a specific GE 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 labeled according to its characteristics as a food product, not according to aspects concerning the environment or production process.
- Differential labeling is not justified as no evidence demonstrates that food products produced through biotechnology may represent any risk to the consumer's 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 labeling would be paid by consumers without necessarily providing better information or increased food security.

H. MONITORING AND TESTING

When applying for commercial approval (Resolution 32/2021), the developer must include a description of the analytical methods available to detect the GE event (usually, PCR and ELISA). In addition, the developer must commit to providing the supplies to perform tests at the authorities' request, including a reference seed sample, and answer for the chosen method's specificity and selectivity.

Materials showing positive results are presumed to correspond to the event under analysis.

There is no official traceability system in place for GE traits in imports and exports. Exporters provide an affidavit stating the GE content of the shipment. Private sector companies (authorized labs) can perform the required tests, and the National Institute of Agricultural Technology (INTA) also provides analyses on a private basis. There is no intention by the government to enforce a regulation for monitoring genome-edited products.

Until 2021, the GE event in INTACTA RR2 PRO of Bayer (formerly Monsanto) was the only GE soybean technology marketed in Argentina under a licensing agreement to guarantee the collection of royalties for its use. Given the Bolsatech system was aimed at detecting this particular event, the developer company financed the genetic tests, that were performed at the Grain Exchanges Arbitration Chamber's labs throughout the country, as per agreement between INASE and the Grain Exchanges.

In July 2021, the Bayer Group announced the suspension of its soybean seed and biotechnology business in Argentina as of the 2021/2022 season, so the detection system was left without financing.

As a result of this situation, Argentina's leading companies discussed how to maintain a sampling and monitoring system that proved useful to allow for the identification of GE technologies and seed varieties, with the oversight of INASE as the regulatory agency in charge of ensuring the rights of the owners of each technology.

The seed industry members designed a new system called *Sembrá Evolución*, which builds upon the detection capabilities of the *Bolsatech* system. Major seed developers in Argentina are involved in the

initiative: *Bioceres, Corteva, DonMario, Illinois, GDM, Syngenta, Dow AgroSciences, Macro Seed, and Stine*. Under this new business model, growers enter into a free-of-charge license agreement that establishes the conditions of use of all the technological developments (germplasm and events) included in the licensed seeds.

The *Sembrá Evolución* system creates the so-called Technological Hectare (HT). The HT represents the value of the genetics and biotechnology contained in the seed, which is paid through the purchase of certified seed.

Growers acquire 1 HT by purchasing 60 kg of certified soybean seeds or 120 kg of certified wheat seeds. With each HT growers obtain 3 tons of credit in the case of soybean and 4 tons of credit in the case of wheat.

Upon purchase, growers are entitled to plant one hectare of the relevant variety and technology. In addition, those interested in producing new seed varieties from replanting their own should purchase as many HT as hectares needed. The HT price, fixed by each company, includes the payment of the seed genetics (germplasm) and, if GE, the use of the biotechnology trait (event).

At the same time, a Hectare Pre-certification Control Program (PPH) is created, to favor farmers who adhere to the model and comply with all the requirements in due time. After harvesting, growers must provide an affidavit stating the variety used and, if applicable, GE events, and deliver the grains to *Bolsatech* operators for technology testing. The growers in the program can handle all seeds without segregating technologies in the harvest or additional testing payments. Growers who do not have a current PPH status must segregate the GE grain and pay royalties for using the technology.

The royalty for the Enlist technology (soy) is 15 USD/Tn for the period beginning on 1 March 2024 and ending on 28 February 2025, while for the Aporte Genético technology (wheat) is USD 9/Tn.

At present, the detection system is funded by Corteva and the only licenses available within the *Sembrá Evolución* business model are Corteva's Aporte Genético and the varieties with the Enlist/Conkesta technologies.

Within this framework, the *Bolsatech* sampling system for technology testing articulates with the *Sembrá Evolución* initiative as a voluntary and free-of-charge system of information and verification of technology and seed varieties, based on the detection of the technology in the grains produced. Participants are encouraged to submit relevant information to the Grain Exchanges Arbitral Chambers' labs, unbiased entities that administer the database.

Sembrá Evolución allows farmers to access new technologies simply by including germplasm and biotech under the same license, bringing predictability both to the farmers and the developers since conditions are fixed in advance for each campaign. all this accounts for the growing adoption levels of this business model.

For more detailed information, please visit <https://sembraevolucion.com.ar/> & <https://www.bolsatech.com.ar/> (both in Spanish).

I. LOW-LEVEL PRESENCE (LLP) POLICY

Intra Mercosur Regulation on setting a mechanism to decrease the occurrence of presence in Low-Level Presence of GE products between states

Based on a proposal from Argentina, Mercosur members signed the resolution MERCOSUR/GMC/RES. N° 23/19 to set an operating mechanism to reduce the risk of trade disruptions between State Parties resulting from the Low-Level Presence of GE organisms not yet approved in at least one of these countries.

When there is commercial authorization that includes the use of GE products in human and/or animal feed 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 authorization, the member country must send to the CBA, the appropriate risk assessment carried out by the national body responsible for biosafety, the information on the status of approval of the event in the main markets of export, and the information submitted by the developer, 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 the 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 decision-making.
- Prepare a report that may recommend that certain LLP situations be contemplated and excluded from penalties.. In that report, each Member Country may define maximum tolerance limits according to its convenience, as well as other technical recommendations as deemed relevant. That report must be recorded as an annex to the CBA minutes.

This process does not entail sharing information on LLP incidents with third parties or for other purposes.

The full text of MERCOSUR/GMC/RES. N° 23/19 can be found at:
https://www.magyp.gob.ar/normativa/_pdf/20190828140001.pdf (in Spanish)

J. ADDITIONAL REGULATORY REQUIREMENTS

None.

K. INTELLECTUAL PROPERTY RIGHTS (IPR)

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. Congress did not pass a new seed law before the elections in October 2019. The latest seed proposal, sponsored by seed manufacturers (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 the farmer's own use of seed by mandating that the price paid by a farmer for seed will cover the intellectual property rights of that product for a minimum period of three years. That is to say, when farmers purchase a bag of seed, they 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 and/or seed multiplication.

Indigenous people and farmers registered under the National Family Farming registry (small-scale and low-income farmers) are not obligated to pay for the seed technology. Another exception is allocated for the use of seeds 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. Other drafts have been submitted that do not have the consensus of the seed industry or the farmer organizations. It remains unclear when Congress will begin debating the seed law or what legislative draft will serve as the basis for discussion in the future.

Argentina's adherence to the UPOV 91 Act was included in the first draft of the Framework Law delivered by the Executive to Congress as soon as the new administration took office. The draft law covered regulations in many areas. Throughout the negotiations, the UPOV article was maintained until the last version of the draft law, when the Executive was forced to withdraw the draft law entirely due to lack of votes.

