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Report Highlights:

Brazil is the second-largest producer of biotech crops in the world with 104 events approved. The total area planted to GE crops reached over 53 million hectares during the recently completed crop year of 2019/2020. Adoption rates for soybeans reached 96.3 percent, followed by 91.8 percent for corn (first crop), 86.7 percent for corn (second crop) and 89.9 percent for cotton. According to Brazilian government data, the average yields for grains and oilseeds increased by 70 percent during the past 15 years, with continued use of biotechnology seeds being a major contributor to this yield growth. The National Technical Commission (CTNBio) is responsible in Brazil for new technologies such as GE animal technology, gene editing including CRISPR technology and microbial biotechnology. In addition to GE plants, this report provides updates on several aspects of these new technologies.

EXECUTIVE SUMMARY

Brazil's grain and oilseed production during the 2019/2020 crop season (October 2019 through September 2020) set another record at 258 million metric tons, up 4.5 percent from the previous crop year. The planted area reached 66 million hectares, an increase of 4.8 percent from the previous year, while productivity increased by 1.7 percent. According to Brazilian government data, the average yields for grains and oilseeds have increased by 70 percent during the past 15 years, and a major reason for this expansion has been the continued use of GE seeds. The adoption rate of GE events during the 2019/20 crop season is likely to reach record levels for area planted in corn, soybeans, and cotton. Although final data is not available, the total area planted with GE corn, cotton, and soybeans likely reached 56 million hectares, with an adoption rate of 94 percent for soybeans, 95 percent for cotton, 90 percent for first-crop corn, and 80 percent for second-crop corn. The outlook for the 2020/2021 crop season, currently being planted, is for continued growth in terms of production volumes. The government announced R$236 billion (about US$45 billion) in total funds available to support farmers in the 2020/2021 crop season, including R$57 billion for investments, of which the portion for innovation and technology increased by 26 percent.

Since 2018, after the publication of Normative Resolution (RN) 16/2018, on October 4, 2018, the National Technical Biosafety Commission (CTNBio) received several letters regarding the use of Innovative Techniques for Improvement of Precision Breeding (TIMP, in Portuguese). In early 2020, CTNBio published RN 24, which changed some aspects of the regulation for approval of stacked events.

Bilateral agricultural trade between Brazil and the United States reached US$6.2 billion in 2019, a decrease of 1.6 percent from the previous year. Brazil exported to the United States about US$5 billion in agricultural commodities and food products, up 3.6 percent, and imported about US$1.2 billion, down 16.1 percent. U.S. agricultural exports to Brazil are primarily commodities required to meet local shortfalls, such as wheat and cotton, while consumer-oriented products account for nearly 20 percent of exports. In 2019, ethanol exports to Brazil reached US$543 million, a decrease of 25 percent from the previous year. The United States and Brazil are competitors in third-country markets, such as China, which is the largest destination of Brazilian exports, mostly GE soybeans. The United States is also a major destination for Brazilian exports, mostly tropical products such as sugar, coffee, tobacco, orange juice, and wood products.

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PART A: Production and Trade

a) Product Development

Brazilian and multinational seed companies and public sector research institutions are working on the development of various genetically engineered (GE) plants. Currently, there are a number of GE crops in the pipeline awaiting commercial approval, of which the most important are potatoes, papaya, rice and citrus. Most of these crops are in the early stages of development and approval.

b) Commercial Production

As of October 10, 2020, there are 104 GE events approved for commercial cultivation in Brazil, of which 58 events are for corn, 22 for cotton, 19 for soybeans, one for dry edible beans, one for eucalyptus, and three for sugarcane.

The total area planted to GE crops during the last crop season (2019/20) reached 53.1 million hectares. GE events with herbicide tolerance traits lead in adoption rate with 65 percent of the total area planted, followed by insect resistance with 19 percent, and stacked genes with 16 percent. The widespread adoption of GE events in Brazil has contributed to record soybean and corn crops in recent years, with another bumper crop forecast for the 2020/2021 crop season.

- **Soybeans:** The adoption rate of GE soybean seeds in 2019/20 was 96.3% percent.
- **Corn:** The adoption rate of GE corn seeds in 2019/20 was 91.8 percent (first crop) and 86.7 percent (second crop).
- **Cotton:** The adoption rate of GE cotton in 2019/20 was 89.9 percent.
- **Dry Edible Beans**: Approved in 2011 and planted in 2020, the adoption rate is not available.
- **Eucalyptus**: Although recently approved, GE eucalyptus is not yet commercially cultivated**.**
- **Sugarcane**: GE sugarcane planted area during 2019/20 is estimated at only 5,000 hectares, compared to over 10 million hectares of sugarcane planted in Brazil.

