Required Report: Required - Public Distribution **Date:** December 27, 2022

Report Number: AR2022-0023

Report Name: Agricultural Biotechnology Annual

Country: Argentina

Post: Buenos Aires

Report Category: Biotechnology and Other New Production Technologies

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Report Highlights:

The Government of Argentina (GOA) approved two new genetically engineered (GE) events in 2022 (one soybean and one maize). In November 2021, Brazil's regulatory agency approved the commercialization of wheat flour containing the HB4 drought tolerance event grown in Argentina. As a result of this approval by Argentina's most important export market for wheat, the GOA granted full approval for seed commercialization. Due to concerns from several Argentine farmer organizations and exporters, the GOA created an audit commission, which will operate within the National Seed Institute (INASE). In addition, the developer stated that the company will produce HB4 wheat under an identity-preserved production system and, for the moment, will not openly commercialize the event.

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 since then it has shown unprecedented growth in area planted: 99 percent of soybeans, 99 percent of corn and 100 percent of cotton planted in Argentina are 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, which will primarily be used in food. HB4 wheat is a drought resistant GE wheat variety developed by Bioceres, which carries a gene originally discovered in sunflowers. 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. In order to address concerns from farmer organizations and exporters that the approval could put wheat exports at risk, the GOA created an audit commission within the National Seed Institute (INASE). Although Brazil has not yet approved the importation and sale of the HB4 wheat in the form of grain or seed, 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. Bioceres stated that the company will produce HB4 wheat under an identity-preserved production system based and, for the moment, will not freely commercialize it.

Argentina's seed royalty system 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 China is a key export market for Argentine biotech 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 commercialization in Argentina.

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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 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. Plants developed with either of these platforms would not be considered transgenic. Bioheuris is reportedly working with several other companies to develop new varieties of soybeans, sorghum, rice, cotton, and alfalfa.

b) COMMERCIAL PRODUCTION

Argentina is the world's third largest producer of biotech crops, after the United States and Brazil, with 50 biotech crop events approved for production and commercialization, including: 17 soybean events, 17 maize events, 10 cotton events, three alfalfa events, one safflower event, one potato event, and one wheat event.

Soybeans

Released in 1996, glyphosate-tolerant soybeans have been adopted at a very high rate in Argentina and encompass almost all of the estimated 16.3 million hectares of soybeans planted for the marketing year (MY) 2021/22 season, while conventional seed accounted for 1.5 percent of soybeans planted. The new technology has 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 eight 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 2021/22 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.

For the first time in Argentina, in the MY 2021/22 season, Enlist soybeans tolerant to 2,4D, glyphosate, and glufosinate-ammonium carrying the event DAS-44406-6 from Corteva Agriscience were planted. This variety was planted on 191,000 hectares.

The Argentine soybean industry is oriented almost entirely towards exports. 16 percent of soybeans are exported as whole beans while the remaining 84 percent are crushed and exported as meal or oil. The vast 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).

In May 2022, a new soybean event from Bayer Argentina was approved for industrial processing: MON-87751-7.

For more detailed information on soybean production in Argentina, please see the Argentina Oilseeds and Products Annual Report.

Corn

In the MY 2021 season, 6.55 million hectares of corn were harvested, the highest area in the last 21 seasons. GE corn adoption was 99.6 percent, of which 7.3 percent corresponds to single, herbicide-tolerant (HT) or insect resistant (IR) events and 92.3 percent to stacked events (HTxRI). Glyphosate tolerant Bt2 hybrids showed an adoption of 86 percent for all corn at the country level.

Argentine farmers have been using stacked corn events for 10 years across all regions of the country. Over the last decade, there has been rapid adoption of maize stacked events from 25 percent in the MY 2012/12 season to 84 percent in the 2021/22 season. These stacked events reduce the 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 and soil moisture, 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-planted corn. 50 percent of Argentine growers who have adopted the Bt technology also use the refuge system, which contributes to the sustainability of Bt technology by reducing the selection pressure on targeted insect populations, therefore delaying the onset of natural resistance.

The MY 2021 corn crop produced 52 million tons. From this crop, 41 million tons was exported, 9.5 million tons were used for animal feed, and the remainder was used for food, seed, and industrial uses.

Cotton

The Argentine 2021 cotton season accounts for an estimated 490,000 planted hectares. According to the National Seed Institute (INASE), GE cotton encompassed 96 percent of the area planted, of which 75 percent corresponded to stacked HT and IR events and 25 percent to HT cotton. No new cotton events have been approved in 2021 or 2022.