The Argentine Seed Association (ASA) supported the Government's proposal, considering that the adherence to the UPOV Act 91 is a qualitative leap in terms of recognition of the breeder's rights. ASA organized meetings with different institutions to provide information on the meaning of moving from the UPOV Act 78 to UPOV 91. The work was done jointly with the authorities of INASE, and the UPOV authorities collaborated. ASA gained support for a note sent to the legislators of the Chamber of Deputies, backed by over 30 institutions from various agro-industrial sectors.

Biosafety Law

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

L. CARTAGENA PROTOCOL RATIFICATION

Argentina has been a party to the Convention on Biological Diversity since 1992 and it was ratified in 1994 (Law No. 24,375). The Secretariat of Agriculture, Livestock, and Fisheries provides technical advice and representation at the meetings convened by the Secretariat: COP-MOP, SBSTTA, SBI, Cartagena Protocol, COP-MOP- PN, Post 2020 Global Biodiversity Framework and the Working Groups convened.

Argentina signed the Cartagena Biosafety Protocol in May 2000 in Nairobi, Kenya, but has not yet ratified it. However, the country complies with the biosafety assessment requirements for modern biotechnology products. In addition, GOA officials work with the other LATAM countries towards harmonization by actively participating in the meetings.

Argentina is still undergoing a consultation process, analyzing and debating with all the involved sectors the position the country will take in this respect. Contacts within the government of Argentina expressed the intention not to ratify the Cartagena Protocol.

In 2024, representatives of Argentina from the National Directorate of Bioeconomy of the Secretariat of Agriculture, Livestock, and Fisheries (SAGyP) are expected to participate in the next COP-MOP celebrated in Cali, Colombia, in October 2024.

M. INTERNATIONAL TREATIES AND FORUMS

Argentina-Brazil: Cooperation on Biosafety of Modern Biotechnology Products

On October 20, 2022, Argentina and Brazil signed a cooperation agreement on the biosafety of modern biotechnology products. The agreement sets up an institutional cooperation mechanism that allows joint submissions to regulatory agencies responsible for evaluating modern agricultural biotechnology products (National Directorate of Bioeconomy, CONABIA in Argentina, and CTNbio in Brazil), to request authorization for their commercial release.

The agreement seeks to create a mechanism that reduces regulatory costs and processing time for public institutions and local private companies. It also ensures synchronized biosafety approvals between the countries, facilitating global market access and preventing regulatory discrepancies that could cause unnecessary trade interruptions or issues related to the low-level presence of biotechnology products.

The first three applications for joint assessment under this Agreement were submitted in 2024: INTA's edited potato, Novozymes' GE yeast for bioethanol production, and bio input from the Brazilian company Sempre Agtech. In the first week of September, CTNBio informed that INTA's edited potato that was jointly assessed was reported as "non-GE".

MERCOSUR Agreement on Biosafety: Creation of the International Biosafety Network of Products derived from Modern Biotechnology:

In June 2024, Argentina, Brazil, Paraguay, and Uruguay created the International Biosafety Network of Products derived from Modern Biotechnology. The network will be made up of the regulatory agencies of each of the four countries that control and guarantee the biosafety of GE Organisms, as well as those that regulate gene editing and the rest of the so-called "NBT".

Argentina participated in several groups and networks during the year:

- The International Biosafety Network of Products derived from Modern Biotechnology:
- South-South Cooperation: Conformation of The Bio-Innovation Group of Global South Countries (BIO)
- Participation in Multilateral Forums
- WTO-SPS Committee.
- *OECD*.
- Global Low-Level Presence Initiative (GLI).
- Agricultural Biotechnology Commission of MERCOSUR's GTS N° 08 Agriculture.
- Agricultural Southern Council: Working Group on Policy for Biotechnology
- Convention on Biological Diversity (CBD) and Cartagena Protocol
- Like Minded Group Meeting (Saint Louis, EEUU, 2023): Argentina was co-organizer of the event in conjunction with the US.
- International Society for Biosafety Research (ISBR)

N. RELATED ISSUES

- **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 soybean events be approved in China before 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 this sense, the China-Argentina Joint Working Group on Agricultural Biotechnology, led by SAGyP and MARA officials holds yearly meetings to review new events, avoid asynchrony, and authorize events of commercial interest to both countries.

In February 2024, China approved the import of the DBN-Ø8ØØ2-3 soybean for processing. The event was developed by the Chinese company DNB (DaBeiNong) and filed for commercial authorization in Argentina by the Argentine company INDEAR. As from that moment, this product can be produced, traded, and exported to China and globally.

- **The BidesarrollAR program was discontinued in 2024.**

PART C. MARKETING

A. PUBLIC/ PRIVATE OPINIONS

The Argentine public is not usually engaged in discussions about GE plants or derived products. Only small non-governmental organizations or civil society groups fight against transgenic products. However, GE crops (regardless of the intended use or trait) are associated with plant protection products popularly considered harmful to the environment and health. For years, there has been growing activism against the use of glyphosate.

In 2021, the announcement of the HB4 drought-tolerant wheat approval that is also tolerant to glufosinate-ammonium sparked controversy among consumers. Meanwhile, most Argentine scientists and farmers use biotechnology to improve crop yields while reducing inputs. However, several agro-industrial chain representatives (farmers, stockpilers, miller organizations, and exporters) expressed serious concerns about the approval of HB4 wheat. They worry that HB4 wheat might impact the sale of Argentine wheat in foreign markets, particularly in those countries that have not yet approved the technology.

B. MARKET ACCEPTANCE/ STUDIES

Post is unaware of any relevant country-specific studies on the marketing of GE plants and plant products.

As mentioned above, the announcement of the HB4 drought-tolerant and glufosinate-tolerant wheat approval has raised controversy among consumers and members of the agricultural industry. Representatives of the agricultural value chain (farmers, stockpilers, millers' organizations, and exporters) have expressed their opposition to the approval of HB4 wheat. The possible presence of the GE event in foreign shipments could cause interruptions in the commercialization of the grain in markets that have not yet approved the technology. Under this context, Bioceres declared the company's decision not to commercialize HB4 seeds yet, and to manage it under an identity-preserved system.

CHAPTER 2. ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

A. RESEARCH AND PRODUCT DEVELOPMENT

Argentina has limited development of GE and genome-edited animals. In addition, the field of GE and edited animals was reduced in the country after the 2020 pandemic for reasons specific to research groups and challenges in project funding.

As with GE plants, research and development activities with GE animals of agricultural use require authorization by the relevant authority, upon risk assessment by the Coordination of Innovation and Biotechnology and CONABIA. The list of applications for the confined use of GE animals currently assessed and the trials conducted are not public information, so only limited data is available.

In 2023, researchers from the *University of Buenos Aires (UBA)*, in collaboration with CONICET and INTA, successfully produced the first genetically edited pigs in Latin America. These pigs were modified to eliminate the gene responsible for hyperacute rejection during organ transplants.