c) Exports

Brazil is one of the leading exporters of biotech soybeans, corn, and cotton. China is the main importer of Brazilian biotech soybeans and cotton, followed by the European Union. Corn exports are mainly

bound for Iran, as well as Vietnam and other Asian countries. Brazil is also an exporter of conventional soybeans, although these exports are expected to fall due to the declining area. According to trade sources, planting conventional soybeans is more expensive, and the 10-15 percent price premium barely covers the extra cost of production.

d) Imports

On November 3, Brazil's Agriculture Ministry (MAPA) issued normative instruction No. 60, 2020 meant to facilitate imports of genetically modified (GMO) corn and soybean from the United States. This Normative Instruction revokes the provision of MAPA Normative Instruction No. 29, 2010 (Article 6, paragraph 4), which outlines the information that must appear on an import license (IL) for products intended to be used in animal feed or for veterinary use. As it stands, the updated normative instruction changes information importers must provide on the import license. Please note that the normative instruction does not establish approval for GMO corn and soybean varieties that have not been approved by CTNBio. The Post view is confirmed by interlocutors from the private industry, as well as by regulators. As such, asynchrony in biotech approvals may still present a hurdle to U.S. corn and soybean exports to Brazil. (For more information see GAIN report: Ministry of Agriculture Changes Import License Requirement to Facilitate Corn and Soybean Imports)

Post would like to note that interlocutors have suggested that in extraordinary circumstances - such as the novel coronavirus pandemic and the new import duty regime - requests for event approval may be expedited. In the event of an urgent event submission, Post believes that the technical criteria for the approval will remain the same. It is also imperative to note that the applicant must already be registered with CTNBio. If no previous registration exists, the company registration may be requested in parallel with the approval of the event/ technology.

The National Technical Biosafety Commission (CTNBio) allows imports of GE events into the country on a case-by-case basis. The agricultural ministers of Argentina, Bolivia, Brazil, Chile, Paraguay, and Uruguay participated in the Southern Agricultural Council (CAS) meeting in late May 2019 and delivered a joint statement calling for the region to work together to reduce the asynchrony in the approvals of biotech events. However, no further action has been reported on this issue.

e) Food Aid

Brazil is not a food aid recipient from the United States. Brazil is a source of food aid for some countries in Africa and Central America. Brazil donates mostly rice and dry beans, which are currently not commercialized biotech products.

PART B: Policy

a) Regulatory Framework

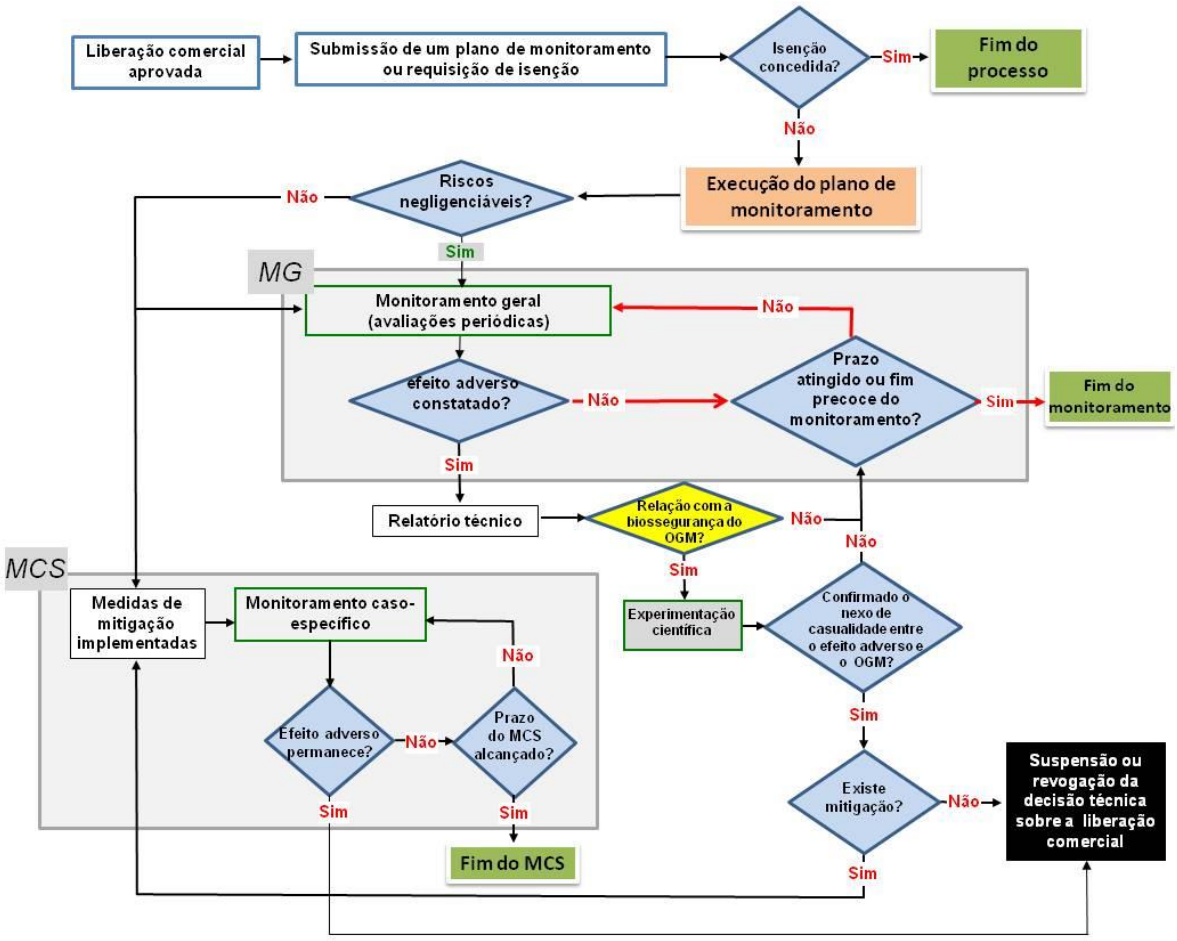
Law #11,105 of March 25, 2005, outlines the regulatory framework for agricultural biotechnology in Brazil, but Law #11,460 of 2007, and Decree #5,591 of 2006, modified this law. There are two main governing bodies regulating agricultural biotechnology in Brazil:

1. The National Biosafety Council (CNBS, in Portuguese). This council falls under the Office of the President and is responsible for the formulation and implementation of the national biosafety policy (PNB, in Portuguese) in Brazil. It establishes the principles and directives of administrative actions for the federal agencies involved in biotechnology. It evaluates socio-economic implications and national interests regarding the approval for commercial use of biotech products. No safety considerations are evaluated by CNBS. Under the Chief of Staff of the Office of the President, CNBS is comprised of 11 cabinet ministers and needs a minimum quorum of six ministers to approve any relevant issue.

2. The National Technical Biosafety Commission (CTNBio, in Portuguese) was initially established in 1995 under the first Brazilian biosafety law (Law #8,974). However, under the current law, CTNBio was expanded from 18 to 27 members to include official representatives from 9 ministries of the federal government; 12 specialists with scientific and technical knowledge from 4 different areas including animal, plant, environment, and health (3 specialists from each area); and 6 specialists from other areas such as consumer defense and family farming. Members of CTNBio are elected for a term of two years with a possibility of being re-elected for an additional two years. CTNBio is under the Ministry of Science and Technology. All technical issues are debated and approved by CTNBio. Imports of any agricultural commodity for animal feed or for further processing, or any ready-to-consume food products, and pet food containing biotech events must be pre-approved by CTNBio. Approvals are on a case-by-case basis and the timeline is indefinite. Law #11,460 of March 21, 2007, modified Article 11 of Law #11,105 of March 24, 2005, and established that a simple majority of the 27 CTNBio board members is needed to approve new biotechnology products.

On June 18, 2008, CNBS decided that it would only review administrative appeals that are of national interest, involving social or economic issues, as per the Brazilian biotechnology laws. CNBS will not evaluate technical decisions on biotech events that are approved by the CTNBio. CNBS considers all approvals of biotech events by CTNBio as conclusive. This important decision, along with the change in majority voting, eliminated a major barrier for the approval of biotech events in Brazil.

Brazil´s Review Process for GE Products



b) Commercial Approvals

Cotton

Crop - Year	Trait Category	Applicant	Event	Trait Description	Uses within Brazil
Cotton 2019	GHB811xT-304-40xGHB119xCOT102xCOT102	BASF		Herbicide Tolerant, Insect Resistant	Textile Fibers Food and Feed
Cotton 2019	Herbicide Tolerant/Insect Resistant	Dow	DAS-21023-5 X	Herbicide Tolerant Insect resistant	Textile Fibers Food and Feed

			DAS – 24236-5X SYNIR102-7 X DAS-81910-7		
Cotton 2018	COT102xMON15985xMON 88913xMON88701	Monsanto		Herbicide Tolerant, Insect Resistant	Textile Fibers Food and Feed
Cotton 2018		Monsanto	MON88913xMON88701	Herbicide Tolerant, Insect Resistant	Textile Fibers Food and Feed
Cotton 2018		BASF	T304-40xGHB 119xCOT102	Herbicide Tolerant, Insect Resistant	Textile Fibers Food and Feed
Cotton 2018	Herbicide Tolerant	Dow	DAS 81910-7	Herbicide Tolerant	Textile Fibers Food and Feed
Cotton 2018	Insect Resistant	Dow	DAS-21023-5xDAS 24236-5XSYN-IR 102-7		Textile Fibers Food and Feed
Cotton 2017	Herbicide Tolerant Insect Resistant	Bayer	BCS-GH002-5xBCS-GH004-BCSGH005-8xSYN-IR102-7		Textile Fibers Food and Feed
Cotton 2017	Herbicide Tolerant	Monsanto	MON88701-3		Textile Fibers Food and Feed
Cotton 2016	Herbicide Tolerant Insect Resistant	Monsanto	COT102xMON15985 X88913		Textile Fibers Food and Feed
Cotton 2012	Herbicide Tolerant	Bayer	GHB614 T304-40xGHB1A	Gossypium hirsutum L.	Textile Fibers Food and Feed
Cotton 2012	Herbicide Tolerant Insect Resistant	Monsanto	MON 15985 X 89913		Textile Fibers Food and Feed
Cotton 2012	Herbicide Tolerant	Bayer	GHB614 LL Cotton 25	Gossypium hirsutum L.	Textile Fibers Food and Feed