Wheat

Argentina planted 6.4 million hectares of wheat during the 2021 season. The top 10 percent of the producers planted more than half of the wheat area, and the top 30 percent planted more than 78 of wheat area. 18 new varieties were registered in the National Register of Cultivars (RNC) in 2021, none of them GE.

For the second 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 INASE, during the 2021-22 season, almost 53,000 hectares were planted, and 124,000 tons were harvested. The company has seeds for multiplication and produces flour in mills exclusively used for this grain, maintaining the segregation of conventional flour. Bioceres has stated its commitment to maintain the HB4 seed closed-loop management system and that HB4 seeds or flour will not be openly commercialized.

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 as being genetically engineered. Argentina requires that biotech events be approved in main importing countries before any domestic commercialization to avoid possible trade disruptions.

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 recent years, the rate of Chinese approvals has lagged behind other importing countries such as Mexico, Japan, and South Korea, hampering producers' access to new seed technologies. A 2018 paper, written by a trade association representing the seed and chemical manufacturers, analyzes the agricultural and broader economic impacts of the delays in Chinese biotech approvals and can be found at: https://croplife.org/?s=The+Impact+of+Delays+in+Chinese+Approvals+of+Biotech+Crops

Notwithstanding the above-mentioned delays, the Chinese Ministry of Agriculture has promulgated a number of policies and regulations since the beginning of 2022 with the

objective of opening a path for commercialization of major GE crops. According to some analysts, Chinese developed GE maize and soy could reach the market around 2023.

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. Thanks to a severe drought in 2018 the Argentine soybean crushing industry needed to source soybeans to maintain its processing levels and imported soybeans in large quantities from the United States for the first time since 1997. 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, 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

FAS Buenos Aires is unaware of any biotechnology-related trade barriers.

PART B: POLICY

a) REGULATORY FRAMEWORK

Table 1. Legal terms related to plant biotechnology.

Legal term (in Spanish)	**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.
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	Escape	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.
Nueva combinación de material genético	New combination of genetic material	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 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 Biotechnology and Innovation**, 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 approval 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.

- **The 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 Biotechnology and Innovation regulators, CONABIA's responsibility is to enforce agricultural biotech product regulations with a focus on assessing the potential environmental impact of releasing biotech crops into Argentina´s agroecosystem, as well as enacting updated normative regulations. Under Argentina's regulatory framework, CONABIA must complete GE products assessments within 180 days of their submission. The Food and Agriculture Organization of the United Nations (FAO) recognized CONABIA as a Center of Reference for the biosafety of GE events.

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

- **The National Directorate of Agricultural Food Markets (DNMA)** (Dirección Nacional de Mercados Agroalimentarios in Spanish) 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 main destination markets (those markets that receive more than 1 percent of total exports of that crop, such as China for soybeans and Brazil for wheat and corn) and identifies possible trade disruption risks. In those cases where an event was not approved in a relevant importing country, the DNMA recommends that the event be approved on a conditional basis. According to the regulatory framework, DNMA provides an evaluation within 45 days.

- **The National Seed Institute (INASE)** establishes requirements for seed registration in the National Registry of Cultivars. Once an event has been approved, the variety or hybrid carrying it can be registered and the producer can proceed to the GE seed's commercialization.

When offices have completed a new event´s environmental, food and feed safety, and trade impact assessments, they produce independent decision documents recommending the approval or disapproval of the event under evaluation. The Coordination submits a final report with the three recommendations to the Secretariat for Bioeconomy, Food, and Regional Development. The Secretariat makes the final decision on the approval of GE products.

Complete text of Resolution 763/11(general guidelines of the regulatory framework) 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 approval is valid

within the entire Argentine territory and does not expire. 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 contain DNA.

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 approval for safe use in the environment, and for human, animal, and crop health. Events must also receive commercial assessment approval that their use will not cause trade disruptions in Argentina's major export markets. The Secretariat of Agriculture publishes a list of events that are approved, which can be found here (in Spanish): https://www.argentina.gob.ar/agricultura/alimentos-y-bioeconomia/ogm-vegetal-eventos-con-autorizacion-comercial

First commercial scale-production of GE Wheat

In 2020, Argentina became the first country in the world to approve GE wheat for commercial production 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 Argentina flour per year, as well as 5 million tons of wheat imported 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.

Following the approval, farmer and exporter organizations were concerned that it might put Argentine wheat exports at risk in Argentina's major export 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 on the use of 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.

- The developer may keep up to 20 percent of harvested grain as seed, identifying its place of storage and its conditions. However, for the 2021/22 crop season, the conservation of up to half of the harvested grain was authorized as "propagation material".

