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Report Highlights:

The Government of Argentina (GOA) approved five new genetically engineered (GE) events in 2023 (two soybean and three corn). Argentina and Brazil continue to be at the forefront of biotechnology and signed the Cooperation Agreement on Biosafety of Modern Biotechnology Products on October 20, 2022. During 2023, Paraguay and Uruguay joined the cooperation agreement and began the due diligence necessary to sign the documentation. In 2023, Argentina also promoted the creation of the Bio Innovation Group (BIO) for South-South Cooperation. The FAO-CONABIA (Food and Agriculture Organization, and the National Advisory Committee on Agricultural Biotechnology) agreement was renewed for the third time for the period 2023-2027, as the only global biosafety center for modern biotechnology. Th Government of Argentina (GOA) approved five new genetically engineered (GE) events in 2023 (two soybean and three corn). Argentina and Brazil continue to be at the forefront of biotechnology and signed the Cooperation Agreement on Bi

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT POLICY

EXECUTIVE SUMMARY

With more than 26 million hectares (HA) planted with genetically engineered (GE) soybean, corn, and cotton crops, Argentina has the third largest area of GE crops under cultivation in the world. The commercial adoption of GE crops began in 1996 with the introduction of herbicide tolerant soybeans, and has seen unprecedented growth in area planted since. Currently100 percent of soybeans, 99 percent of corn, and 100 percent of cotton planted in Argentina is genetically engineered.

While in the past Argentina has primarily been a producer of GE crops destined for feed and fiber, it is now the first major wheat exporter to commercialize GE wheat for food use. HB4 wheat is a drought resistant, GE wheat variety developed by Bioceres, which carries a gene originally discovered in sunflowers. The approval in Argentina raised concerns among several farmer organizations and exporters, as they understand this approval might put Argentine wheat exports at risk in other markets. In order to address these concerns, the GOA created an audit commission within the National Seed Institute (INASE). The GOA considered that the biosafety approval granted to flour derived from HB4 wheat met the regulatory requirement for major market approval and granted full approval for HB4 seed commercialization in May 2022.

For the third consecutive season, the company Bioceres sowed HB4 wheat under a system of special contracts of preserved identity and the strict control of the National Seed Institute (INASE) to avoid possible leakage of GE material that could impact the production chain or exporters. However, the announcement in early 2023 to partner with additional seed multipliers, companies that sell seeds to farmers but do not develop new varieties themselves, marks an advance for the adoption of Bioceres' proprietary HB4 wheat.

The seed royalty system continues to be an unresolved issue. Argentine law allows farmers to save and replant seed and does not offer 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.

China’s approval of GE events continues to be a top trade priority for Argentina as it is a key export market for Argentine biotech-derived agricultural products. Since 2015, the Government of Argentina (GOA) has included a conditional statement in every approval of a GE soybean event that the event must be approved in China before domestic commercialization. In April 2022, the Ministry of Agriculture of the People's Republic of China authorized the importation and commercialization of the GE HB4 soybean, paving the way for its planting and commercialization in Argentina. This marks a milestone for the country, as it is the first time that an Argentine biotech crop developed entirely within the country has been approved in an export market. China is the world's largest importer of soybeans and one of Argentina's most important trading partners.

In January 2023, China approved two alfalfa varieties of interest to Argentina, MON-ØØ163-7 and MON-ØØ1Ø1-8 from Bayer. Today, there is only one alfalfa (MON-ØØ179-5) of commercial interest to Argentina pending approval in China.

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PART I: MARKETING

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CHAPTER 1. PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

A) RESEARCH AND PRODUCT DEVELOPMENT

Argentina has several public research groups and biotechnology companies that are researching new potential plant products, but due to the early stage of their development no information is publicly available. The stage of development of the products is unknown, while confined field trials conducted are confidential.

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

The Faculty of Agronomy of the University of Buenos Aires (FAUBA) and the National Council for Scientific and Technical Research (CONICET) obtained a patent from the U.S. Patent and Trademark Office for a gene that increases plant photosynthesis and improves yields without negatively affecting growth or development. They have already tested its effectiveness in potatoes and have proposals to incorporate the technology in soybean, corn, alfalfa, and cannabis.

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. The former uses targeted protein evolution strategies and rational target site design to identify mutations that confer herbicide resistance in crops allowing gene variants selection and comparing their efficiency in microbial systems in anticipation of crops. The second combines in vitro culture protocols with gene-editing techniques to introduce precise changes in the GE genome to confer herbicide resistance to plants. In neither case would the developments generate GE plants. According to the company, *Bioheuris* is currently working in the following species:

Soybeans to develop management systems in high-yielding soybean varieties in alliances with *Santa Rosa Semillas*, *Grupo Don Mario,* and *ACA companies.*

Sorghum: in alliance with *Tobin,* editing lines to bring new hybrids to global markets.

Rice: started a variety and hybrid improvement program to optimize the integrated management of rice with genome editing with *Adecoagro's Itá Caabó* breeding farm.

Cotton: Together with *Gensus,* they are developing herbicide-resistant varieties to combat weeds through genome editing (CrisprCas9).

Alfalfa: generation of integrated weed management systems in high-productivity cultivars.

In 2019, the company signed an agreement with BioGenerator (https://biogenerator.org), to incubate its synthetic biology laboratory at the Helix Center in Saint Louis, Missouri (http://www.helixcenter.org/).

B) COMMERCIAL PRODUCTION

Argentina is the world's third largest producer of biotech crops, after the United States and Brazil, with 73 biotech crop events approved for production and commercialization, including: 20 soybean events, 40 maize events, seven cotton events, two alfalfa events, one safflower event, two potato, and one wheat event. 2022/23 total area planted with biotech varieties accounts for 24,5 million hectares.

Soybeans

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 planted for the MY 2022 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 important 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. In the last nine seasons, the use of varieties using stacked IR and HT soybean events has reported significant growth: from 7 percent in the MY 2014/15 season, to 28.5 percent in the MY 2022 season. 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 oriented almost entirely towards exports. Sixteen percent of soybeans are exported as whole beans while the remaining percent is crushed and exported as meal or oil. The great majority of soybean meal and oil is exported, with a small remainder (12 percent and 6 percent of total supplies, respectively) directed to local feed operations or industrial consumption (20 percent of total oil supplies).

Four new soybean events were authorized in late 2022 and 2023: DNB-Ø8ØØ2-3 (INDEAR); SYN-E3272-5 (Syngenta); MON-Ø4Ø32-6 x ACSGMØØ6-4 (GDM) and DNB-Ø9ØØ4-3xDNB-Ø8ØØ2-3 (OCDE denomination) from INDEAR S.A.

For more detailed information on soybean production, please see the Argentina Oilseeds Report: https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Oilseeds%20and%20Products%20Annual_Buenos%20Aires_Argentina_AR2023-0004

Corn

Argentine corn production in MY 2023/24 is projected at a record 54.0 MMT. Despite some financial problems because of a poor MY 2022/23, Post projects the planted acreage for commercial corn at about 7 million HA, similar to the sowing expectation of the previous marketing year. GE corn adoption was 99.6%, of which 7.3% corresponds to single, herbicide-tolerant (HT) or insect resistant (IR) events and 92.3% to

stacked events (HTxRI). Glyphosate tolerant Bt2 hybrids showed an adoption of 86% for all corn at the country level.

Argentine farmers have been using stacked corn events for ten years across all regions of the country. Over the last decade, there has been rapid adoption of maize stacked events from 25% in the MY 2012/12 season to 86% in the 2022/23 season. These stacked events reduce the number of treatments and amount of crop protection products applied and consequently their associated costs. Use of stacked events also allows for better crop health, higher yield potential and an easier drying process.

The use of stacked events for insect and weed control becomes 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, Fifty percent of growers who adopted the Bt technology also used the refuge system. Although a desirable level of refuge adoption has not been reached, a new increase in refuge adoption contributes to the sustainability of Bt technology since it reduces the selection pressure on targeted-insect populations delaying the onset of natural resistance.