Cotton 2011	Glyphosate Herbicide	Monsanto	MON 88913	Gossypium hirsutum L.	Textile Fibers Food and Feed
TwinLink 2011	Glyphosate Herbicide	Bayer	T 304-40 x GHB 119	Gossypium hirsutum L.	Textile Fibers Food and Feed
GlyTol cotton 2010	Herbicide Tolerant	Bayer	GHB 614	Gossypium hirsutumm L.	Textile Fibers Food and Feed
Round Ready Cotton 2009	Herbicide Tolerant Insect Resistant	Monsanto	MON 531 x MON 1445	Gossypium hirsutum L. Glyphosate Herbicide	Textile Fibers Food and Feed
Bollgard II Cotton 2009	Insect Resistant	Monsanto	MON 15985	Gossypium hirsutum L.	Textile Fibers Food and Feed
Wide Strike Cotton 2009	Insect Resistant Herbicide Tolerant	Dow AgroScience	281-24-236/3006-210-23	Gossypium hirsutum L. Herbicide glufosinate ammonium	Food and Feed
Liberty Link Cotton 2008	Herbicide Tolerant	Bayer	LL Cotton 25	Gossypium hirsutum L. Glyphosate Herbicide Ammonium	Textile Fibers Food and Feed
Round Ready Cotton 2008	Herbicide Tolerant Insect Resistant	Monsanto	MON 1445	Gossypium hirsutum L. Glyphosate Herbicide	Textile Fibers Food and Feed
Bollgard Cotton, 2005	Insect Resistant	Monsanto	BCE 531	Lepidoptera Order	Textile Fibers Food and Feed

Corn

Crop - Year	Trait Category	Applicant	Event	Trait Description	Uses within Brazil
Corn 2020	Herbicide Tolerant/Insect Resistant	Dow	MON-89034-3xDAS-01507 – SYN-IR162-4 x MON-00630-6x DAS 40278-9		Food and Feed
Corn 2020	Herbicide Tolerant	DuPont	NK603xT25xDAS-40278		Food and Feed
Corn 2019	Herbicide Tolerant/Insect Resistant	Monsanto	MON 00603-6X ACS-ZM 0033-2x DAS40278-9		Food and Feed
Corn 2019		Monsanto	MON 87427xMON 87419x NK603	Herbicide Tolerant	Food Feed Imports
Corn 2019		Dow	MON 87427-7xMON 89034-3xDAS 01507-1x MON 87411-9xDAS 59122-7xDAS 40278-9	Herbicide Tolerant and Insect Resistant	Food Feed Imports
Corn 2018	Insect resistant Herbicide Tolerant	Monsanto	87427xMON89034x MIR162xMON87411		Food, Feed, Imports
Corn 2018		Syngenta	3272		Food, Feed, Imports

Corn 2018	Insect Resistant Herbicide Tolerant	Syngenta	MZIR 098		Food, Feed Imports
Corn 2018	Insect Resistant Herbicide Tolerant	Monsanto	MON 89034xTC1507x MIR162xNK603x DAS40278-9		Food, Feed, Imports
Corn 2017	Herbicide Tolerant Insect Resistant	Syngenta	SYN-BT011-1 xSYN-IR162-4 xMON89034 xMON00021-9		Food, Feed, Imports
Corn 2017	Herbicide Tolerant Insect Resistant	Syngenta	SYN-BT011-1 xSYN-IR162-4 xMON89034		Food, Feed, Imports
Corn 2017	Insect Resistant	Syngenta	SYN-IR162-4xMON89034		Food, Feed, Imports
Corn 2017	Herbicide Tolerant Insect Resistant	Monsanto	MON89034-3xDAS01507-1 xMON00603-6 xSYN-IR162-4		Food, Feed, Imports
Corn 2017	Herbicide Tolerant Insect Resistant	Dow	MON89034 xTC1507xNK603 xMIR162		Food, Feed, Imports
Corn 2017	Insect Resistant	Syngenta	MIR162 xMON89034		Food, Feed, Imports
Corn 2017	Herbicide Tolerant Insect Resistant	Syngenta	Bt11xMIR162 xMON89034		Food, Feed, Imports