Argentina does not regulate cell nuclear transfer (SCNT) cloning or the resulting cloned animals.

B. COMMERCIAL PRODUCTION

Although there are regulations in place for the commercial approval of GE animals, there is no commercial production in Argentina, neither for agricultural purposes nor for biomedical research, pharmaceutical production, or organ production for transplantation.

Although several cloned cattle have been sold commercially, since the European community banned the importation of animals and products derived from cloned and transgenic animals, the interest of

producers in cloning bulls and cows that export their milk and meat production has decreased. Currently, there is almost no activity with this species, mostly due to concerns regarding trade barriers in the European Union.

The equine industry has remained at the forefront of all embryonic technology, which has allowed the country to become a leader in the breeding, production, and reproduction of horses. Argentina has gained worldwide recognition for its polo teams and two horse cloning and reproductive technology laboratories are located in the country (*Kheiron Biotech y Clonargen*).

Both companies export commercially cloned horses and specimens regularly (animals, embryos, and semen). According to the Chamber of the National Equine Industry (Camine), the largest market is the United States. Likewise, Argentine researchers offer know-how and scientific developments to camel breeders in the United Arab Emirates.

C. EXPORTS

None. Argentina does not export GE animals, livestock clones, or products from these animals, including genetics (semen and embryos) to the United States or any other country. However, the country exports cloned horses and embryos. There is no record of how many of the polo horses exported each year are cloned.

D. IMPORTS

Argentina does not import biotech animals, and there are no records available for the importation of livestock or horse clones, offspring of clones, or products of these animals imported.

E. TRADE BARRIERS

Post is unaware of any country-specific trade barriers.

PART E: POLICY

A. REGULATORY FRAMEWORK

Legal term (in official language)	Legal Term (in English)	Laws and Regulations where term is used	Legal Definition (in English)
<i>Acumulación de eventos</i>	Stacked events	<ul style="list-style-type: none"> Resolution 63/19 	Accumulation by sexual crossbreeding of transformation events that were obtained separately, as well as retransformation or cotransformation resulting in separate inserts.
<i>Agroecosistema</i>	Agroecosystem	<ul style="list-style-type: none"> Resolution 79/17 Resolution 	Ecosystem managed and/or adapted for agriculture, forestry, livestock and/or aquaculture/ aquaculture production.

		63/19	
<i>Aislamiento</i>	Isolation	<ul style="list-style-type: none"> Resolution 79/17 	Actions or mechanisms to avoid the flow of genetic material to sexually compatible species close to the release site.
<i>Animal/es regulado/s</i>	Regulated animal(s)	<ul style="list-style-type: none"> Resolution 79/17 	Animal(s) and/or biological material(s) with reproductive capacity generated within the framework of the project (whether GM or not) and their progeny, imported regulated OAGM and their progeny, pregnant females of possible OAGM and, if applicable, other animals of wild genotype involved in the project whose management could have an impact on biosecurity measures.
<i>Bioseguridad</i>	Biosafety	<ul style="list-style-type: none"> Resolution 79/17 	A set of measures or processes designed to minimize the risks associated with a given GMO and the activities that may be carried out with it. Modern biotechnology: a) the application of "in vitro" nucleic acid techniques, including recombinant nucleic acid and direct injection of nucleic acid into cells or organelles, or b) fusion of cells beyond the taxonomic family that overcome natural physiological barriers to reproduction or recombination and are not techniques used in traditional breeding and selection.
<i>Biotecnología Moderna</i>	Modern Biotechnology	<ul style="list-style-type: none"> Resolution 63/19 	The application of: (a) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or (b) fusion of cells beyond the taxonomic family, which overcome natural physiological barriers to reproduction or recombination and which are not techniques used in traditional breeding and selection.
<i>Confinamiento</i>	Confinement	<ul style="list-style-type: none"> Resolution 79/17 	Set of containment and/or isolation measures and/or techniques adopted to avoid possible risks to human or animal health or to the agroecosystem.
<i>Construcción genética</i>	Genetic construct	<ul style="list-style-type: none"> Resolution 79/17 	A DNA segment consisting of ONE (1) or more contiguous nucleotide sequences, which is proposed to be used in the animal generation

		<ul style="list-style-type: none"> Resolution 412/2 	methodology.
<i>Escape</i>	Scape	<ul style="list-style-type: none"> Resolution 79/17 	Unintentional release of regulated animal(s) during confinement that may pose potential risks to human or animal health or to the agroecosystem.
<i>Liberación confinada</i>	Confined release	<ul style="list-style-type: none"> Resolution 79/17 	Experimental release and/or production of regulated animal(s) under confinement conditions.
<i>Material biológico regulado</i>	Regulated biological material	<ul style="list-style-type: none"> Resolution 79/17 	Regulated animals and products derived from or reproductive material of regulated animals.
<i>Organismo Genéticamente Modificado (OGM)</i>	Genetically Modified Organism (GMO)	<ul style="list-style-type: none"> Resolution 63/19 	Any biological entity capable of transferring or replicating genetic material that possesses a novel combination of genetic material obtained through the application of modern biotechnology. For the purposes hereof, it is hereby clarified that animal GMOs include sterile animals, embryos, and any biological material with reproductive capacity.
<i>Material biológico con capacidad reproductiva</i>	Biological material with reproductive capacity	<ul style="list-style-type: none"> Resolution 79/17 Resolution 63/19 	Structures with the capacity to autonomously give rise to a new individual, e.g., eggs and cysts.
<i>Evento</i>	Event	<ul style="list-style-type: none"> Resolution 63/19 	Individual transformation event, consisting of the insertion of a defined genetic construct into the genome. The multiple copies tandem insertion of the same construct or of different constructs shall be considered the same event. In the case of re-transformations or co-transformations resulting in separate insertions, the resulting animal GMO will be considered to contain an accumulation of as many events as there are different insertions.
<i>Nueva Técnica de Mejoramiento genético</i>	New Breeding Technique	<ul style="list-style-type: none"> Resolution 21/21 	Stable and joint insertion into the genome of ONE (1) or more genes or DNA sequences that are part of a defined construct.

Argentina has procedures in place for requesting the commercial approval of GE animals that exclude gene-edited animals from the regulation (Resolution 63/19 and Resolution 21/21, respectively). With this update, Argentina's GE animals regulation perfectly mirrors the regulation for GE crops, having the same provisions for different kinds of applications (field trials, commercial release) and products (gene-edited, stacks).

The approval process for the commercialization of biotech animals involves the following agencies within the Secretariat of Agriculture, Livestock and Fisheries: The *Coordination of Innovation and Biotechnology* of the National Directorate of Bioeconomy, the *National Advisory Committee on Agricultural Biotechnology (CONABIA)*, *National Service of Agricultural and Food Health and Quality (SENASA)* and *National Directorate of Agricultural Food Markets (DNMA) (Dirección Nacional de Mercados Agroalimentarios)*. The approval process for a GE animal is the same as for GE plants (See Chapter 1, Part B.a). The duration of the process is not estimated, given that no applications have been submitted. The approval is valid for the entire Argentine territory and does not have an expiration date, i.e. once the GE animal has been approved, it does not have to be re-registered for the time being. Agricultural animals can be used in biomedical research, pharmaceutical production, or organ production transplants, but currently, there are no GE animals approved in the country.