The marketing year 2022 corn campaign produced an estimated of 52 million tons. Most of the grain is exported (41 million of tons), and the remaining corn is estimated to be directed to local feed operations or industrial consumption: 9.5 million of tons for animal feed, and the remaining is estimated for food, seed and industry (including ethanol).

Cotton

The Argentine 2022 cotton season accounts for an estimated 470,000 planted hectares. According to the National Seed Institute (INASE), GE cotton encompassed 100% of the area planted, of which 75% corresponded to stacked HT and IR events and 25% to HT cotton. No new events were approved in 2022 and 2023 so far.

Wheat

Production in marketing year (MY) 2023/24 is forecast to rebound to 19.5 million metric tons (MMT) after MY 2022/23 which was badly affected by drought and late frosts. Post projects harvested area at 6.5 million hectares (HA) and an average yield at 3.0 MT/HA, somewhat lower than the average trend yield. Ten percent of the producers concentrate more than half of the wheat area, and 30% concentrate more than 78% (11,241 total producers). Argentina is a top global wheat exporter, although production for the 2022/2023 harvest suffered a 50% drop in expected output compared to last season due to historic drought conditions last year and earlier this year.

For the third consecutive season, the company *Bioceres* sowed HB4 wheat under a system of special contracts of preserved identity and the strict control of the National Seed Institute (INASE) to avoid possible leakage of GE material that could impact the production chain or exporters. According to the

national agency, during the 2022/23 season, almost 50,000 hectares were planted. The company has seeds for multiplication and production 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 includes a group of 45 seed multiplier firms, and that translates to a significant expansion from last season when there were only three seed multiplier companies authorized to work with HB4 seeds.

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

C) EXPORTS

Argentina is a net exporter of GE commodities to numerous markets in the world, including the United States. Export documentation for grains declares the GE content. The country does not treat non-DNA-containing products derived from GE plants to be genetically engineered. Argentina requires that biotech events be approved in main importing countries before any domestic commercialization to avoid 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. As a result of a severe drought in 2022/23 the Argentine soybean crushing industry needed to source beans to maintain its processing levels and imported soybeans in large quantities from neighboring countries. During a major drought in 2018 in order to facilitate these imports, Argentine regulatory agencies enabled the possibility of granting approvals for food, feed and processing (FFP) without approval for cultivation. As a result, in 2018 Argentina imported soybean varieties from the United States and Brazil containing events approved for FFP but not for cultivation.

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

Import Policy

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 FFP, but not cultivation. 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 following its publication. Currently, the procedure is included in the new regulations (See Part B.a).

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

a)

Legal term (in official language)	**Legal Term (in English)**	**Laws and Regulations where term is used**	**Legal Definition (in English)**
Acumulación de eventos	Stacked events	• 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.
Agroecosistema	Agroecosystem	• Resolution 32/21 • Resolution 45/22	Ecosystem managed and/or adapted for agriculture, livestock, aquaculture, fisheries, forestry and agro-industrial production.
Biotecnologia moderna	Modern biotechnology	• 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.
Construcción	Construct	• 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).

Evento	Event	• Resolution 32/21 • Resolution 45/22	Individual transformation event, consisting of the insertion of a defined genetic construct into the genome. Multiple copies tandem insertion of the same construct or of different constructs shall be considered the same event.
Organismo Genéticamente Modificado (OGM)	Genetically Modified Organism (OGM)	• 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.
Actividades confinadas	Confined activities	• 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.
Condiciones de Aislamiento	Insulation Conditions	• 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.
Bioseguridad	Biosafety	• 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.
Escape	Scape	• Resolution 45/22	Unintentional dissemination of pollen and/or viable propagating material of a regulated plant GMO that occurs by any

			means.
Liberación (del OGM vegetal)	Plant GMO release	• Resolution 45/22	The controlled introduction of a regulated plant GMO into the agroecosystem.
Material Regulado	Regulated Material	• 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.
OGM vegetal regulado	Regulated plant GMO	• 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.
PLAN DE MANEJO DE RESISTENCIA DE INSECTOS (PMRI)	INSECT RESISTANCE MANAGEMENT PLAN (PMRI)	• 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.
Nueva técnica de mejoramiento genético	New breeding technique	• 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 presented by their conventional counterparts.

Under provisions described in Resolution 763/11, the approval process for the commercialization of biotech seeds involves the following agencies within the Secretariat of Agriculture, Livestock and Fisheries:

- The *Coordination of Innovation and Biotechnology*, within the National Directorate of Bioeconomy, is the focal point for agrobiotechnology issues in the country. The office is responsible for the environmental assessment of applications for the confined use (Resolution 45/22) or authorization of GE organisms of agricultural use (Resolution 32/2021), also, for writing and updating the regulations that rule these products. Regulators assess GE organism applications and advise CONABIA´s members whether to authorize or not the release or approval of a GE organism. CONABIA advises the Undersecretary of Food, Bioeconomy and Regional Development, the authority that finally grants the commercial authorization.

-*National Advisory Committee on Agricultural Biotechnology (CONABIA)* is a multi-sectoral organization composed of agrobiotechnology experts from academia and the public and private sector.

With the advice of the Coordination of Innovation and Biotechnology regulators, CONABIA's responsibility is to enforce agro-biotech product regulations with a focus on the environmental impact assessment of releasing biotech crops into Argentina´s agroecosystem and enacting updated normative regulations. 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.

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

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

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

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

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 disruptions 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 provides an evaluation within 45 days.

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

When offices have completed the new event´s environmental risk, food and feed safety, and trade impact assessments, they elaborate independent decision documents recommending the approval or not of the event under evaluation. The Coordination submits a final report with the three recommendations to the Undersecretariat for Bioeconomy, Food, and Regional Development. The Undersecretariat makes the final decision on the authorization of GE products.

Complete 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 two years. 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 been yet authorized in a relevant importing country, the Undersecretariat may issue an approval conditioned to such authorization. That is the case for GE soybeans in China or GE wheat in Brazil.

-*National Seed Institute (INASE)*

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 producer can proceed to the GE seeds commercialization.

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 (links all 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 that their use will not disrupt Argentina's major export markets. The Secretariat of Agriculture publishes a list of events that are approved.

First commercial scale-production of GE Wheat

In 2020, Argentina became the first country in the world to approve GE wheat when the GOA approved HB4 Wheat developed by the Argentine company *Bioceres Crop Solutions* under a joint venture with the French company *Florimond Deprez*. The wheat is tolerant to drought and to ammonium glufosinate. The company reports that the crop can sustain good yields even in case of severe drought, displaying 19.5 percent greater yield as compared to non- GE wheat in similar conditions.

The commercial approval for HB4 Wheat was contingent upon approval in Brazil, Argentina's most important market for wheat. Over the last five years Brazil imported approximately 300,000 tons of flour per year compared to 5 million tons of wheat as grain.

In November 2021, the Brazilian National Biosafety Commission (CTNBio) unanimously endorsed biosafety conditions for flour obtained from HB4 Wheat and granted approval for its commercialization despite concerns from Brazilian millers' associations. In Argentina several farmer and exporter organizations raised concerns, that this approval might put Argentine wheat exports at risk in other markets.

In order to address these concerns, the GOA created an audit commission, which operates within INASE. INASE issued Resolution 535/2021, to set tight controls of the activities with the HB4 wheat. In general terms this resolution sets the following parameters of control:

- The developer of the product must report the current inventory of stocks in each of the processing plants and/or storage places with geo -reference of their location, reporting of any classified material, unclassified material, discards and purge materials.

- The developer may keep up to twenty percent as seed, identifying, in that case, the place of storage and its conditions, in order to allow control and verification. For the 2022/23 crop season, the conservation of up to half of the harvested volume is authorized as "propagation material", and the company is in charge of the processing (with loss of germination power), and final destination of the remainder subsequently informing the Commission.

- The owner of the harvested material shall report the results of the purges carried out to the harvesting equipment and processing plants, as well as the cleaning of the storage places of the material. The company also shall report, at the request of the Commission, the results of the analyses carried out on the purge material in order to verify compliance with the established confinement.