Corn 2017	Herbicide Tolerant Insect Resistant	Syngenta	Bt11xMIR162 xMON89034 xGA21		Food, Feed, Imports
Corn 2016	Approved only for human and animal food	Monsanto	MON87460		Food, Feed, Imports
Corn 2016	Approved only for human and feed	Syngenta	3272		Food, Feed, Imports
Corn 2016	Herbicide Tolerant	Monsanto	MON87427		Food, Feed, Imports
Corn 2016	Herbicide Tolerant Insect Resistant	Monsanto	MON97411		Food, Feed, Imports
Corn 2016	Herbicide Tolerant Insect Resistant	Dow AgroSciences	MON89034-3x MON88017-3x DAS01507x DAS59122-7		Food, Feed, Imports
Corn 2016	Herbicide Tolerant Insect Resistant	Dow AgroSciences	MON89034x TC1507xNK603 xDAS40278-9		Food, Feed, Imports
Corn 2015	Fertility Restauration	Du Pont	SPT 32138		Food, Feed, Imports
Corn 2015	Herbicide Tolerant Insect Resistant	Syngenta	BT11xMir162		Food, Feed, Imports
Corn 2015	Insect Resistant	Syngenta	5307		Food, Feed, Imports

Corn 2015	Herbicide Tolerant Insect Resistant	Syngenta	BT11xMIR162x MIR604xTC1507 x5307xGA21		Food, Feed, Imports
Corn 2015	Herbicide Tolerant	Dow AgroSciences	DAS40278x9x NK603		Food, Feed, Imports
Corn 2015	Herbicide Tolerant Insect Resistant	Du Pont	TC1507xMON810 xMIR162		Food, Feed, Imports
Corn 2015	Insect Resistant	Du Pont	MON 810x MIR 162		Food, Feed, Imports
Corn 2015	Herbicide Tolerant Insect Resistant	Du Pont	MIR 162xNK603		Food, Feed, Imports
Corn 2015	Herbicide Tolerant Insect Resistant	Du Pont	TC 1507xMIR 162		Food, Feed, Imports
Corn 2015	Herbicide Tolerant Insect Resistant	DuPont	TC1507, MON 00810-6, MIR 162, MON 810	Herbicide Tolerant	Food, Feed, Imports
Corn 2015	Herbicide Tolerant	DuPont	TC1507 X MON 810, MIR 162 X MON 603	Glufosinate Herbicide Ammonium	Food, Feed, Imports
Corn 2015	Herbicide Tolerant	Monsanto	NK603 x T25	Glyphosate and Glufosinate Herbicides	Food, Feed, Imports
Corn 2015	Herbicide Tolerant	Dow Agro Science	DAS 40278-9	Herbicide Tolerant	Food, Feed, Imports
Corn 2014	Insect Resistant	Syngenta Seeds	MIR 604		Food, Feed, Imports
Corn 2014	Glyphosate Tolerant Insect Resistant	Syngenta Seeds	MIR 604 Bt11xMIR162 xMIR604xGA21	Glyphosate Tolerant Glufosinate Ammonium	Food, Feed, Imports
Corn 2013	Herbicide Tolerant Insect Resistant	Dow AgroSciences and DuPont	TC 1507 DAS 59122-7	Glyphosate	Food, Feed, Imports

				Herbicide Ammonium	
Corn 2011	Herbicide Tolerant Insect Resistant	Monsanto	MON 89034 X MON 88017	Glyphosate Herbicide	Food, Feed, Imports
Corn 2011	Herbicide Tolerant Insect Resistant	DuPont (Pioneer)	TC1507 X MON 810	Glyphosate Herbicide Ammonium	Food, Feed, Imports
Corn 2011	Herbicide Tolerant	DuPont (Pioneer)	TC 1507 x MON 810 x NK 603	Glyphosate Herbicide Lepidoptera R.	Food, Feed, Imports
Corn 2010	Herbicide Tolerant Insect Resistant	Monsanto	MON 89034 x TC 1507 x NK 603	Glyphosate Herbicide Ammonium	Food, Feed , Imports
Corn 2010	Herbicide Tolerant Insect Resistant	Monsanto	MON 88017	Glyphosate Herbicide Ammonium	Food, Feed, Imports
Corn 2010	Herbicide Tolerant Insect Resistant	Monsanto	MON 89034 x NK 603	Glyphosate Herbicide Ammonium	Food, Feed, Imports
Corn 2010	Herbicide Tolerant Insect Resistant	Syngenta	BT 11 x MIR 162 x GA 21	Glyphosate Herbicide Ammonium	Food, Feed, Imports
Corn 2009	Herbicide Tolerant Insect Resistant	DuPont Brasil	TC 1507 x NK 603	Glyphosate T olerant Insect Resistant	Food, Feed, Imports
Corn 2009	Insect Resistant	Monsanto	MON 89034	Lepidoptera Resistant	Food, Feed, Imports
Corn 2009	Insect Resistant	Syngenta	MIR 162	Lepidoptera Resistant	Food, feed, Imports
Corn 2009	Herbicide Tolerant Insect Resistant	Monsanto	MON 810 x NK 603	Glyphosate Tolerant Lepidoptera R.	Food, Feed, Imports
Corn	Herbicide Tolerant Insect Resistant	Syngenta	BT 11 x GA 21	Glyphosate Tolerant	Food, Feed, Imports