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

Under this controlled system, during MY 2021/22, Bioceres reported planting almost 53,000 hectares of HB4 wheat in 372 sites, spanning 12 provinces, by 225 producers. In February 2022, 124,000 metric tons were harvested. A summary of the GOA report with information on HB4 wheat production can be found at the following link: https://www.argentina.gob.ar/sites/default/files/trigo_hb4_15_febrero.pdf.

Although Brazil has not yet approved the importation and sale of the HB4 wheat in the form of grain or seed, the GOA considered that the event met requirements for an import authorization and granted full approval for HB4 seed commercialization in May 2022 via Resolution 27/22. HB4 wheat varieties have been already registered with INASE.

During 2022 HB4 wheat was approved for food and feed uses by regulatory agencies in the United States, Colombia, Nigeria, Australia, South Africa, and New Zealand.
In a document for investors, Bioceres stated that it continues producing HB4 wheat under an identity-preserved production system based on special contracts with selected growers. For the moment, Bioceres does not openly commercialize HB4 wheat.

Bioceres' representatives stated that during the MY 2022/23 season, HB4 wheat producers will manage the crop under biosafety conditions, and then must deliver all harvested grain to the company. In this way, Bioceres is seeking to ensure that there is no dispersion of pollen or grains and to prevent leakage of the transgenic event.

China authorizes Argentine HB4 drought resistant soybeans

Since 2015, all soybean product approvals have been conditioned on Chinese approval prior to 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 2021/22 season 23,000 hectares of HB4 soy were planted in 195 sites.

HB4 soybeans are also authorized in the United States (August 2019), Brazil (May 2019), Paraguay (2019), and Canada (2021). 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.

New GE corn and soybean approvals

In July 2022, GOA approved a new stacked corn product from Corteva Agriscience Argentina (MON-ØØ6Ø3-6 x ACS-ZMØØ3-2 x DAS-4Ø278-9) via Resolution 141/21. The GE crop is tolerant to herbicides based on glyphosate, glufosinate-ammonium, 2,4-D or to herbicides of the aryloxyphenoxypropionic acid family (Haloxyfop, Quizalofop). The full text of Resolution 141/21 can be found in the following link:
In addition, a new soybean event from Bayer Argentina was approved for industrial processing: MON-87751-7 in May 2022.

c) STACKED OR PYRAMIDED EVENT APPROVALS/AUTHORIZATIONS

A regulation approved in late 2019 changed the way that stacks were assessed and approved. It eliminated the need to assess or approve stacked events that had been approved previously as individual events and that were considered to have a low risk of interacting negatively with other events. For SENASA's food and feed safety assessment, it is possible to submit a letter requesting approval of any particular stacked event in accordance with this process.

Resolution 32/21, issued in late 2021, implemented the current process used to evaluate stacked events for environmental safety. Under Resolution 32/21, 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 to CONABIA and the Coordination of Innovation and Biotechnology with relevant information.

If all individual events included in the stack have been assessed positively by CONABIA, the information on the prior consultation request should focus on possible interactions between the individual events contained in the stacked event and the resulting combined traits.

A complete application must be submitted for any individual events included in the stack that have not been previously assessed by CONABIA. However, this application may be

evaluated jointly with the prior consultation request for the stacked 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 its assessment of the environmental safety of the stacked event, its intermediate stacked events, and any other individual events not previously evaluated.

d) FIELD TESTING

In Argentina, regulations for experimental field trials of non-commercial GE events and for seed counter-season multiplication for export are regulated under a permit-based system described in Resolution 45/22.

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 all activities with GE seeds (planting, harvesting, importing, exporting, processing, and storage) to the regulatory agency. 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.

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 to implement a regulatory framework that considers certain, non-transgenic products obtained with genome editing techniques to not be subject to approval requirements for products considered by Argentina to be “genetically modified organisms.” Since then, several other countries have enacted similar regulations.

Argentine policymakers and regulators debated for over three years to clarify the status of products derived from new breeding techniques such as genome editing under the existing biotechnology regulatory framework. During the debate, policymakers and regulators noted that no disagreements emerged in interpreting the terms “genetically modified organism” or “modern biotechnology”. 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 new breeding techniques, such as genome editing, is regulated as a “genetically modified organism”. The following are the main foundational criteria under the Argentine regulation:

Case by Case Analysis

In 2021 the GOA implemented Resolution 21/21 of the Secretariat of Food, Bioeconomy and Regional Development with the intention of improving the previous regulation on crops derived from new breeding techniques. This regulation established procedures to determine which products are considered to be “genetically modified organisms. To this end, applicants submit a prior consultation request to the Coordination of Innovation and Biotechnology and CONABIA with relevant information on each product that is assessed by regulators to establish if the result of the breeding process is a “new combination of genetic material”.