Complete text of Resolution 535/21 (in Spanish) can be found at:
https://www.boletinoficial.gob.ar/detalleAviso/primera/253893/20211203

Under this controlled system, during MY 2022/23, Bioceres reported to the government the planting of almost 50,000 hectares of HB4 wheat in 334 sites.

Brazil granted full approval to HB4 wheat in March 2023, while in Argentina HB4 wheat varieties have been already registered. As seed registration regulations are required, the commercialization of wheat seeds carrying the event could begin only after the registration of the varieties in the INASE Cultivar Registry is completed. Complete text of Resolution 27/22 can be found at:
https://www.magyp.gob.ar/sitio/_pdf/RES_27-2022%20BO.pdf (In Spanish)

Farmers, millers, stockpilers organizations and exporters once again expressed their concern regarding the possible impact this approval may have on the commercialization of Argentine wheat in foreign markets, especially in those that have not yet approved the technology.

HB4 wheat has been approved for food and feed uses by regulatory agencies in the United States, Colombia, Nigeria, Australia, Indonesia, New Zealand, and South Africa.

In a document for investors, *Bioceres* stated it continues producing HB4 wheat under an identity-preserved production system based on special contracts with selected growers and, for the moment, does not openly commercialize it.

https://investors.biocerescrops.com/events-and-presentations/default.aspx

The promise of higher yields of HB4 for wheat crops finds fertile ground in times characterized by high temperatures and increasing drought every year. In the balance of 2022, the National Meteorological Service of Argentina identified an intensification of drought in the Pampas and Litoral regions, with scarce rainfall especially in the center and north of the country. The conclusion is dramatic: 2022 was the third consecutive year of La Niña, a phenomenon that decreases the probability of rainfall, and was among the 14 driest years since 1961.

For a country that depends on commodity exports, the economic impact is major: Argentina's grain and oilseed export revenues fell 61% between January 2022 and 2023. This year, the forecast is for a 28% drop in agricultural exports in the country and a 40% drop in Argentina's wheat harvest due to the drought.

Data from the 2022/2023 planting of HB4 wheat, the most recent so far, records more than 50,000 hectares planted. There is still no data for 2023/24, but contacts within Bioceres expressed that they are aiming to expand HB4 wheat cultivation to areas with limited productivity due to low water availability. The objective is to reach 40% of the wheat area planted in Argentina in the next three to five years.

In 2023, Paraguay authorized HB4 wheat for production, food and feed.

China authorizes Argentine HB4 drought resistant soybeans.

Since 2015, all soybean approvals have been additionally conditioned on Chinese approval prior to these events being planted commercially in Argentina. In April 2022, the Ministry of Agriculture of the People's

Republic of China authorized the importation and commercialization of the GE HB4 soybean, paving the way for its planting and commercialization in Argentina.

As is the case for wheat, Bioceres multiplied HB4 Soybean under an identity-preserved production system. During the MY 2022/23 season 20,000 hectares of HB4 soy were planted in 195 sites with an average yield of 2,400 kg/ha.

HB4 soybeans are also authorized in the United States (August 2019), Brazil (May 2019), Paraguay (2019), and Canada (2021), and for food and feed in China. Soybeans with the HB4 gene are currently being multiplied in both Argentina and the United States, with the expectation of a commercial release in the near future. In the United States, this business is being conducted as part of *Verdeca,* a joint venture between the *Instituto Agrobiotecnológico Rosario (INDEAR),* which is the research and development branch of *Bioceres,* and *Arcadia AgroSciences*.

C) STACKED OR PYRAMIDED EVENT APPROVALS

A regulation approved in late 2019 changed the way that stacks were assessed and authorized and eliminated the need to assess or authorize stacked events that had been authorized previously as individual events, and that were considered to have a low risk of interacting negatively with other events. This regulation was eliminated in late 2021:
https://magyp.gob.ar/sitio/areas/biotecnologia/conabia/_pdf/RES_032-2021_3%20anexos.pdf (In Spanish)

Under 2021 new regulations, a stacked event is one 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 case-by-case and follows the Problem Formulation methodology.

If all individual events included in the stack 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.

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

At the end of the risk analysis, the Coordination of Innovation and Biotechnology, together with CONABIA, concludes 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 the food and feed safety assessment of SENASA, it is possible to submit a letter requesting approval of the particular stacked event as described at the beginning of the 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: (In Spanish) (https://www.magyp.gob.ar/normativa/_pdf/20220704094400.pdf).

When applying for a permit, local and international developers must submit information about the event, the confined activities, 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, “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 of the Undersecretariat of Food, Bioeconomy and Regional Development with the intention of improving 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) that 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.

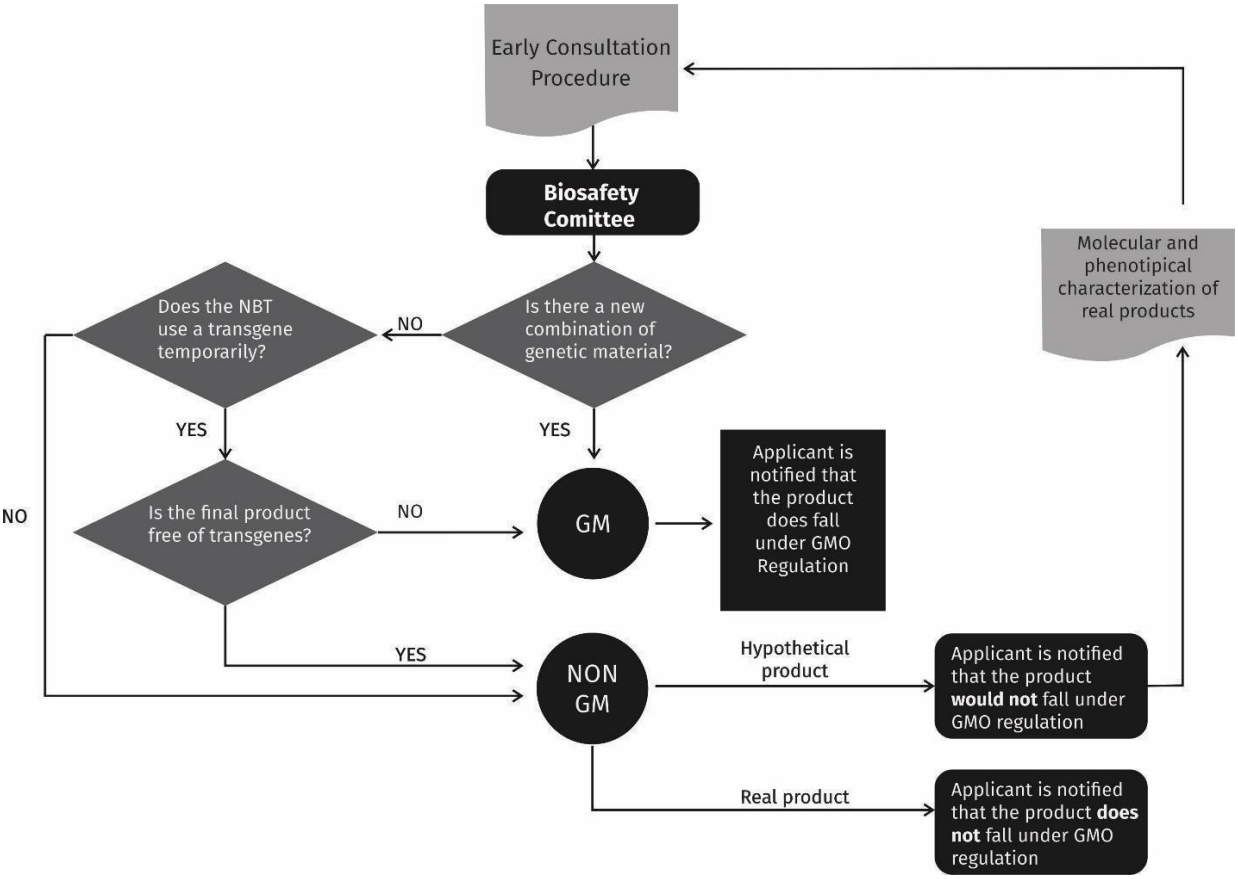
A genetic change is regarded as a “new combination of genetic material” when a stable and joint insertion of one or more genes or DNA sequences that are a part of a genetic construct are introduced permanently into the plant genome. With this criteria, “NBT”-derived products containing INDELS, nucleotide 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 from the authorities stating if the described product falls under the agricultural biotechnology regulations or not. 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 must be also reported by the regulatory commission. 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 make-up. In the event that 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.