2009				Lepidoptera R.	
Corn 2008	Herbicide Tolerant Insect Resistant	Dow AgroScience	Tc 1507 Herculex	Glyphosate ammonium Herbicide Tolerant	Food and Feed
Corn 2008	Herbicide Tolerant	Syngenta	GA 21	Glyphosate Tolerant	Food and Feed
Corn 2008	Herbicide Tolerant	Monsanto	Roundup Ready 2 NK 603	Glyphosate Tolerant	Food and Feed
Corn 2008	Insect Resistant	Syngenta	Bt 11	Lepidoptera resistant	Food and Feed
Corn 2007	Insect Resistant	Monsanto	MON 810 Guardian	Lepidoptera resistant	Food and Feed
Corn 2007	Herbicide Tolerant	Bayer CropScience	Liberty Link T 25	Ammonium Glyphosate tolerant	Food and Feed
Imported Corn 2005	Herbicide Tolerant Insect Resistant	Bayer	Cry 9 (C) NK 603	Glyphosinate Ammonium Lepidoptera Resistant	Feed

Soybeans

Crop - Year	**Trait Category**	**Applicant**	**Event**	**Trait Description**	**Uses within Brazil**
Soybeans 2019		TMG	HB4 and HB4xRR	Herbicide and Drought Tolerant	Food and Feed
2019		TMG	HB4	Drought Tolerant	Food and Feed
Soybeans 2018		Monsanto	MON87751xMON 97708xMON87701 xMON89788		Food and Feed
Soybeans		Du Pont	DP-305423-1x		Food and Feed

2018			MON 04032-6		
Soybeans 2017	Herbicide Tolerant Insect Resistant	Dow	DAS 44406-6 x DAS 81419-2	Herbicide Tolerant Insect Resistant	Food and Feed
Soybeans 2017	Insect Resistant	Monsanto	DAS 87751-7	Insect Resistant	Food and Feed
Soybeans 2017	Herbicide Tolerant	Monsanto	MON 87708-7xMON 89788	Herbicide Tolerant	Food and Feed
Soybeans 2016	Herbicide Tolerant	Monsanto	MON 87708-9	Herbicide Tolerant	Food and Feed
Soybeans 2016	Herbicide Tolerant Insect Resistant	Dow Agro Science	DAS 81419-2	Herbicide Tolerant Insect Resistant	Food and Feed
Soybeans 2015	Herbicide Tolerant	Bayer	MST-FG072-2 A5547-127	Herbicide Tolerant	Food and Feed
Soybeans 2015	Herbicide Tolerant	Dow Agro Science	DAS 44406-6	Herbicide Tolerant	Food and Feed
Soybeans 2015	Herbicide Tolerant	Bayer	MST-FG072-2	Herbicide Tolerant	Food and Feed
Soybeans 2015	Herbicide Tolerant	Dow Agro Science	DAS 68416-4	Herbicide Tolerant Gluphosinate ammonium	Food and Feed
Soybeans 2010	Herbicide Tolerant Insect Tolerant	Monsanto	MON 87701 x MON 89788 (Intacta RR2 PRO)	Glyphosate Herbicide Tolerant Insect	Food and Feed

				Resistant	
Soybeans 2010	Herbicide Tolerant	Bayer	Liberty Link A 2704-12	Gluphosinate ammonium	Food and Feed
Soybeans 2010	Herbicide Tolerant	Bayer	Liberty Link A5547-127		Food and Feed
Soybeans 2010	Herbicide Tolerant	Bayer	Liberty Link A 5547-127	Gluphosinate ammonium	Food and Feed
Soybeans 2009	Herbicide Tolerant	BASF Embrapa	BPS-CV 127-9	Herbicide Tolerant Imidazolinone class	Food and Feed
Soybeans Roundup Ready 2008	Herbicide Tolerant	Monsanto (Monsoy)	Roundup Ready GTS-40-30-2	Glyphosate Herbicide Tolerant	Food and Feed

Source: CTNBio

c) Stacked Event Approvals

Stacked events follow the same approval process as single events as they are treated as new events. In Brazil, it is estimated that stacked events account for 20 percent of the total area planted to GE crops.