Resolution 63/19 (Environmental risk assessment for the approval of GE animals, including regulation for stacks, "NBT"-derived animals)

<http://servicios.infoleg.gob.ar/infolegInternet/verNorma.do?resaltar=true&id=327185>

Resolution 412/02 (Food and feed safety assessment for the approval of GE organism)

The Coordination of Innovation and Biotechnology and CONABIA conduct the environmental assessment for confined field trials and other activities (import, export, derived-product processing, and animal welfare requirements) with non-commercial GE animals under Resolution 79/17 and recommend the Secretariat the issuance of the permit (see Part D, Field Testing). SENASA carries out periodic inspections to verify compliance with the required biosafety conditions and GE animals and derived-products stocks.

Resolution 79/17 (Confined field trials with GE animals, "NBT"-derived animals)

<http://servicios.infoleg.gob.ar/infolegInternet/verNorma.do?id=287337>

Non-commercial GE animal-derived products must be handled under the permit and comply with different containment conditions according to the characteristics of each product (e.g., if it can enter into the food chain or it has reproductive potential such as semen or embryos) and its associated risks.

Argentina does not regulate cell nuclear transfer (SCNT) cloning or the resulting cloned animals.

B. APPROVALS/ AUTHORIZATIONS:

None. See section C, Innovative biotechnologies, for information on genome-edited animals that Argentina has designated as "non-GMO".

C. INNOVATIVE BIOTECHNOLOGIES

As described above for "NBT"-derived crops, in 2021 the GOA enforced Resolution 21/21 of the Undersecretariat of Food, Bioeconomy and Regional Development to improve the previous regulations

on “NBT”-derived animals included under Resolutions 79/17 and 63/19. The Resolution established the same procedure used for “NBT”- derived plants to determine the criteria under which animals obtained by new breeding techniques involving modern biotechnology fall under “GMO” regulation (See Chapter 1, Part B.E).

Resolution 21/21 (“NBT”-derived animals)

<https://www.argentina.gob.ar/normativa/nacional/resoluci%C3%B3n-21-2021-346839>

So far, Argentina has evaluated twenty-one animals produced by “NBT”; eight already developed animals and thirteen hypothetical cases were submitted for evaluation. All evaluated animals, except one bovine, were considered "non-GMO". Evaluations involved the following species and characteristics:

- Cattle: hypoallergenic milk, double muscling, increased heat tolerance, and polled.
- Horses: double muscling, sexual reversion.
- Swine: edited for xenotransplantation.
- Tilapia: double muscling.

D. LABELING AND TRACEABILITY

The Argentine Rural Society has created a Genealogical 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.

E. ADDITIONAL REGULATORY REQUIREMENTS

None.

F. INTELLECTUAL PROPERTY RIGHTS (IPR)

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

G. INTERNATIONAL TREATIES AND FORUMS:

In August 2024, Representatives of the National Directorate of Bioeconomy, the Coordination of Innovation and Biotechnology and SENASA participated in the 5th International Virtual Workshop on Regulatory Approaches for Agricultural Applications of Animal Biotechnologies. The GOA presented on GE Animals and “NTB” regulations in Argentina, and the outcomes of the Bilateral Agreement on Biosafety between Argentina and Brazil and MERCOSUR Agreement Agreement on Biosafety: Creation of the International Biosafety Network of Products derived from Modern Biotechnology (Argentina, Brazil, Paraguay, and Uruguay)

H. RELATED ISSUES:

- **The form "Should my product be regulated?"**

As for biotech plants, the form “Should my product be regulated” is available for biotech animal developers. See full description in Chapter 1, Part B.n.

- **The BidesarrollAR program was discontinued in 2024.**

PART F. MARKETING

A. PUBLIC/PRIVATE OPINIONS

While Argentina is a strong international competitor in the plant biotechnology business, the animal biotechnology field is still a developing niche with limited public outreach. GE and genome-edited animals, livestock clones, or their offspring have not caused any public comment in Argentina, and no active organizations are lobbying for or against their use.

B. MARKET ACCEPTANCE/ STUDIES

As mentioned before, the animal biotechnology business is a niche under development in Argentina that has not raised significant public comment. GE and genome-edited animals are not currently being commercialized.

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

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

A. COMMERCIAL PRODUCTION

To date, Argentina has not yet had any applications for GE microbe risk assessments for the production of food ingredients nor for the inclusion of a derived product in the list of authorized ingredients in food production. Also, there is limited information about food ingredients production or use derived from microbial biotechnology. In addition, no prior consultation requests have been submitted to the regulatory agency to assess whether a genome-edited organism falls under "GMO" regulations including microorganisms intended for food ingredients production.

B. EXPORTS

To date, Argentina has not commercially authorized any GE microbes for use in the food industry. Therefore, there are neither official statistics nor estimates on exports of microbial biotechnology products.

C. IMPORTS

There are neither official statistics nor estimates on imports of microbial biotechnology products. However, Argentina imports alcoholic beverages, dairy products, and processed products that may contain microbial biotech-derived food ingredients such as enzymes.

D. TRADE BARRIERS

Post is unaware of any trade barrier for these kinds of products.

PART H: POLICY

A. REGULATORY FRAMEWORK

Legal term (in official language)	Legal Term (in English)	Laws and Regulations where term is used	Legal Definition (in English)
<i>Agroecosistema</i>	Agroecosystem	<ul style="list-style-type: none"> Resolution 05/18 	Ecosystem managed and/or adapted for agriculture, livestock, fish farming/aquaculture, fisheries and forestry production.
Bioseguridad	Biosafety	<ul style="list-style-type: none"> Resolution 05/18 Resolution 52/19 	A set of measures or processes aimed at minimizing the risks associated with a given product (the MGM) and/or activity to the current state of knowledge.
Condiciones controladas	Controlled conditions	<ul style="list-style-type: none"> Resolution 05/18 	Conditions in which the activities with the MGM allow minimizing possible risks to human, animal or plant health and to the environment with due attention to accident prevention and waste control.
Escape	Scape	<ul style="list-style-type: none"> Resolution 05/18 	Unintentional dissemination and/or uncontrolled persistence of MGM by any means.