Flowchart of “NBT” applications for determination of regulatory status in Argentina



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

- **Cartagena Protocol Definition**

For transboundary movements of GE and genome edited crops, Argentina currently bases its regulation on language similar to that in 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 highlights the following characteristics:

- The procedure determines if a product obtained by an "NBT" should be excluded 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”.

Complete 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 last eight years, Argentina has assessed several plants developed using genome editing. One hundred twenty four, (twenty-eight existing and eighty-six hypothetical cases) 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 2015-2023 period:

- 46.8 percent were presented by mixed domestic/foreign entities, 45.2 percent by domestic entities, and 7.9 percent by foreign entities.
- 76.1 percent were presented by private entities, 21.5 percent by public entities, and 2.4 by mixed entities.
- 84.9 percent of the products presented were plants, 11.1 percent were animals, and 4 percent were microorganisms.

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

Following the policies of the National Bioeconomy Directorate to accompany local developers, the form "Should my product be regulated?" was created on the Ministry of Agriculture, Livestock and Fisheries website (In Spanish) (https://www.magyp.gob.ar/conabia/) in September 2021.

This new process seeks to simplify queries from entities interested in submitting applications for trials with GE and genome edited products and simplifies the process for developers who do not have experience in regulatory processes. It will provide guidance, among other things, on what regulations apply when requesting a permit.

Developers of genome edited products can ask if products would be regulated by CONABIA. After completing the form, the Coordination of Innovation and Biotechnology will answer to guide the way forward.

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 there is no evidence that demonstrates that food products produced through biotechnology may represent any risk for the consumers' health.
- In the case of agricultural products, of which the majority are commodities, the identification process would be complicated and expensive. The increased production costs due to labeling would be paid by consumers without necessarily providing better information or increased food security.

H) MONITORING AND TESTING

When submitting the application for commercial approval (Resolution 32/2021), the developer must include a description of the analytical methods available to detect the GE event (in general, PCR and ELISA). In addition, the developer must commit to providing the supplies to perform tests at the request of the authorities, including a reference seed sample and is responsible for the method specificity and selectivity. All positive material can be presumed to correspond to the event analyzed.

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. There are private companies (authorized labs) which have the capability to perform the required tests, and the National Institute of Agricultural Technology (INTA) does analysis on a private basis. There is no intention by the government to set in place a provision for monitoring genome edited products.

Since 2016, biotech testing of some export shipments has been conducted under the *Bolsatech* program, a voluntary system implemented by the Grain Boards of Trade in the country and endorsed by INASE with the resulting information managed by the national agency. This was not intended to identify unapproved events but was meant to help collect royalties for technology providers since IPR rights for biotech seeds in Argentina are difficult to enforce, especially for those autogamous crops such as soybeans and wheat.

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. In July 2021, the Bayer Group announced the suspension of its soybean seed and biotechnology business in Argentina as of the 2021/22 season, so the detection system was left without financing.

Other companies in the country discussed how to maintain the system that allows the identification of GE technologies and seed varieties used by each producer so that INASE can ensure the rights of the owners of each technology.

In addition to the *Bolsatech* program, seed industry members designed a new system called "*Sembrá Evolución" that* was partially released in June this year for the 2022/23 season. Many 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, the producer must first sign a "License of Use" that establishes the conditions of use of all the technological developments (germplasm and events) included in the soybean and wheat varieties released by the company. The contract is free of charge and does not commit the producer to purchase seed, but it is a condition for its use and accessing the benefits of the model.

The *Sembrá Evolución* system considers the producer's use of seed rights and creates the so-called Technological Hectare (HT). When a producer buys certified seed (one HT seed per 1.5 40 kg bags), he acquires an "HT credit" that entitles him/her to plant one hectare of that variety. In addition, those interested in producing new seed varieties from replanting his/her 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) will be created, seeking benefit producers who adhere to the model and comply with all the requirements in due time. After harvesting, the producer has to provide an affidavit stating the variety used and, if applicable, GE events, and deliver the products to *BolsaTech* operators for technology testing. The producers in the program can handle all seeds without segregating technologies in the harvest or additional testing payments. Producers who do not have a current PPH status must segregate the GE grain and pay royalties for using the technology. Each developer will be responsible for the collection of royalties from its technology (germplasm and GE event).

In the 2022 season, *Enlist* soybeans carrying the event DAS-44406-6 from *Corteva Agriscience* were planted for the first time in Argentina. At this moment, it is the only GE crop under the "Sembra Evolución" system. New non- GE soybean and wheat varieties are expected to be included under the platform shortly. For the full deployment of this new system, it is necessary to define details on how the sampling, the analyses, and the royalty's payment will be carried out. In addition, INASE must approve it before its implementation.

Probably, the detection of events will be using molecular biology methods (ELISA, PCR, lateral flow immunoassay strip). It is also being considered the implementation of methodologies involving images and artificial intelligence for different varieties of soybean and wheat identification to collect the royalties

associated with the intellectual property of the germplasm. For more detailed information, please see: https://sembraevolucion.com.ar/

I) LOW LEVEL PRESENCE (LLP) POLICY

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

Based on a proposal from Argentina, Mercosur members signed resolution MERCOSUR/GMC/RES. Nº 23/19 in order to set an operating mechanism to reduce the risk of trade disruptions between states 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 use in human and/or animal feed of GE products 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 applicant, excluding information classified as "confidential". For the implementation of this mechanism, the developers of the authorized event must have previously submitted the request for commercial evaluation of the product in the other member countries.

Having all 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 a decision making.

-Prepare a report to recommend exclusive approval for GE LLP situations. In that report, each member country may define maximum tolerance limits according to its convenience, as well as other technical recommendations it deems 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.

Complete text of MERCOSUR/GMC/RES. Nº 23/19 (in Spanish) can be found at: https://www.magyp.gob.ar/normativa/_pdf/20190828140001.pdf

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 elections in October 2019. The latest seed proposal, sponsored by seed manufactures (via the Argentine Seed Association) and some of the major farmer groups, appears to provide clearer rules in the marketing of seed technologies and IPR protections. The proposed law facilitates producer's own use of seed by mandating that the price paid by producer for seed will cover the intellectual property rights of that product for a minimum period of three years. That is to say, when the producer purchases a bag of seed, he/she will pay for the rights to utilize the biotechnology, germplasm and products obtained from the seed for the three-year period or longer. Although the law does not limit the final use or transfer of seed technologies, it grants the right to the owner of the protected seed technology to require payment for the own use of seed in each subsequent propagation and/or seed multiplication.

Indigenous people and producers registered under the National Family Farming registry (small scale and low- income producers) are not obligated to pay for the seed technology. Another exception is allocated for the use of seed for research and development purposes. The proposal strengthens the authority of the National Seed Institute, allowing it to have access to any crop or its product to implement this law, sanctioning anyone who limits this effort or provides false information. However, this was not the only proposal that was submitted to Congress. There have been other drafts submitted, which do not have the consensus of the seed industry nor the farmer organizations. It is unclear when the Congress will begin debating the seed law, or what legislative draft will serve as the basis for discussion in the future.

Biosafety Law

The above mentioned 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 provide 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 are very active in working 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. However, Post's contacts believe that this is very unlikely to occur in the near future.

Representatives of Argentina have participated in the CBP- biannual Conference of the Parties serving as the Meeting of the Parties (COP-MOP). They have also taken part in Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA), the Subsidiary Body on Implementation (SBI) and the Working Group on the Post-2020 Global Biodiversity Framework (WG2020) meetings.