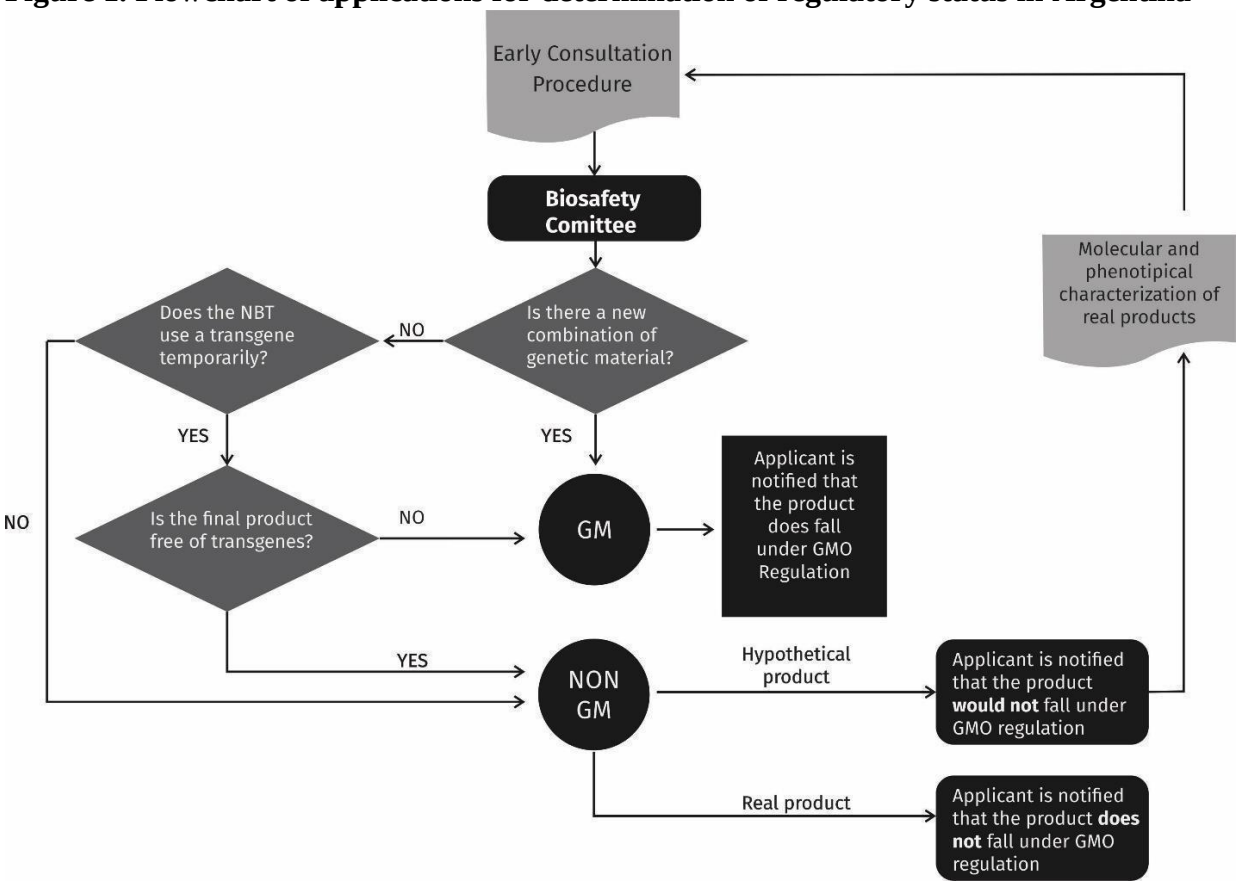
A genetic change is regarded as a “new combination of genetic material” when a stable and joint insertion of one or more genes or DNA sequences that are a part of a genetic construct are introduced permanently into the plant genome. With these criteria, products derived from new breeding techniques containing INDELS, nucleotide substitutions, and ALLELE replacements are not considered to be “genetically modified organisms” and are therefore excluded from related regulations. In order for a product to be excluded from such regulations, evidence must also demonstrate 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 “genetically modified organism” regulation or not. If the product is not regarded as” genetically modified”, but its features and/or novelty led 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.

A crop derived from new breeding techniques falls under regulations for “genetically modified organisms” until authorities decide that it is not regarded as “genetically modified", and therefore it must be handled as such until receiving a regulatory determination (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 as “genetically modified”. 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.