Establecimiento	Location	<ul style="list-style-type: none"> Resolution 05/18 	Physical space in which an activity is carried out that uses agricultural species - understood as agricultural, livestock, fishery, aquaculture/aquaculture, fishing and forestry uses - or that could potentially be used in an agricultural context.
Fines agroindustriales	Agro-industrial purposes	<ul style="list-style-type: none"> Resolution 05/18 Resolution 52/19 	Industrial processes that use materials from or derived from agriculture, such as biomass production, biomaterials and biofuels.
Liberación experimental	Experimental release	<ul style="list-style-type: none"> Resolution 05/18 	Intentional controlled/contained introduction of a GMM into the agroecosystem for experimental or testing purposes, including monitoring and mitigation of potential unintended effects.
Microorganismo	Microorganism	<ul style="list-style-type: none"> Resolution 05/18 	Any microbiological scale entity, cellular or non-cellular, capable of reproducing itself or transmitting genetic material, including viruses, viroids and cultured animal and plant cells used for the production of the latter.
Microorganismo genéticamente modificado	Genetically modified microorganism	<ul style="list-style-type: none"> Resolution 05/18 	A genetically modified microorganism is any microorganism that possesses a new combination of genetic material whose origin is given by the application of modern biotechnology techniques.
Sitio de liberación	Release site	<ul style="list-style-type: none"> Resolution 05/18 	Delimited portion of land where the experimental release of the MGM is proposed to take place.

Organismo Genéticamente Modificado	Genetically Modified Organism	<ul style="list-style-type: none"> Resolution 412/02 	An organism containing genetic information acquired by recombinant DNA techniques.
Evento de Transformación	Transformation Event	<ul style="list-style-type: none"> Resolution 412/02 Resolution 52/19 	The stable insertion of ONE (1) or more defined genetic constructs into the genome is called a transformation event.
Biología Moderna	Modern Biotechnology	<ul style="list-style-type: none"> Resolution 52/19 	Application of "in vitro" nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family, that overcome natural physiological barriers to reproduction or recombination and are not techniques used in traditional breeding and selection.
Construcción	Construction	<ul style="list-style-type: none"> Resolution 52/19 	A nucleic acid segment consisting of one or more contiguous nucleotide sequences proposed to be introduced into the microorganism.
Nueva combinación de materia genética	New combination of genetic material	<ul style="list-style-type: none"> Resolution 52/19 Resolution 21/21 	Insertion into the microbial genome, in a stable and joint form, of ONE (1) or more genes or nucleic acid sequences that form part of a defined genetic construct.

Argentina regulates GE microorganisms, alive or dead, to be used for agro-industrial purposes or in the agricultural context (this could include microorganisms used in the food chain).

GE microorganisms' regulations mirror the ones for GE crops (See Chapter 1, Part B.a) and animals. The country regulates confined field trials under Resolution 05/18. As for other GE organisms, the Coordination of Innovation and Biotechnology and CONABIA conduct the environmental assessment for confined field trials while SENASA carries out periodic inspections to verify compliance with the required biosafety conditions.

In addition, Argentina has procedures in place for requesting the commercial approval of GE microorganisms, as well as for excluding gene-edited “non-GMO” microorganisms from the GE organism regulation.

As above mentioned for GE crops and animals, the approval process for the commercialization of biotech microorganisms involves the following agencies within the Secretariat of Agriculture, Livestock and Fisheries: The *Coordination of Innovation and Biotechnology*, within the National Directorate of Bioeconomy, *National Advisory Committee on Agricultural Biotechnology (CONABIA)*, *National Service of Agricultural and Food Health and Quality (SENASA)* and *National Directorate of Agricultural Food Markets (DNMA)* (*Dirección Nacional de Mercados Agroalimentarios in Spanish*). Resolutions 52/19 and 412/02 define procedures and criteria for the environmental risk assessment and the food and feed safety assessment for the approval of the GE microorganism, respectively.

Resolution 05/18 (Confined field trials with GE microorganisms):

<http://servicios.infoleg.gob.ar/infolegInternet/verNorma.do?id=314800> (in Spanish)

Resolution 412/02 (Food and feed safety assessment for the approval of GE organism):

<http://servicios.infoleg.gob.ar/infolegInternet/verNorma.do?id=74376> (in Spanish)

Resolution 52/19 (Environmental risk assessment for the approval of GE microorganisms):

<http://servicios.infoleg.gob.ar/infolegInternet/verNorma.do;jsessionid=11FC864FA6087BD0BF4818A2461A1902?id=325917> (in Spanish)

Resolution 21/21 (“NBT”-derived microorganisms):

<https://www.argentina.gob.ar/normativa/nacional/resoluci%C3%B3n-21-2021-346839> (in Spanish)

As described above for genome-edited crops and animals, in 2021 the GOA enforced Resolution 21/21 of the Undersecretariat of Food, Bioeconomy and Regional Development that established the same procedure used for genome-edited plants and animals to determine the criteria under which microorganisms obtained by new breeding techniques involving modern biotechnology falls under agricultural biotechnology regulations (See Chapter 1, Part B.E).

Resolution 21/21 (“NBT”-derived microorganism):

<https://www.argentina.gob.ar/normativa/nacional/resoluci%C3%B3n-21-2021-346839> (in Spanish)

SENASA establishes requirements for bio-input registration. Only once the product is registered, the developer is allowed to proceed to its commercialization.

The Argentinian Food Code (Código Alimentario Argentino – CAA, in Spanish) is a set of technical food science and commercial identification provisions created by Law #18284 and put into force by Decree 2126/71 whose Annex I is the technical text of the CAA. The main goal of the CAA is to protect public health and good faith in commercial transactions of food products within the national territory of Argentina. CAA is organized into 22 chapters, focusing on different food safety and food production standards by theme (establishments, labeling, food packaging, food additives, dairy product, confectionery, etc.) that include provisions referring to general conditions of factories and food trade, the conservation and treatment of food, the use of utensils, containers, wraps, labeling and advertising of food, specifications on different types of food and beverages, adjuvants and additives). No official

translation to English is available. The Argentinian Food Code can be consulted on the ANMAT website:

<https://www.argentina.gob.ar/anmat/codigoalimentario> (in Spanish):

The Food Code is a "positive" code. This means that it is only allowed/ permitted to do/sell what it is positively expressed /said/ established therein; that is to say, the only authorized practices, food elaborations or additives are those mentioned in the standard. Thus, those not described are excluded/ not permitted, even though no prohibition is listed in the Code.

The Code defines and describes thoroughly what any food, drink, additive, stimulant, fruitive, seasoning, adjuvant, dietary supplement, food packaging, and materials must comply to be authorized. It should be noted that the requirements of the Food Code include the raw materials involved in its production, the materials that come into contact with them (such as packaging, and containers) labeling, and the manufacturing conditions and procedures, such as GMP or HACCP.

The CAA is updated and modified frequently, by the National Food Commission (Comisión Nacional de Alimentos- CONAL in Spanish). CONAL technical body that is in charge of the advisory, support, and monitoring tasks of the National Food Control System, established by Decree 815 of 1999. incorporation of new products and processes, as well as updated provisions at the international level, is promoted and foreseen. These updates are done by joint resolutions from the Ministry of Health and the Secretariat of Agriculture, Livestock and Fisheries.