In early 2020, CTNBio published Normative Resolution #24, which changes the approval process for staked events. Articles 3 and 4 of the new rule aim to reduce the approval time of an event to 6-7 months, compared to the previous average of 2-3 years. However, if one of the events in the stack does not have previous approval by CTNBio, the requestor will have to present full agronomic data and a risk analysis, which will take 2-3 years. Translation of the articles related to these changes are:

> *Art. 3. At the discretion of CTNBio, upon consultation, the analysis and issuance of a new technical opinion for GMOs that contain more than one event, combined through classical genetic improvement, and that have previously been approved for commercial release by CTNBio may be dispensed within accordance with Section B of Annex I of this Normative Resolution.*
>
> *Art. 4. The decision favorable to the commercial release of a Genetically Modified Organism - GMO that contains more than one event, combined through classic genetic improvement, whose*

individual events have previously been approved for commercial release by CTNBio, will apply to the possible combinations individual events.

d) Field Testing

CTNBio is responsible for granting prior approval for all field trials in Brazil. The technology provider must obtain from CTNBio a Certificate of Quality in Bio Safety (CQBs) to perform field-testing. All providers must create an Internal Biosafety Commission (CIBio) and indicate for each specific project a principal researcher, defined in CTNBio's regulations as the "Principal Technical Officer." The provider's CIBio is an essential component for monitoring and testing the work of genetic engineering, manipulation, production, and transportation of GE crops, as well as enforcing biosafety regulations.

e) Innovative Biotechnologies

There are no changes in the regulatory framework regarding innovative biotechnologies. However, there are other updates.

On January 15, 2018, CTNBio published Normative Resolution (NR) #16, which established the requirements to evaluate Precision Breeding Innovation (TIMP, in Portuguese) and encompasses the so-called New Breeding Technologies (NBTs). CTNBio regulates NBTs on case-by-case basis and exempts these products from regulation when there is no insertion of transgenes. Thus, in some cases, the full risk assessment and management of "GMOs" must be applied, while in other cases products deriving from NBTs and innovative precision improvements may be exempt. Note: These exempt products are not identified publicity.

Specialists consider this a hybrid system, focusing mainly on the characteristics and safety of the final product. It considers whether an introduced genetic material is absent, as well as the risk level classification of the modified organism. When applicable, it also considers information on how the manipulated genes or genetic elements function and whether the product has already been approved for marketing in other countries.

According to NR #16, CTNBio can exempt new products from the same "GMO" regulatory assessment. However, since Brazil's previous provisions consisted of "GMO" regulation heavily triggered by the genetic modification procedures used, NR #16 contains an annex with a list of NBT procedures that may create a product not considered a "GMO." It includes the caveat that the resolution is not limited to these examples and may ultimately apply to other forthcoming technologies. Please see an informal translation of NR #16 in the appendix of this report.

Brazil had the first agricultural product resulting from CRISPR technology in 2018: an edible corn that contains a higher concentration of amylopectin. The grain has two types of starch: amylose (25

percent) and amylopectin (75 percent). Currently, the Brazilian agricultural research service (EMBRAPA) is developing two projects using CRISPR technology in four crops: soybeans, corn, edible beans, and sugarcane. Post has no further information about this development.

According to CTNBio, during the entire year of 2019, the National Technical Biosafety Commission (CTNBio) received six consultation letters (versus seven in 2018) under the terms of article two of the referred regulation regarding several products (not listed by CTNBio). Four consultation letters were approved for TIMP, one rejected, and the other remains pending.

On July 22, 2020, EMBRAPA and Agri-Food Canada signed a Memorandum of Understanding (MOU) that formalizes technical cooperation between the two institutions. The MOU consolidates a partnership that has been in place since the mid-2000s in the areas of wheat breeding and climate change and opens doors for new research and innovation in advanced fields of science such as gene editing and precision agriculture. The areas of gene-editing and digital and/or precision agriculture were listed by the institutions as priority issues for cooperation, not only regarding grains, but also with other crops and livestock of mutual interest. Two workshops in November of 2020 will define teams and priority lines of research in those areas, and the scientific cooperation projects will start in 2021.

U.S.-based Corteva Agriscience and EMBRAPA recently signed a partnership agreement for research using CRISPR. The implementation of the agreement will allow EMBRAPA to use the technology in all plant species it works with and in microorganisms for agricultural use. The first research project underway calls for the use of the CRISPR technology to develop drought-tolerant and nematode-resistant soybean varieties.