Representatives of Argentina from the National Directorate of Bioeconomy of the Secretariat of Agriculture, Livestock, and Fisheries (SAGyP) have participated in the last COP-MOP celebrated in Montreal, Canada, in December 2022, making significant contributions to the correct elaboration and interpretation of Goal 17 of the Post 2020 Global Biodiversity Framework and other binding documents of the CBD regarding with modern biotechnology and agricultural activity.

M)INTERNATIONAL TREATIES AND FORUMS

Argentina-Brazil: cooperation on biosafety of modern biotechnology products

On October 20, 2022, Argentina and Brazil signed the cooperation agreement on biosafety of modern biotechnology products.

The Agreement was the result of the coordination carried out between the regulatory institutions of both countries during the years prior to the signing of the Agreement. It is worth mentioning that officials from the SAGyP and SENASA of Argentina and CTNbio, MCyT and MAPA of Brazil were part of it, seeking to establish a cooperation mechanism to reduce costs and regulatory time for developers, especially for local enterprises such as EMBRAPA and INTA, and/or local private companies.

Both countries have scientific and technological systems with many years of experience in the matter, internationally recognized national regulatory systems, and local developments of biotechnological products that invite us to establish new regional cooperation mechanisms to promote the development of these products, their correct evaluation of biosafety, and its insertion in world markets. Such is the case of HB4 technology for soybeans and wheat and INTA's bovine leukosis vaccine in Argentina, and EMBRAPA's bean development in Brazil.

Argentina and Brazil are trading partners, suppliers of safe and secure food to the world and of ecosystem and productive services, which coordinate common positions and messages in different global forums: MERCOSUR, CAS, WTO, OECD, FAO, Convention on Biological Diversity, IICA, GLI, G20, etc. Both countries are aware of the need to promote the use of technology applied to their production to generate "more with less" and to contribute to the adaptation and mitigation of climate change.

The objective of the Memorandum between Argentina and Brazil is to constitute a bi-national institutional link between the regulatory agencies (DNB-CONABIA-CTNbio) in charge of the analysis and commercial authorization of modern biotechnology products for the agricultural field.

To this end, it is intended to build an institutional cooperation mechanism to jointly receive requests (if the applicants so intend) for the evaluation and commercial release of modern biotechnology products, which are of interest to both the public and private entities that request them. request, as well as for the productive policy strategy of the Ministries of Argentina and Brazil.

The intention is to deepen synchronization in the approval of biotechnological events to avoid asynchronies that lead to unnecessary interruptions in trade and situations of low presence. In this way, to deepen bilateral trade relations, while guaranteeing security for the countries' productive agroecosystem and safety for human and animal food, in order to promote sustainable productive systems and food security in the region and in the world.

It is expected that Paraguay and Uruguay join the agreement in coming months.

Argentina participated of several groups and networks during the year:

- Formation of 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
- Convention on Biological Diversity (CBD) and Cartagena Protocol
- Like Minded Group Meeting (Saint Louis, United States, 2023): Argentina was co-organizer of the event in conjunction with the United States
- 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 soybeans events be approved in China prior to any domestic commercialization. The industry and government consistently stress to Chinese authorities the importance of timely, science-based safety reviews for new events to avoid asynchronous approvals that lead to trade disruptions. In this sense, the China-Argentina Joint Working Group on Agricultural Biotechnology, led by SAGyP and MARA officials and held once a year, meets to review new events, avoid asynchrony and authorize events of commercial interest to both countries.

In January 2023, China authorized two Bayer alfalfa products (MON-ØØ163-7 and MON-ØØ1Ø1-8) that were of interest to Argentina. There is only one alfalfa product (MON-ØØ179-5) of commercial interest in Argentina pending approval in China today.

- **A new program launched to promote the bioeconomy and circular economy: BiodesarrollAR.**

The Secretariat of Agriculture, Livestock, and Fisheries launched a new plan aimed at small and medium-sized companies in the agricultural and agro-industrial sectors. It is called "*Programa Nacional Biodesarrollo Argentino*" ("BiodesarrollAR", in English National Argentine Biodevelopment Program), which will operate under the Undersecretariat of Food, Bioeconomy, and Regional Development.

Its general objective is to promote and foster the development, innovation, adoption, and production of bioproducts of the bioeconomy, which include the areas of biotechnology, bio inputs, biomaterials, and bioenergy, by micro, small and medium-sized companies, as well as cooperatives and public and mixed research entities.

Within this framework, those initiatives focused on promoting regional development and adding value at source will be prioritized. The program emphasizes that the development of the biobased products industry is a tool for making progress in the sustainability of agrifood and agro-industrial production.

The specific actions to be carried out under the program are as follows:

a) To accompany bio-developers in the management of activities with regulated agricultural biotechnology products.

b) coordinate and connect bio-developers with public, private, and mixed entities for projects and product development.

c) Generate public-private associative processes for investing in initiatives at their final stages of development, promoting the scaling up.

d) Provide financing instruments for bioeconomy bioproduct development projects whose prototypes are in a position to advance in their productive and commercial scaling-up levels.

e) To offer technical assistance in solving-problems, as well as to provide tools and instruments aimed at the development of their bioproducts.

f) To disseminate the actions carried out within the framework of BiodesarrollAR, such as publications, activities in the territory, and related events.

The beneficiaries will be all micro, small and medium-sized enterprises, public entities, and mixed (public-private) associations engaged in advanced bio-based development initiatives.

Therefore, the program will provide two types of assistance: technical and financial, to be executed with resources from the National Agri Industry Trust Fund (Fondagro).

In 2023, two calls were opened, and more than 150 projects were received.

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. Campaigns (one of them under the hashtag in Spanish #connuestropanno, #withourbreadno) led by groups of environmentalists, famous cooks, and influencers interested in consuming food produced phytosanitary-free and environment issues moderately reached the general public.

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 ofHB4 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. In addition, they stated that the Argentine market has no experience consuming GE wheat, and there are requests from national and international food companies operating in the country to buy only non-GE wheat or flour.

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. Social media campaigns such as #connuestropanno (in English, #withourbreadno) promoted by groups of famous chefs and influencers reached the general public. In addition, the bakery and candy company *Havanna* announced an agreement with *Bioceres* to use HB4 wheat in one of its flagship products in 2021. Activist groups launched a pressure campaign on social networks against including GE flour in that product, and the manufacturer retracted after consumer complaints. In 2022, *Bioceres* announced that it engaged in talks with a craft beer producer to generate a variety based on HB4 wheat.

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 and flour yet, and to manage it under an identity-preserved system.

A group of experts from Bolsa de Cereales de Buenos Aires (Buenos Aires Grain Exchange) presented the paper *25 Years of Genetically Modified Crops in Argentine Agriculture,* in May 2021. The paper shows the economic and environmental impact of the adoption of GE seeds in Argentine agriculture in soybean, corn and cotton crops. They analyzed the effects for the farmers, the country and the environment.

Studies show that the adoption of GE crops has brought significant benefits to Argentina. Cumulative gross margins in the period under analysis are estimated at USD 158 billion. Out of the total benefits, 92% (USD 146 MM) correspond to soybean cultivation, 7% (USD 10.9 MM) to corn, and the rest (USD 2.1 MM) to

cotton. Considering the increase in foreign exchange due to higher exports, the 25 years of GE crop production represented an additional USD 153 billion. In terms of the additional employment demanded by value chains as a result of GE crops, an average of 93,000 jobs were created per season.

Further studies show that in environmental terms, GE crops have made it possible to significantly mitigate the impact of primary production on the environment. Environmental benefits were estimated on two fronts. First, benefits are due to the reduced use and toxicity of agrochemicals applied to the soil. In this regard, the case of GE soybeans stands out, with a 30% environmental impact reduction compared to conventional soybeans. On the other hand, environmental benefits were estimated due to the enhanced adoption of no-till farming as a result of the use of GE crops. In this regard, benefits were identified from both the reduced use of fossil fuels and the increased rate of carbon sequestered in the soil that arises from applying this practice of conservation agriculture.