In 2019, the CAA's Art.1263 was amended under Resolution 16/2019 to include enzymes derived from microorganisms (GE or not) allowed as technology adjuvants for use in the food and beverage industry. Article 1263 establishes the protocol by which new enzymes may be admitted, as technology adjuvant, upon submission of information from the applicant (characterization of the enzyme, the producing GE microorganism, and the production method) and satisfactory evaluation. The full text of the Resolution 16/2016 is in the following link:

<https://www.boletinoficial.gob.ar/detalleAviso/primera/205739/20190417> (in Spanish)

CAA incorporates standards agreed upon within the Southern Cone Common Market (Mercado Común del Sur- Mercosur, in Spanish) framework, which in turn are influenced by standards from 1) Codex Alimentarius, 2) the European Food Safety Authority (EFSA), and 3) the U.S. Food and Drug Administration (FDA).

Decree N° 815/1999 established the creation of the National Food Control System (SNCA). The SNCA guarantees the application of CAA. In addition, Decree N° 815 establishes the creation of the National Food Commission (CONAL), which is an advisory body that provides support and monitoring to SNCA. CONAL is integrated by representatives of the National Ministry of Health, the National Drug, Food and Medical Devices Administration (ANMAT), the National Ministry of Agriculture, Livestock and Fisheries of the National Service of Agrofood Health and Quality (SENASA), the Undersecretary for Consumer Defense and the 24 jurisdictional/ provincial food control representatives. In addition, the CONAL's Advisory Committee is made up of industry and consumer organization representatives.

Two national agencies have the authority to enforce CAA standards in Argentina:

SENASA - (National Service for Agrofood Safety and Quality - *Servicio Nacional de Sanidad y Calidad Agroalimentaria*), which covers food products including fresh, chilled, frozen, and thermo-

processed products and by-products of animal, plant and seafood origin. It also covers mixed (with animal and/or vegetable-origin content) canned products containing over 60 percent of animal-origin ingredients, and food preparations containing over 80 percent of animal-origin ingredients. SENASA is an independent agency under the authority of the Secretary of Agriculture, Livestock and Fisheries.

INAL - *Instituto Nacional de Alimentos*– National Food Institute, which is an agency under the National Administration of Drugs, Food, and Medical Technology (ANMAT – *Administración Nacional de Medicamentos, Alimentos y Tecnología Médica*). It regulates consumer-ready food products, health supplements, and both alcoholic and non-alcoholic beverages, except for wine.

Sometimes, SENASA and INAL have overlapping responsibilities. Thus, FAS recommends that exporters rely on their local importers to get their products registered with the appropriate organization. Each agency requires specific documentation to register imported products and the local importer/ agent must complete the registration process. When the shipment arrives at Customs, products are inspected (for labels, shelf-life, temperature, etc.) to confirm that the information in their files matches the actual shipment and, in some cases, is subject to the Food Surveillance Program held by INAL before their release.

B. APPROVALS/ AUTHORIZATIONS

There are no GE microorganisms approved to be used in the food industry or GE-derived food ingredients registered in Argentina. To date, no applications have been submitted for the approval or registration of these biotech products.

In the last year, SAGYP-CONABIA-SENASA has authorized two vaccines for animal health that contain GE microorganisms and six yeast for bioethanol production:

- *Saccharomyces cerevisiae*- strains GICC03486 (GPY10009), GICC03506 (GPY10023), GICC03578 (GPY10168) y GICC03588 (GPY00603) (DANISCO ARGENTINA S.A.); SCY011(NOVOZYMES BIOAG S.A.) and Fermboost (MRLALLFERM S.A.).
- Vaccine against *Mycoplasma hyopneumoniae* and Porcine Circovirus Nexhyon Strain (HIPRA ARGENTINA S.A).
- Vaccine against Canine Parvovirus Nobivac Puppy DP PLUS 630a Strain (INTERVET ARGENTINA S.A).

For more detailed information, please visit:

<https://www.argentina.gob.ar/agricultura/alimentos-y-bioeconomia/microorganismos-gm-con-autorizacion-comercial>

The list of field trial or approvals applications currently being assessed, and the trials conducted are not public information.

Argentina has assessed nine microorganisms for agricultural use produced using genome editing techniques, two of them hypothetical. All microorganisms assessed except for one were regarded as “non-GMO”. The list of microorganisms derived from genome editing excluded from the “GMO” regulations and the applications currently under evaluation are not public information.

To date, Argentina has not commercially authorized any GE microbes for use in the food industry.

C. LABELING AND TRACEABILITY

There are no mandatory labeling regulations for microbial biotech-derived food in Argentina.

D. MONITORING AND TESTING

No sampling or analysis is performed in the case of import/export of processed foods that may contain a microbial biotech-derived food ingredient.

E. ADDITIONAL REGULATORY REQUIREMENTS

None.

F. INTELLECTUAL PROPERTY RIGHTS (IPR)

GE microorganisms can be patented in Argentina. Wild-type microorganisms cannot be patented, but the methods for their industrial production and agricultural products based on them are patentable.

G. RELATED ISSUES

- **The form "Should my product be regulated?"**

As for biotech plants, the form “Should my product be regulated” is available for biotech microorganism developers. See full description in Chapter 1, Part B.n.

- **The BidesarrollAR program was discontinued in 2024.**

PART I: MARKETING

A. PUBLIC/PRIVATE OPINIONS:

Post is not aware of any public concern over the use of microbial biotechnology.

B. MARKET ACCEPTANCE/STUDIES:

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

Annex: GE Crops Approved in Argentina

Unless otherwise clarified, the following events were approved for food, feed, and cultivation purposes.

Crop	Trait Category	Event	Applicant	Year
Soybean	Glyphosate Herbicide Tolerance	40-3-2(MON-Ø4Ø32-6)	Nidera S. A.	1996

Corn	Resistance to Lepidoptera	176(SYN-EV176-9)	Ciba-Geigy	1998
Corn	Glufosinate Ammonium Tolerance	T25(ACS-ZMØØ3-2)	AgrEvo S. A.	1998
Cotton	Resistance to Lepidoptera	MON 531(MON-Ø531-6)	Monsanto Argentina S.A.I.C.	1998
Corn	Resistance to Lepidoptera	MON 810 (MON-ØØ81Ø-6)	Monsanto Argentina S.A.I.C.	1998
Cotton	Glyphosate Herbicide Tolerance	MON 1445 (MON-Ø1445-2)	Monsanto Argentina S.A.I.C.	2001
Corn	Resistance to Lepidoptera	Bt 11 (SYN-BT011-1)	Novartis Agrosem S.A.	2001
Corn	Glyphosate Herbicide Tolerance	NK 603 (MON-00603-6)	Monsanto Argentina S.A.I.C.	2004
Corn	Resistance to Lepidoptera and Glufosinate Ammonium Tolerance	TC 1507 (DAS-Ø15Ø7-1)	Dow AgroSciences S.A. and Pioneer Argentina S.A	2005
Corn	Glyphosate Herbicide Tolerance	GA 21(MON-00021-9)	Syngenta Seeds S.A.	2005
Corn	Glyphosate Herbicide Tolerance and Resistance to Lepidoptera	NK603x MON810 (MON-ØØ6Ø3-6 x MON-ØØ81Ø-6)	Monsanto Argentina S.A.I.C.	2007