Figure 1. Flowchart of 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

Flexibility for Future Technologies

Argentina decided that a new regulation on new breeding techniques should not be based on a closed list or description of particular technologies but should be flexible and applicable to existing or forthcoming technologies. Argentina policymakers revealed that, given the differences in uses of a new breeding technique by different research groups, it was challenging to reach "satisfactory" legal definitions of the various technologies.

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

- The procedure determines if a product obtained by a new breeding technique should be evaluated as being "genetically modified".
- The prior consultation request should include information on the organism involved, the new breeding technique 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 living modified organisms/genetically modified organisms" from the Cartagena Biosafety Protocol.

Complete text of Resolution 21/21 can be found at:
https://www.argentina.gob.ar/normativa/nacional/resoluci%C3%B3n-21-2021-346839

In the last seven years, Argentina has assessed several plants produced using new breeding techniques. 48 products, (23 existing and 25 hypothetical cases) were submitted for evaluation. All crops derived from new breeding techniques were regarded as "non-GMO" and fell under conventional seed regulations. The list of plants derived from new breeding techniques that are excluded from regulations for "genetically modified organisms" and the list of applications that are currently under evaluation are not publicly available.

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 (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 organisms and new breeding techniques 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 planning to generate a new breeding technique-derived product can ask if it 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 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 considering 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. To date, there are no provisions 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 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. As the Bolsatech system was implemented in order to detect this particular event, the developer company financed the genetic tests. However, in July 2021, the Bayer Group announced the suspension of its soybean seed and biotechnology business in Argentina as of the 2021/22 season, and 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 2022 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), they acquire an "HT credit" that entitles them to plant one hectare of that variety. In addition, those interested in producing new seed varieties from replanting their own seeds 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 following agreement between participating companies and INASE. This program will seek to 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 requiring 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 2021/2022 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. The detection of events will likely use molecular biology methods (e.g., ELISA, PCR, lateral flow immunoassay strip). INASE is also considering 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 Low Level Presence
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 a commercial authorization that includes use in human and/or animal feed of GE products in any member country, that country must inform the other member countries of said authorization, within the scope of the Committee on Agriculture Biotechnology (CBA) of the Working Subgroup N 8 "Agriculture (SGT N 8), within 30 calendar days from the date of authorization. When communicating the authorization, the member country must send various items to the CBA, including 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 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 protections 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 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, they 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.

Under the proposed law, 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.

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 countries towards regulatory 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. It has become public that Argentina has been firmly working toward ratification of the Protocol. However, FAS Buenos Aires believes that this is very unlikely to occur in the near future.

Representatives of Argentina have participated in the 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.

m) INTERNATIONAL TREATIES AND FORUMS

During 2021 and 2022, Argentina has not joined any new international treaties related to agricultural biotechnology.

Participation in Multilateral Forums

World Trade Organization Committee on Sanitary and Phytosanitary (SPS) Measures.
Argentina participates in the SPS Committee working group on approval procedures created in 2020. See detailed information on the working group in the following document: https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/G/SPS/W328R1A1.pdf&Open=True

Organization for Economic Co-operation and Development (OECD).
In 2022, experts from the Coordination of Innovation and Biotechnology participated in two OECD working groups on agricultural biotechnology: the Working Group on Harmonization of Biotechnology Oversight and the Working Group on Novel Food and Feed Safety. They also took part in ad hoc working groups such as the new breeding technique-derived organisms and the "Safe-by-Design project proposal" groups.

Global Low-Level Presence Initiative (GLI).
Argentina has been a member of the Global Low-Level Presence Initiative (GLI) since 2012. GLI holds regular meetings attended by member countries, observers, and organizations and also works with industry to better understand trade barriers, potential solutions, and impacts. Argentina participated in the GLI 8th meeting held in 2022.

Agricultural Biotechnology Commission of MERCOSUR's GTS N° 08 Agriculture.
Mercosur countries meet periodically twice a year, to address issues of biotechnology and biosafety, synchrony of approval of events, new technologies, an international position as a bloc vis-à-vis third countries, and participation in multilateral instances.

Working Group on Public Policies on Biotechnology (WG5) of the Southern Agricultural Council (CAS).
The Southern Agricultural Council (CAS) is the agriculture ministerial forum for consultation and coordination of regional activities of Argentina, Bolivia, Brazil, Chile, Paraguay, and Uruguay. Its main objective is to define the priorities of agriculture businesses and take positions on issues of regional interest to articulate the development of agreed actions.