A study has been made on the prospective impact on the innovation economy of genome-edited organisms of agricultural use: Whelan, A. I., Gutti, P., & Lema, M. A. (2020). Gene editing regulation and innovation economics. *Frontiers in Bioengineering and Biotechnology*, *8*, 303.

CHAPTER 2. ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

A) RESEARCH AND PRODUCT DEVELOPMENT

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

As with GE plants, research and development activities with GE animals of agricultural use are under CONABIA regulation. 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 Argentina, public and private groups are looking to develop genome-edited animals or plan to import them. The National Institute of Agricultural Technology (INTA) developed edited cow embryos without the allergenic protein beta-lactoglobulin gene, in order to breed cows that could produce hypoallergenic milk. In addition to this, a group at the Faculty of Agriculture of the University of Buenos Aires (FAUBA- UBA) plans to obtain genome-edited and GE pigs for xenotransplantation. Meanwhile, *BioMill* (formerly *BioSidus*) developed GE cows that express human growth hormone in their milk and GE cows that express antibodies against rotavirus in their milk. Argentine regulations include considerations for GE insects. In 2022, a submission was presented by Oxitec Company for GE fall armyworm (Spodoptera frugiperda) with the intention of its use as a biological control. The submission is currently in the evaluation stage.

The American company *Recombinetics/Acceligen* and the Argentine company *Kheiron* signed an agreement in June 2019 focused on precision breeding in Argentina to introduce new commercial traits in cattle derived from elite genetic lines. The intended end goal of this strategic alignment will be commercializing precision-bred animals that generate highly valued germplasm products for the global market with an emphasis on adaptability traits for climate change. The use of *Recombinetics'*s genome editing platform,

combined with *Kheiron*'s in-vitro embryo production, cloning, and genome editing platform and infrastructure, will allow single generation production of market-ready animals without sacrificing diversity and estimated breeding values for performance. The companies signed an alliance on a series of projects in Argentina to produce multiple animal product lines to solve existing concerns in the cattle industries.

Their first product would be animal breeds with improved heat tolerance and that are polled (hornless). These products have been presented to the Argentine Biosafety Commission CONABIA for their revision in 2019. In their first meeting of May 2020, the Commission recommended that these animals should be considered as "non-GMO." They also seek to generate horses and cows with increased musculature.

The U.S. company *AquaBounty* submitted for consultation a tilapia fish that has been genome edited to increase productivity through faster growth and lower feed requirements. Argentine regulators considered it to be "non-LMO."

Argentina does not regulate cell nuclear transfer (SCNT) cloning or the resulting cloned animals. The country has been proactive on the issue, including collaboration between scientists of different Argentine research centers (mainly University of Buenos Aires, the University of San Martin, and INTA) with counterparts in the United States, Canada, Australia, New Zealand and the European Union, among others.

B) COMMERCIAL PRODUCTION

Although there are regulations for the 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.

A number of cloned cattle have been sold commercially. However, 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. Although more than 400 cloned cattle animals were generated in Argentina in previous years, 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 been recognized worldwide for its polo teams and two of the five horse cloning and reproductive technology laboratories in the world are located in the country (*Kheiron Biotech* y *Clonargen).* Argentina holds the world record for the number of commercially cloned horses and its specimens are exported on a regular basis (animals, embryos and semen). The company *Kheiron Biotech* reports that during 2021 they obtained 250 cloned animals while *Clonargen* generated 1000 cloned embryos. According to the Chamber of the National Equine Industry (Camine), the largest market is the United States. It is followed by the United Kingdom, Chile, United Arab Emirates, Saudi Arabia and 37 other destinations. 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 3,000 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 horses 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

a)

Legal term (in official language)	Legal Term (in English)	Laws and Regulations where term is used	Legal Definition (in English)
Acumulación de eventos	Stacked events	• Resolution 63/19	Accumulation by sexual crossbreeding of transformation events that were obtained separately, as well as retransformation or cotransformation resulting in separate inserts.
Agroecosistema	Agroecosystem	• Resolution 79/17 • Resolution 63/19	Ecosystem managed and/or adapted for agriculture, forestry, livestock and/or aquaculture/ aquaculture production.
Aislamiento	Isolation	• Resolution 79/17	Actions or mechanisms to avoid the flow of genetic material to sexually compatible species close to the release site.
Animal/es regulado/s	Regulated animal(s)	• 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.
Bioseguridad	Biosafety	• 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.
Biotecnología Moderna	Modern Biotechnology	• 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.
Confinamiento	Confinement	• 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.
Construcción genética	Genetic construct	• Resolution 79/17 • Resolution 412/2	A DNA segment consisting of ONE (1) or more contiguous nucleotide sequences, which is proposed to be used in the animal generation methodology.
Escape	Scape	• 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.
Liberación	Confined release	• Resolution 79/17	Experimental release and/or production

confinada			of regulated animal(s) under confinement conditions.
Material biológico regulado	Regulated biological material	• Resolution 79/17	Regulated animals and products derived from or reproductive material of regulated animals.
Organismo Genéticamente Modificado (OGM)	Genetically Modified Organism (GMO)	• 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.
Material biológico con capacidad reproductiva	Biological material with reproductive capacity	• Resolution 79/17 • Resolution 63/19	Structures with the capacity to autonomously give rise to a new individual, e.g., eggs and cysts.
Evento	Event	• 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.
Nueva Técnica de Mejoramiento genético	New Breeding Technique	• 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 now has procedures in place for requesting the commercial approval of GE animals, as well as for excluding gene-edited animals from the regulation (Resolution 63/19 and by Resolution 21/21). With this

update, the regulation for GE animals in Argentina perfectly mirrors the regulation for GM 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*, 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).* The approval process for a GE animal is the same as for GE plants (See Chapter 1, Part B.a). The duration time is not estimated, given that there were no application submissions. The approval is valid for the entire Argentine territory and does not have an expiration time, i.e. once the GE animal has been approved, it does not have to be re-registered. Agricultural animals can be used in biomedical research, pharmaceutical production, or organ production transplantation, 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)

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

The Coordination of Innovation and Biotechnology and CONABIA conduct the environmental assessment for confined field trials and other activities (import, export, derived-product processing) with non-commercial GE animals under Resolution 79/17 and recommend the Secretariat the issuance of the permit (see Part D, FIled 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 contemplates 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 with the intention of improving 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 falls under “GE” 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 ten animals produced by NBT. One already developed animal, and nine hypothetical cases were submitted for evaluation. All evaluated animals, except one bovine, were considered as "non-GMO". The precise list of animals derived from NBTs excluded from the “GMO” regulations and the applications currently under evaluation is not public information.

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 Government of Argentina. 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:

None.

H)) RELATED ISSUES:

- **The first "cultured meat" tasting in Latin America in Buenos Aires**

In 2016, the pharmaceutical laboratory *Craveri*, with 20 years of experience in human tissue engineering, generated the start-up "*Bio Ingeniería en la Fabricación de Elaborados*" (BIFE that means “steak” in Spanish). This start-up develops meat through cultivation techniques to ensure global food security and reduce the environmental burden of food production.

In July 2021, the company held the first "cultured meat" tasting in Latin America in Buenos Aires. The culture was made with bovine muscle proteins (without adipose tissue or fat) for four weeks and cost over 1000 USD. The process consists of four stages: multiplication of cells (neoblasts) extracted from a sample of a muscle biopsy, formation of muscle fibers, manufacture of the product, and recovery of the residues.

The company has posited several benefits of cultured meat listed below:

The consumption of cultured meat is a healthy alternative given that it presents notable advantages at a nutritional and healthcare level. Among them, it stands out the notorious reduction of the incidence of diseases of animal origin using strict quality control rules, impossible to apply to the production of traditional livestock.

Cellular agriculture has the possibility of controlling the amount of fat in meat, turning it into a lean and healthy food product that provides all the benefits of animal protein. In the same sense, it is not necessary to cultivate non-edible parts such as bone, the nervous system, the respiratory system, and the digestive system, avoiding waste.

Regarding the environment, cellular agriculture is considerably more efficient since it decreases energy use, the extension of land required, and the water needed by traditional livestock. Thus, the development of lab-grown meat becomes a viable option that promises to meet the population's demand sustainably while mitigating climate change.