Corn	Resistance to Lepidoptera and Glufosinate-ammonium and Glyphosate Tolerance	1507 x NK603 (DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6)	Dow AgroSciences S.A. & Pioneer Argentina S.R.L.	2008
Cotton	Resistance to Lepidoptera	MON531xMON1445 (MON-0531-6 x MON-01445-2)	Monsanto Argentina S.A.I.C.	2009
Corn	Glyphosate Herbicide Tolerance and Resistance to Lepidoptera	Bt11 x GA21 (SYN-BT011-1 x MON-00021-9)	Syngenta Agro S.A.	2009
Corn	Glyphosate Herbicide Tolerance and Resistance to	MON 88017-3	Monsanto Argentina S.A.I.C.	2010
Corn	Resistance to Lepidoptera	MON89034-3	Monsanto Argentina S.A.I.C.	2010
Corn	Glyphosate Herbicide Tolerance and Resistance to Lepidoptera and Coleoptera	MON89034x88017	Monsanto Argentina S.A.I.C.	2010
Corn	Resistance to Lepidoptera	MIR 162 SYN-IR162-4	Syngenta Agro S.A.	2011
Soybean	Resistance to Glufosinate-ammonium	ACS-GMØØ5-3	Bayer S.A.	2011

Soybean	Resistance to Glufosinate-ammonium	ACS-GM006-4	Bayer S.A.	2011
Corn	Resistance to Lepidoptera and Coleoptera, and Glyphosate and Glufosinate Tolerance	SYN-BT011-1 x MON-00021-9 x SYN-IR162-4	Syngenta Agro S.A.	2011
Corn	Resistance to Glyphosate and acetolactate synthase (ALS)-inhibiting herbicides	DP-098140-6	Pioneer Argentina S.R.L.	2011
Corn	Resistance to Lepidoptera and Coleoptera, and Glyphosate and Glufosinate Herbicide Tolerance	SYN-BT011-1 x SYN-IR162-4 x SYN-IR604-5 x MON-00021-9 & all stacks in-between	Syngenta Agro S.A	2012
Corn	Resistance to Coleoptera	SYN-IR604-5	Syngenta Agro S.A	2012
	Resistance to Lepidoptera and Glyphosate and Glufosinate-ammonium Tolerance	MON-89034-3 x DAS-01507-1 x MON-00603-6	Dow AgroSciences & Monsanto Argentina S.A.I.C	2012

Corn	Resistance to Lepidoptera and Glyphosate Tolerance	MON-89034-3 x MON-00603-6	Monsanto Argentina S.A.I.C.	2012
Soybean	Resistance to Lepidoptera and Glyphosate Tolerance	MON-87701-2 x MON-89788-1	Monsanto Argentina S.A.I.C.	2012
Soybean	Resistance to Imidazolinones	BPS-CV127-9	BASF Argentina S.A.	2013
Corn	Resistance to Lepidoptera, Glyphosate and Glufosinate Tolerance	DAS-01507-1 x MON-00810-6 x MON-00603-6 (DAS-01507-1 x MON-00810-6) & all stacks in-between	Pioneer Argentina S.R.L.	2013
Corn	Resistance to Lepidoptera, Glyphosate and Glufosinate Tolerance	SYN-BT011-1 x SYN-IR162-4 x DAS-01507-1 x MON-00021-9 & all stacks in-between	Syngenta Agro S.A.	2014
Soybean	Resistance to 2, 4D, Glyphosate and Glufosinate	DAS-44406-6	Dow AgroSciences S.A.	2015
Soybean	High oleic content and glyphosate Tolerance	DP-305423 x MON-04032-6	Pioneer Argentina S.R.L.	2015

Cotton	Resistance to Glyphosate and Glufosinate-ammonium Tolerance	BCS-GH002-5 x ACS-GH001-3 BCS-GH002-5 x ACS-GH001 & all stacks in-between	Bayer S.A.	2015
Soybean	Drought Resistance and Glufosinate Tolerance	IND-00410-5	INDEAR S.A.	2015
Potato	Virus Resistance	TIC-AR233-5	Tecnoplant S.A.	2015
Corn	Resistance to Lepidoptera, Glyphosate and Glufosinate-ammonium Tolerance	DAS-01507-1 x MON-00810-6 x SYN-IR162-4 x MON-00603-6 & all stacks in-between	Pioneer Argentina S.R.L.	2016
Soybean	Glyphosate Tolerance	MON-87701-2 x MON-89788-1 (MON87701xMON89788) & the individual events MON-87701-2 (MON87701) & MON-89788-1 (MON89788)	Monsanto Argentina S.R.L.	2016
Soybean	Resistance to Lepidoptera	MON-87701-2 x MON-89788-1 (MON87701xMON89788) y los eventos individuales MON-87701-2 (MON87701) y MON-89788-1 (MON89788)	Monsanto Argentina S.R.L.	2016

Corn	Resistance to Lepidoptera and Glyphosate and Glufosinate-ammonium	MON-89034-3 x DAS-01507-1 x MON-00603-6 x SYN-IR162-5 & all stacks in-between	Dow Agro Sciences Argentina S.R.L.	2016
Soybean	Resistance to Lepidoptera, Glyphosate and Glufosinate-ammonium	DAS-81419-2 x DAS-44406-6 y DAS-81419-2 & all stacks in-between	Dow AgroSciences Argentina S.R.L	2016
Corn	Resistance to Lepidoptera, Glyphosate and Glufosinate-ammonium	SYN-BT011-1 x SYN-IR162-4 x MON-89034-3 x MON-00021-9 & all stacks in-between	Syngenta Agro S.A.	2016
Soybean	Tolerance to Glufosinate-ammonium – based herbicides and HPPD enzyme inhibitors	SYN-000H2-5	Syngenta Agro S.A. & 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 9 & all stacks in-between	INDEAR	2017
Corn	Tolerance to 2,4 D based herbices and herbicides of the family ariloxifenoxi, Glufosinate-ammonium and glyphosate. Resistance to Lepidoptera	DAS-40278-9 MON-89034-3 x DAS- 01507-1 x MON-00603-6 x DAS-40278-9 & all stacks in-between	Dow AgroSciences Argentina S.R.L.	2018
Soybean	Tolerance to herbicides isoxaflutole, glifosate and amonium glufosinate.	MST-FG072-2 y MST-FG072-2xACS-GM006-4	Bayer S.A.	2018