In March 2019, Argentina submitted a declaration where CAS members agreed on the importance of genome editing techniques in agriculture and claimed that:

1. Crops improved by genome editing have the potential to play a fundamental role in addressing the challenges of agricultural production, contributing to sustainably increasing the food supply.
2. Genome editing can generate crops analogous to those obtained through other conventional breeding methods.
3. CAS countries present public and private investment in the development of improved crops by genome editing. This is because it can accelerate the access of the agricultural producer to new characteristics of agricultural interest, while representing

an opportunity.

A link to this declaration can be found here:
https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=s:/G/SPS/GEN1699.pdf

In March 2022, CAS members released a document stating their position on agricultural biotechnology, which can be accessed using the following link: http://consejocas.org/wp-content/uploads/2022/03/Declaraci%C3%B3n-CAS-Posici%C3%B3n-regional-sobre-las-biotecnolog%C3%ADas-ligadas-al-sector-agropecuario.pdf

Like-Minded Group on Innovative Agricultural Technologies

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

Other multilateral activities in which Argentina participated during 2020-22 include:

- The Regulatory Horizons Council (United Kingdom) (2021).
- Montpellier Institute for Advanced Knowledge on Transitions (MAK'IT) (2021).
- Asia-Pacific Economic Cooperation APEC / Cornell University (2021).
- Eurasian Economic Commission (2021).
- International Seed Federation (ISF) / China Seed Association and China Seed Trade Association (2021).

Bilateral cooperation activities

Argentina offers advice and technical assistance to third countries through cooperation projects on issues related to regulatory frameworks for agricultural biotechnology, communication, public perception, and socioeconomic and biosafety aspects of modern biotechnology products.

Over the past 30 years, Argentinian GOA officials have assisted and provided training in regulatory matters and biosafety assessment to specialists and officials from more than 20 countries.

Argentina carried out the following technical assistance and/or bilateral cooperation activities in agricultural biotechnology during 2020-22:

- Korea (2020)
- Japan (2021)
- Pakistan (2021)
- Mexico (2021)
- Thailand (2021)

- Germany (2021)
- Philippines (2021)
- United Arab Emirates (2021)
- Cuba (2022)
- Egypt (2022)
- EU (2022): 12th EU - Argentina Joint Committee, Trade and Economic Meeting.
- Peru (2022): Fondo Argentino de Cooperación Sur-Sur y Triangular Project "Capacity building for activities with new breeding techniques, including gene editing".
- Germany (2022): German-Argentine Dialogue on Agricultural Innovation.
- China (2022): IV Meeting of the Chinese-Argentine Seed Sub-Committee.
- Brazil (2022): First bilateral cooperation and exchange meeting between biosafety regulatory agencies for biosafety in Argentina and Brazil.
- United States (2022)- Technical mission of government officials from Argentina, Paraguay, and Uruguay to the United States.

n) RELATED ISSUES

BiodesarrollAR

The Secretariat of Agriculture, Livestock, and Fisheries launched a new plan aimed at small and medium-sized companies in the agricultural and agroindustrial sectors. It is called "Programa Nacional Biodesarrollo Argentino" ("BiodesarrollAR"), or the “National Argentine Bio-development Program” in English. This program 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 agri-food and agro-industrial production.

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

- Accompany bio-developers in the management of activities with regulated “genetically modified organisms” other agricultural biotechnology products, and bioproducts.
- Coordinate and connect bio-developers with public, private, and mixed entities for projects and product development.
- Generate public-private associative processes for investing in initiatives at their final stages of development.
- Provide financing instruments for bioeconomy bioproduct development projects whose prototypes are in a position to advance in their productive and commercial scaling-up levels.

- To offer technical assistance in solving-problems, as well as to provide tools and instruments aimed at the development of their bioproducts.
- 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 Agro-Industry Trust Fund (Fondagro).

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 that are controversial in Argentina. 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 against this product (one of them under the hashtag in Spanish #connuestropanno, #withourbreadno) were led by groups of environmentalists, famous cooks, and influencers.

The bakery and candy company Havanna announced an agreement with Bioceres to use HB4 wheat in one of its flagship products in 2021. However, activist groups launched a pressure campaign on social networks against GE flour used in that product, and Havanna decided to back out of the agreement. In 2022, Bioceres announced that it engaged in talks with a craft beer producer to produce a beer using HB4 wheat.