The Bioengineering Division of *Craveri Laboratories* is currently the only type II Cellular Products Processing Plant (EPC II) authorized by competent authorities to carry out cell preparations that require a significant degree of manipulation. At present, there is still no estimated commercial launch date. The biggest challenge facing this practice is to achieve the scale required to streamline the production process and turn cultured meat into a commodity that is easy to reach the market.

- **The form "Should my product be regulated?" was enabled.**

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.

- **A new program launched to promote the bioeconomy and circular economy: BiodesarrollAR.**

As for biotech plants, the program BiodesarrollAR is available for biotech animal developers. See full description in Chapter 1, Part B.n.

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.

The Argentine Polo Horse Association has expressed concern about the possible production of genome-edited polo horses. Of particular concern is genetic therapies and doping to improve performance. To preserve the sport's integrity, they have requested the creation of accurate testing methodologies to detect suspected cases of genetic doping in horses.

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. To date, there is limited information about food ingredients production or use derived from microbial biotechnology. In addition, any prior consultation requests submitted to the regulatory agency to assess whether a genome-edited organism falls under "GMO" regulations included microorganisms intended for food ingredients production.

However, during the 2022-2023 period, SAGy-CONABIA-SENASA has authorized 4 recombinant vaccines for animal health:

- Fermboost™ MR. Genetically modified yeast (Saccharomyces cerevisiae), with improved ethanol production capacity from starch.
- Reconvinant HVT-ND virus present in Poulvac Procerta HVT-ND vaccine. Protects against Marek's (MD) and Newcastle (ND) diseases in chickens.
- Reconvinant HVT-IBD virus present in Poulvac Procerta HVT-IBD vaccine. Protects against Marek's (MD) and gumboro disease (infectious bursitis)
- INTA vaccine BLV DX 6073 Vaccine against bovine leukosis

Highlighting the nationally developed INTA vaccine “INTA vaccine BLV DX 6073” against bovine leucosis.

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 to these kinds of products.

PART H: POLICY

A) REGULATORY FRAMEWORK

a)

Legal term (in official language)	**Legal Term (in English)**	**Laws and Regulations where term is used**	**Legal Definition (in English)**
Agroecosistema	Agroecosystem	• Resolution 05/18	Ecosystem managed and/or adapted for agriculture, livestock, fish farming/aquaculture, fisheries and forestry production.
Bioseguridad	Biosafety	• 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	• 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	• Resolution 05/18	Unintentional dissemination and/or uncontrolled persistence of MGM by any means.
Establecimiento	Location	• 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	• 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	• 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	• 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	• 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	• 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	• Resolution 412/02	An organism containing genetic information acquired by recombinant DNA techniques.
Evento de Transformación	Transformation Event	• 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.
Biotecnología Moderna	Modern Biotechnology	• 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	• Resolution 52/19	A nucleic acid segment consisting of one or more contiguous nucleotide sequences proposed to be introduced into the

			microorganism.
Nueva Técnica de Mejoramiento genético	New Breeding Technique	• 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 one for GM 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).* Resolution 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 Spanis)

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 animals 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-inputs 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 CAA is to protect public health and the good faith in commercial transactions of food products within the national territory of Argentina.CAA is organized in 22 chapters, focusing on different food safety and food production standards by theme (establishments, labeling, food packaging, food additives, dairy product, confectionery, etc.) hat 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 doing / selling that which is positively expressed /said/ established in it; 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 supplements, 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, containers) labeling and the manufacturing conditions and procedures, such as GMP or HACCP.

The CAA is updated and modified on a frequent basis, 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. 1263establishes 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.

There are two national agencies that have the authority to enforce CAA standards in Argentina:

SENASA - (National Service for Agrofood Safety and Quality, in Spanish - 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, in Spanish – National Food Institute, which is an agency under the National Administration of Drugs, Food, and Medical Technology (ANMAT – Administración Nacional de Medicamentos, Alimentos y Tecnologia Médica, in Spanish). It regulates consumer-ready food products, health supplements, and both alcoholic and non-alcoholic beverages, with the exception of 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 prior to release.

B) APPROVALS/ AUTHORIZATIONS

There are no GE microorganisms approved to be used in the food industry nor GE derived food ingredients registered in Argentina. To date, no applications have been submitted for the approval or registration of these biotech products.

On the other hand, in May 2022, GOA approved the genetically engineered Bovine Leukosis Virus BLVDX6073, developed by the National Institute of Agriculture Technology (INTA), to be used in the production of veterinary vaccines. The full text of Resolution 28/22 is found in the following link:

ttps://www.boletinoficial.gob.ar/detalleAviso/primera/271894/20220916 (In Spanish)

In the last year, four other vaccines for animal health that contain GE microorganisms were approved:

(1) Recombinant virus cPC V1-2b present in vaccine Fostera Gold PCV-MH, phenotype of protection of pigs against Porcine Circovirus Type 2a and Type 2b (PCV2) and respiratory disease due to Mycoplasma hyopneumoniae;

(2) Recombinant virus cPC V1-2b present in vaccine Fostera Gold PCV; phenotype of protection of pigs against Porcine Circovirus Type 2a and Type 2b (PCV2);

(3) Recombinant virus vHVT310 present in the Vaxxitek HVT + IBD + NDEl vaccine, that protects against Marek disease (MD), infectious bursitis (or Gumboro) and Newcastle disease (ND);

(4) Nexhyon inactivated recombinant vaccine strain, present in the MHYOSPHERE PCV ID pig vaccine, that protects pigs against Porcine Circovirus Type 2a and respiratory disease due to Mycoplasma hyopneumoniae.

In June of 2023, CONABIA gave a favorable evaluation to the decision document of the GE virus vHVT317 present in the Vaxxitek HVT-IBD-ILT vaccine from the company Boehringer Ingelheim S.A. The vaccine protects chickens against Marek's disease (MD), infectious bursitis (IBD, Gumboro disease) and infectious laryngotracheitis (ILT).

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

Finally, Argentina has assessed five microorganisms for agricultural use produced using genome editing, none of them hypothetical. All microorganisms assessed except for one were regarded as “non-GMO”. The list of microorganisms derived genome editing excluded from the “GMO” regulations and the applications currently under evaluation are not public information.

C) LABELING AND TRACEABILITY

There are no mandatory labeling regulations for microbial biotech derived in 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?" was enabled.**

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.

- **A new program launched to promote the bioeconomy and circular economy: BiodesarrollAR.**

As for biotech plants, the program BiodesarrollAR is available for biotech microorganism developers. See full description in Chapter 1, Part B.n.

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	Resolution
Soybean	Glyphosate Herbicide Tolerance	40-3-2	Nidera S. A.	SAPyA N° 167 (25-3-96)
Soybean	Resistance to Glufosinate Ammonium	A2704-12	Bayer S.A.	(2011)
Soybean	Resistance to Glufosinate Ammonium	A5447-127	Bayer S.A.	(2011)
Cotton	Resistance to Lepidoptera	MON 531	Monsanto Argentina S.A.I.C.	SAGPyA N°428 (16-7-98).
Cotton	Glypohosate Herbicide Tolerance	MON 1445	Monsanto Argentina S.A.I.C.	SAGPyA N° 32 (25-4-01).
Cotton	Resistance to Lepidoptera and Glyphosate Tolerance	MON 1445 x MON 531	Monsanto	(2009

Corn	Resistance to Lepidoptera	176	Ciba-Geigy	SAPyA N° 19 (16-1-98).
Corn	Glufosinate Ammonium Tolerance	T25	AgrEvo S. A.	SAGPyA N° 372 (23-6-98)
Corn	Resistance to Lepidoptera	MON 810	Monsanto Argentina S.A.I.C.	SAGPyA N° 429 (16-7-98).
Corn	Resistance to Lepidoptera	Bt 11	Novartis Agrosem S.A.	SAGPyA N° 392 (27-7-01).