Corn	Tolerance to glyphosate and to Glufosinate-ammonium and Resistance to Lepidoptera and Coleoptera	SYN-05307-1 y SYN-BT011-1xSYN- IR162-4xSYN-IR604-5xDAS-01507- 1xSYN-05307-1xMON-00021-9 & all stacks in-between	Syngenta Agro S.A.	2018
Corn	Tolerance to glyphosate and Resistance to Lepidoptera and Coleoptera	MON-87427-7, MON-87411-9, MON- 87427-7 x MON-89Ø34-3 x SYN-IR162-4 x MON-87411-9 & all stacks in-between	Monsanto Argentina S.R.L.	2018
Alfalfa	Tolerance to glyphosate and decrease in the content of lignin	MON-ØØ179-5, MON-ØØ1Ø1-8 y MON-ØØ179-5 x MON-ØØ1Ø1-8	INDEAR	2018
Soybean	Only for processing (Food, Feed and Processing)	MON-877Ø8-9 x MON-89788-1	MONSANTO	2018
Potato	Resistance to viruses	TIC-AR233-5	Tecnoplant S.A.	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.	2018
Soybean	Tolerance to glyphosate and glufosinate. Drought Resistance.	IND-ØØ41Ø-5 x MON-Ø4Ø32-6 (OCDE)	INDEAR S.A.	2018
Cotton	Glyphosate Tolerance and herbicide inhibitors of HPPD	BCS-GH811-4	BASF Agricultural Solutions	2019

Soybean	Tolerance to glyphosate and glufosinate	DBN-Ø9ØØ4-6	INDEAR S.A.	2019
Corn	Tolerance to herbicides formulated based on products of the family of ariloxifenoxi and 2,4,-D, Glufosinate-ammonium and glyphosate, and Resistance to lepidoptera.	MON-89Ø34x DAS-O1507 x MON - 00603 x SYN-IR162-4 x DAS- 40278-9	DOW AgroSciences Argentina S.R.L	2019
Cotton	Tolerance to Glufosinate-ammonium, 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 stacked events in-between & the events BCS-GHØØ4-7 y BCS-GHØØ5-8	BASF AgroSciences Argentina S.R.L	2019
Corn	Tolerance to glyphosate and glufosinate. Resistance to lepidoptera	MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-88Ø17-3 x DAS-59122-7	Monsanto Argentina S.R.L., Dow AgroSciences Argentina S.R.L. & Pioneer Argentina S.R.L.	2019
Corn	Tolerance to Glufosinate-ammonium, glyphosate and Resistance to lepidoptera	MON-87427-7 x MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-88Ø17-3 x DAS-59122-7	Monsanto Argentina S.R.L.	2019
Corn	Tolerance to Glufosinate-ammonium, glyphosate and Resistance to lepidoptera	MON-87427-7 x MON-89Ø34-3 x MON-ØØ6Ø3-6	Monsanto Argentina S.R.L.	2019

Corn	Tolerance to Glufosinate-ammonium, glyphosate and Resistance to lepidoptera	MON-87427-7 x MON-89034-3 x SYN-IR162-4 x MON-00603-6	Monsanto Argentina S.R.L.	2019
Cotton	Resistance to insects and lepidoptera	SYN-IR102-7	Syngenta Agro S.A.	2019
Wheat	Tolerance to drought and Glufosinate-ammonium	IND-00412-7	INDEAR S.A.	2020 & 2022
Corn	Resistance to lepidoptera, coleoptera, Tolerance to glyphosate, glufosinate, and Dicamba	MON-87427-7 x MON-89034-3 x SYN-IR162-4 x MON-87411-9 x MON-87419-8 x MON-00810-6	Monsanto Argentina S.R.L	2021
Alfalfa	Tolerance to glyphosate	MON-00163-7	INDEAR S.A	2021
Corn	Tolerance to glyphosate, glufosinate, and Dicamba	MON-87427-7 x MON-87419-8 x MON 00603-6	Monsanto Argentina S.R.L	2021
Wheat	Tolerance to drought and Glufosinate-ammonium	IND-00412-7	INDEAR S.A	2020 & 2022
Soybean	(Food, Feed and Processing only)	MON-87751-7	Monsanto Argentina S.R.L	2022
Corn	Tolerance to herbicides based on glyphosate, glufosinate-ammonium, 2,4-D or to herbicides of aryloxyphenoxypropionic acid family	MON-00603-6 x ACS-ZM003-2 x DAS-40278-9 & intermediate stacks	CORTEVA AGRISCIENCE ARGENTINA S.R.L	2022

Soybean	Resistance against attack by certain lepidopteran insects and tolerance to herbicides based on glufosinate ammonium.	DNB-Ø8ØØ2-3	INDEAR S.A.	2022
Corn	It expresses the AMY797E alpha-amylase enzyme and confers tolerance to glyphosate and Glufosinate-ammonium herbicides and better behavior against attack by lepidopteran insects.	SYN-E3272-5	Syngenta Agro S.A.	2023
Corn	It expresses the AMY797E alpha-amylase enzyme and confers tolerance to glyphosate and glufosinate ammonium herbicides and better behavior against attack by lepidopteran insects.	SYN-E3272-5 x SYN-BTØ11-1 x SYN-IR162-4 x MON-ØØØ21-9	Syngenta Agro S.A.	2023
Soybean	Tolerant to herbicides based on glyphosate and glufosinate ammonium	MON-Ø4Ø32-6 x ACSGMØØ6-4	GDM	2023
Corn	Lepidoptera resistant and tolerant glyphosate and Glufosinate-ammonium	SYN-BTØ11-1 x SYN-IR162-4 x MON-ØØ6Ø3-6	Syngenta Agro S.A.	2023
Soybean	Lepidoptera resistant and tolerant glyphosate and glufosinate ammonium	DNB-Ø9ØØ4-3xDNB-Ø8ØØ2-3	INDEAR S.A	2023
Cotton	HPPD, glyphosate and Glufosinate-ammonium tolerance and protection against certain Lepidoptera	BCS-GHØØ4-7 x BCS-GHØØ5-8 x BCS-GH811-4 x SYN-IR1Ø2-7	BASF Argentina S.A.	2023

Soybean	Raw material for agroindustrial processing for food and feed use	MON-87751-7 x MON-87701-2 x MON- 87708-9 x MON-89788-1	Monsanto Argentina S.R.L	2024
Soybean	Tolerance to HPPD inhibitor herbicides and protection against potato cyst nematodes (PCN)	BCS-GM151-6	BASF Argentina S.A.	2024
Corn	Enhanced yield and Glufosinate-ammonium tolerance	DP-202216-6 x MON-00603-6 x DAS-40278-9,	Corteva Seeds Argentina S.R.L.	2024

Source: <https://www.argentina.gob.ar/agricultura/alimentos-y-bioeconomia/ogm-vegetal-eventos-con-autorizacion-comercial> (in Spanish)

Attachments:

No Attachments