Meanwhile, most Argentine scientists and farmers support the use biotechnology to improve crop yields while reducing inputs. Given that Argentina has been a leader in biotechnology adoption, dialogue and communication between scientists, farmers, private companies, consumers, government, and regulatory organizations are necessary.

b) MARKET ACCEPTANCE/STUDIES

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

A group of experts from Bolsa de Cereales de Buenos Aires (Buenos Aires Grain Exchange), A. Tejeda Rodriguez, Santiago Rossi, Nicolas Jorge & Eduardo Trigo, presented in May 2021 the paper *25 Years of Genetically Modified Crops in Argentine Agriculture*, showing 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 percent (USD 146 MM) correspond to soybean cultivation, 7 percent (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 percent 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 used in agriculture: 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 animals is limited in Argentina. Research on GE 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 regulated by CONABIA. The list of applications for the confined use of GE animals currently assessed and the trials conducted are not public information, so only limited data is available.

In Argentina, public and private groups seek to develop or import genome edited animals. The National Institute of Agricultural Technology (INTA) developed genome edited cow embryos without the allergenic protein beta-lactoglobulin gene, in order to breed cows that could produce hypoallergenic milk. In addition, a group at the Faculty of Agriculture of the University of Buenos Aires (FAUBA-UBA) plans to obtain GE pigs for xenotransplantation. Meanwhile, BioMill (formerly BioSidus) developed GE cows that express human growth hormone in their milk.

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-GMO."

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. 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

Table 2. Legal terms related to animal biotechnology.

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	Escape	• 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 confinada	Confined release	• Resolution 79/17	Experimental release and/or production 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 combinación de material genético	New combination of genetic material	• 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 certain genome-edited animals from regulation (Resolution 63/19 and by Resolution 21/21). With this update, the regulation for GE animals in Argentina

perfectly mirrors the regulation for GE crops, having the same provisions for different kinds of applications (field trials, commercial release) and products (genome-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 Biotechnology and Innovation*, 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). 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) can be found here:
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) can be found here:
http://servicios.infoleg.gob.ar/infolegInternet/verNorma.do?id=74376

As with GE plants, the Coordination of Biotechnology and Innovation 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 Chapter 1, Part B.d, Field Testing). SENASA carries out periodic inspections to verify compliance with the required biosafety conditions and GE animals and derived-products stocks.

Resolution 79/17 (Confined field trials with GE animals, new breeding technique-derived animals) can be found here:
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 Part B.c, Innovative biotechnologies, for information on genome edited animals that Argentina has designated as “non-GMO”.

c) INNOVATIVE BIOTECHNOLOGIES

As described in Chapter 1 for crops derived from new breeding techniques, in 2021 the GOA enforced Resolution 21/21 of the Secretariat of Food, Bioeconomy and Regional Development with the intention of improving the previous regulations on animals derived from new breeding techniques included under Resolutions 79/17 and 63/19. The Resolution established the same procedure used for new breeding technique-derived plants to determine the criteria under which animals obtained by breeding techniques involving modern biotechnology fall under regulations for "genetically modified organisms" (See Chapter 1, Part B.e).

Resolution 21/21 (New breeding technique-derived animals)
https://www.argentina.gob.ar/normativa/nacional/resoluci%C3%B3n-21-2021-346839

So far, Argentina has evaluated ten animals produced by new breeding techniques. 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 new breeding techniques excluded from the "GMO" regulations and the applications currently under evaluation is not public information.

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.e.

d) LABELING AND TRACEABILITY

The Argentine Rural Society has created a Genealogical Registry for cloned animals to assist owners and prospective owners of cloned animals. However, this is not an official traceability system adopted by the GOA. At present, there is no official traceability system managed by the government.

e) ADDITIONAL REGULATORY REQUIREMENTS

None.

f) INTELLECTUAL PROPERTY RIGHTS (IPR)

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

g) INTERNATIONAL TREATIES AND FORUMS

Representatives of the National Bioeconomy Directorate (DNB) participated in the following events:

- June 2022: Meeting with representatives of the international organization "Gene Drive Network" (https://genedrivenetwork.org/) to discuss prior to the Convention on Biological Diversity meetings in Nairobi and share views on biotechnology and gene drive issues.
- July - September 2002: Animal Biotech Workshop bi-weekly meetings organized by IICA and USDA to promote the application of biotechnology and biosafety in agricultural production animals.
- September 2022: 4th International Workshop on Regulatory Approaches for

Agricultural Applications of Animal Biotechnologies held in Sao Paulo, Brazil. The DNB organized presentations by Argentina on biotechnology regulation in Argentina (specifically on biotech animals), on the Codex Alimentarius, and on national developments. SENASA and INTA were invited to participate.

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 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 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.