Corn	Glyphosate Herbicide Tolerance	NK 603	Monsanto Argentina S.A.I.C.	SAGPyA N° 640 (13-7-04).
Corn	Resistance to Lepidoptera and Glufosinate Ammonium Tolerance	TC 1507	Dow AgroSciences S.A. and Pioneer Argentina S.A	SAGPyA N° 143
Corn	Glyphosate Herbicide Tolerance	GA 21	Syngenta Seeds S.A.	SAGPyA N° 640 (22-08-05)
Corn	Glyphosate Herbicide Tolerance and Resistance to Lepidoptera	NK603x MON810	Monsanto	SAGPyA Nº 78 (28/08/07)
Corn	Resistance to Lepidoptera and Glufosinate Ammonium and Glyphosate	1507 x NK603	Dow AgroSciences S.A. y Pioneer Argentina S.R.L.	SAGPyA Nº 434

	Tolerance			(28/05/08
Corn	Glyphosate Herbicide Tolerance **and** Resistance to Lepidoptera	Bt11 x GA21	Syngenta Seeds S.A.	(2009)
Corn	Resistance to Lepidoptera	MON89034"	Monsanto	(2010)
Corn	Glyphosate Herbicide Tolerance **and** Resistance to	MON 88017	Monsanto	(2010)

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

Corn	Resistance to Lepidoptera and Coleoptera, and Glyphosate and Glufosinate Herbicide Tolerance	MON 89034 x TC 1507 x NK603	Dow Agro Sciences	(2012)

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

Soybean	Drought Resistance	IND410(Hb4)	INDEAR S.A.	(2015)

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

Soybean	Tolerance to glufosinate and enzyme HPPD inhibitors	SYN-000H2-5	Syngenta Agrosciences & Bayer S.A.	2017
Safflower	Expression of bovine pro-quimosin in	IND-10003-4, IND-10015-7, IND-10003-4 x IND-10015-7	INDEAR	Dec7, 2017

	seeds			
Corn	Tolerance to a herbicides base de 2,4 D and herbicides of the family ariloxifenoxi, ammonium glufosinate and glyphosate. Resistance to Lepidoptera	DAS-40278-9 MON-89034-3 x DAS-01507-1 x MON-00603-6 x DAS-40278-9 and all the stacked in between	Dow AgroSciences Argentina S.R.L.	March, 2018
Soybean	Tolerance to herbicides isoxaflutole, glfosate and amonium glufosinato.	MST-FG072-2 y MST-FG072-2xACS-GM006-4	Bayer S.A.	March, 2018
Corn	Tolerance to glyphosate and to ammonium glufosinate and Resistance to Lepidoptera and Coleoptera	SYN-05307-1 y SYN-BT011-1xSYN-IR162-4xSYN-IR604-5xDAS-01507-1xSYN-05307-1xMON-00021-9 and all the stacked in between	Syngenta Agro S.A.	March, 2018
Corn	Tolerance to glyphosate and Resistance to Lepidoptera y Coleoptera	MON-87427-7, MON-87411-9, MON- 87427-7 × MON-89Ø34-3 × SYN- IR162-4 × MON-87411-9 and all the stacked in between	Monsanto Argentina S.R.L.	May, 2018
Alfalfa	Tolerance to glyphosate and decrease in the	MON-ØØ179-5, MON-ØØ1Ø1-8 y	INDEAR	July 2018

	content of lignin	MON-ØØ179-5 x MON-ØØ1Ø1-8		
Soybean	Only for processing (Food, Feed and Processing)	MON-877Ø8-9 x MON-89788-1	MONSANTO	July, 2018

Potato	Resistance to viruses	TIC-AR233-5	Tecnoplant S.A.	August, 2018
Corn	Tolerance to glyphosate and Resistance to Lepidoptera y Coleoptera	MON-87427-7 x MON-89Ø34-3 x MON-88Ø17-3	MONSANTO ARGENTINA S.R.L.	August 2018
Soybean	Tolerance to glyphosate and gluphosinate. Drought Resistance.	IND-ØØ41Ø-5 x MON-Ø4Ø32-6 (OCDE)	INDEAR	October 2018
Cotton	Glyphosate Tolerance and herbicides inhibitors of HPPD	BCS-GH811-4	BASF	February 2019
Soybean	Tolerance to glyphosate and gluphosinate	DBN-Ø9ØØ4-6	INDEAR	February 2019
Corn	Tolerance to herbicides formulated based on products of the family of ariloxifenoxi an 2,4,-D, ammonium gluphosinate and glyphosate, and Resistance to lepidoptera.	MON-89O34x DAS-O1507 x MON -OO603 x SYN-IR162-4 x DAS-40278-9	DOW Argentina	April 2019

Cotton	Tolerance to ammonium gluphosinate, glyphosate and Resistance to lepidoptera	SYN-IR1Ø2-7 y BCS-GHØØ2-5 x BCS-GHØØ4-7 x BCS-GHØØ5-8 x SYN-IR1Ø2-7, the intermediate stacked and the events BCS-GHØØ4-7 y BCS-GHØØ5-8	BASF	June 2019

Corn	Tolerance to glyphosate and gluphosinate. Resistance to lepidoptera	MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-88Ø17-3 x DAS-59122-7	MONSANATO + DOW +PIONEER Argentina	August 2019
Corn	Tolerance to ammonium gluphosinate, glyphosate and Resistance to lepidoptera	MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7	MONSANTO ARGENTINA	August 2019
Corn	Tolerance to ammonium gluphosinate, glyphosate and Resistance to lepidoptera	MON-87427-7 × MON-89Ø34-3 × MON-ØØ6Ø3-6	MONSANTO ARGENTINA	August 2019
Corn	Tolerance to ammonium gluphosinate, glyphosate and Resistance to lepidoptera	MON-87427-7 x MON-89Ø34-3 x SYN-IR162-4 x MON-ØØ603-6	MONSANTO ARGENTINA	September 2019
Cotton	Resistance to insects and lepidoptera	SYN-IR1Ø2-7	Syngenta	October 2019
Corn	Resistance to lepidoptera, coleoptera, Tolerance to glyphosate, gluphosinate,	MON-87427-7 x MON-89Ø34-3 x SYN-IR162-4 x MON-87411-9 x MON-87419-8 x MON-ØØ81Ø-6	MONSANTO ARGENTINA	November 2021

	and Dicamba			

Alfalfa	Tolerance to Gliphosate	MON-ØØ163-7	INDEAR	November 2021
Corn	Tolerance to glyphosate, gluphosinate, and Dicamba	MON-87427-7 x MON-87419-8 x MON ØØ6Ø3-6	MONSANTO ARGENTINA	November 2021
Wheat	Tolerance to drought and ammonium glufosinate	IND-ØØ412-7	INDEAR	October 2020 & May 2022
Soybean	Only for processing (Food, Feed and Processing)	MON-87751-7	MONSANTO ARGENTINA	May 2022
Corn	Tolerance to herbicides based on glyphosate, glufosinate-ammonium, 2,4-D or to herbicides of aryloxyphenoxypropionic acid family	MON-ØØ6Ø3-6 x ACS-ZMØØ3-2 x DAS-4Ø278-9	CORTEVA AGRISCIENCE ARGENTINA S.R.L	July 2022
Soybean	Resistance against attack by certain lepidopteran insects and tolerance to herbicides based on glufosinate ammonium.	DNB-Ø8ØØ2-3	INDEAR S.A.	Nov2022

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.	January 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.	January 2023
Soybean	Tolerant to herbicides based on glyphosate and glufosinate ammonium	MON-Ø4Ø32-6 x ACSGMØØ6-4	GDM	May 2023

Corn	Lepidoptera resistant and tolerant glyphosate and glufosinate ammonium	SYN-BTØ11-1 x SYN-IR162-4 xMON-ØØ6Ø3-6	Syngenta Agro S.A.	Sep 2023

Soybean	Lepidoptera resistant and tolerant glyphosate and glufosinate ammonium	DNB-Ø9ØØ4-3xDNB-Ø8ØØ2-3 (OCDE denomination)	INDEAR S.A	Oct 2023

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

Attachments:

No Attachments

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No Attachments

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No Attachments