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 animals, livestock clones, and 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 animals are not currently being commercialized.Concerning animals derived from new breeding techniques, 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.

FAS Buenos Aires is not aware of any market studies on animal biotechnology.

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 authorization consultations submitted to regulatory agencies to assess whether a genome-edited organism falls under "GMO" regulations included microorganisms intended for food ingredients production.

b) EXPORTS
To date, Argentina has no GE microbes commercially authorized 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
FAS Buenos Aires is unaware of any trade barrier to these kinds of products.

PART H: POLICY

a) REGULATORY FRAMEWORK

Table 3. Legal terms related to microbial biotechnology.

Legal term (in official language)	**Legal Term (in English)**	**Laws and Regulations where term is used**	**Legal Definition (in English)**
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	• Resolution 05/18	Intentional controlled/contained

experimental	release		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.

See Table 1 and Table 2 for other commonly used terms..

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 regulations that apply to GE crops (See Chapter 1, Part B.a) and animals. The country regulates confined field trials under Resolution 05/18. As for other GE organisms, the Coordination of Biotechnology and Innovation 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 genome-edited "non-GMO" microorganisms from biotechnology regulations.

As mentioned above 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 Biotechnology and Innovation, 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 GE microorganisms, respectively.

Resolution 05/18 (Confined field trials with GE microorganisms)
http://servicios.infoleg.gob.ar/infolegInternet/verNorma.do?id=314800

Resolution 412/02 (Food and feed safety assessment for the approval of GE organism)
http://servicios.infoleg.gob.ar/infolegInternet/verNorma.do?id=74376

Resolution 52/19 (Environmental risk assessment for the approval of GE microorganisms)
http://servicios.infoleg.gob.ar/infolegInternet/verNorma.do;jsessionid=11FC864FA6087BD0BF4818A2461A1902?id=325917

Resolution 21/21 (NBT-derived microorganisms)
https://www.argentina.gob.ar/normativa/nacional/resoluci%C3%B3n-21-2021-346839

As described above for crops and a animals derived from new breeding techniques, in 2021 the GOA enforced Resolution 21/21 of the Secretariat of Food, Bioeconomy and Regional Development that established the same procedure used for new breeding technique-derived plants and animals to determine the criteria under which microbes obtained by breeding techniques involving modern biotechnology falls under regulations for “genetically modified organisms” (See Chapter 1, Part B.e).

Resolution 21/21 (New breeding technique-derived microorganisms) can be found here:
https://www.argentina.gob.ar/normativa/nacional/resoluci%C3%B3n-21-2021-346839

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

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.) that include provisions referring to general conditions of factories and food trade, the conservation and treatment of food, the use of utensils, containers, wraps, labeling and advertising of food, specifications on different types of food and beverages, adjuvants and additives). No official translation to English is available. The Argentinian Food Code can be consulted on the ANMAT website:
https://www.argentina.gob.ar/anmat/codigoalimentario

The Food Code is a "positive" code. This means that it only permits using practices or additives that are 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 is a 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 by CONAL. 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. Art. 1263 establishes the protocol by which new enzymes may be admitted, as technology adjuvant, upon submission of information from the applicant (characterization of the enzyme, the producing GE microorganism, and the production method) and satisfactory evaluation. The full text of the Resolution 16/2016 is in the following link: https://www.boletinoficial.gob.ar/detalleAviso/primera/205739/20190417

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), f 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 Buenos Aires 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.

However, in May 2022, GOA approved the GE Bovine Leukosis Virus BLVDX6073 via Resolution 28/22. This virus was 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 the last year, four other GE vaccines for animal health that contain GE microbes 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.

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 by new breeding techniques, none of them hypothetical. All microorganisms assessed except for one were regarded as "non-GMO". The list of microorganisms derived from new breeding techniques excluded from the "GMO" regulations is not publicly available.

c) LABELING AND TRACEABILITY
There are no mandatory labeling regulations for microbial biotech-derived food products 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 First Official Meeting of the Bio-inputs Commission of the SGT "Agriculture" of the GMC-MERCOSUR was held in September 2022. It was the first formal meeting of the Commission since its creation at the end of 2021, led by Uruguay. Among its agenda items, country members agreed on a 2022-2024 Work Plan with permanent actions and specific actions.

PART I: MARKETING

a) PUBLIC/PRIVATE OPINIONS
FAS Buenos Aires is not aware of any public concern over the use of microbial

biotechnology in Argentina.

b) MARKET ACCEPTANCE/STUDIES
FAS Buenos Aires is not aware of any relevant market studies on microbial biotechnology in Argentina.

Attachments:

No Attachments