In July 2019, the EMBRAPA Genetic Resources and Biotechnology Center promoted its first hands-on course on genome-editing technology through the CRISPR-Cas9 system and its application in obtaining improved plants. The initiative brought together Brazilian and Latin American specialists and represented a regional integration program that consolidates cooperation between Brazil, Argentina, Colombia, Paraguay, and Uruguay.

f) Coexistence

Law #11,105 of March 2005 established the legal framework under which GE crops can be produced and marketed in Brazil. Conventional, or non-GE, crops are produced throughout the country, with agricultural zoning and environmental limitations mostly applicable in the Amazon biome.

Law #9,456 of April 25, 1997, called the Plant Variety Protection Law, established the legal framework for registration of both GE and non-GE seeds, but the law does not favor one over the other. Decree #2,366 of November 5, 1997, established the National Plant Varieties Protection Service under the Ministry of Agriculture, Livestock, and Food Supply (MAPA) and regulates the registration of GE and non-GE seeds. Normative Instruction #04/07, issued by CTNBio, established rules specifically for GE corn, regarding the coexistence of GE and non-GE crops in Brazil.

g) Labeling

There are no new developments regarding the approval by Brazil's lower house of Congress of Bill # 4148/2008. The bill was sent to the Brazilian Senate for final approval, where it remains under review. There is no estimate when the Senate will finalize its review.

On April 29, 2015, Brazil's House of Representatives approved Bill #4148/2008 by a margin of 320 to 135, to amend the current GE-labeling legislation (Executive Order 4,680/2003). The new bill establishes that only products that have more than 1 percent GE material in their final composition must be labeled. Another important change is the decision to withdraw the requirement for a GE label of a "T" symbol in black in a yellow triangle. The bill is still under consideration in the Brazilian Senate and is likely to continue pending there for another year or two. Executive Order 4,680/2003 remains in force per the information below.

On April 24, 2003, the President of Brazil published in Brazil's Federal Register ("Diario Oficial") Executive Order #4,680/03, establishing a tolerance limit of 1 percent for food and food ingredients destined for human or animal consumption containing or being produced with biotech events. The Executive Order declared that consumers need to be informed of the biotech nature of the product.

On December 26, 2003, the Ministry of Justice published Directive #2,658/03, approving the regulations for the use of the transgenic "T" logo. It applied to biotech products for either human or animal consumption, with content above 1 percent. The requirement became effective on March 27, 2004.

On April 2, 2004, the Civil Cabinet of the Presidency published Normative Instruction #1, signed by four cabinet ministers (Civil Cabinet, Justice, Agriculture, and Health), establishing the conditions by which Directive #2,658/03 enforced the labeling of products containing biotech events above the 1 percent limit. In addition to the federal agencies, Normative Instruction #1 also authorized state and municipal consumer defense officials to enforce the labeling requirements.

h) Monitoring and Testing

Monitoring and testing in Brazil relate to risk assessment. CTNBio's obligations are, among others, to conduct case-by-case risk assessments of activities and projects concerning GE crop events and their by-products, to authorize GE crop research activities, and identify activities and products resulting from the use of GE crops and their by-products that could potentially cause environmental degradation or endanger human health. CTNBio issues final decisions about cases in which the activity is a potential or effective cause for environmental degradation, as well as about the need for environmental permits. CTNBio's decision binds other Brazilian government agencies as to the biosafety aspects of GE crops and their by-products.

The Ministry of Agriculture, Livestock, and Food Supply (MAPA) conducts monitoring of GE crop events. According to the legislation in force, MAPA oversees inspection of these events intended for agriculture, animal use, and related fields in the agricultural industry. The Ministry of Health, through the National Surveillance Agency (ANVISA), also inspects the events for toxicology, while the Ministry of the Environment through the Brazilian Institute of Environment and Renewable Natural Resources (IBAMA) monitors and inspects the events and their impact on the environment.

Updates:

DICAMBA

BASF and Bayer are likely to launch in the market, during the 2020/2021 crop year, new, less volatile formulations of the herbicide dicamba that can be used "over the top" without causing "burn down" as occurs with formulations currently registered in Brazil. The compatible seeds bear the trade names Dicamax (BASF) and XtendiMax (Bayer).

PARAQUAT

As of September 22, 2020, Brazil's National Health Surveillance Agency (ANVISA) in the Ministry of Health prohibited the use of the herbicide Paraquat. The decision caused protests from producer associations, mostly soybean farmers, because the prohibition came right before the planting of the 2020/2021 crop. In a no-till system, such as in Brazil, producers claim that other options in the market are more expensive, which can increase costs by over 100 percent, without the same efficiency. On October 7, the National Health Surveillance Agency (Anvisa) decided to extend the deadline for the use of the remaining stocks of products based on the Paraquat molecule held by farmers for the 2020 harvest / 2021.

i) Low Level Presence Policy

Brazil has a zero-tolerance policy for unapproved GE events.

j) Additional Regulatory Requirements

An event approved by CTNBio requires no further review.

k) Intellectual Property Rights (IPR)

Brazil's current biosafety law, which provides a clear regulatory framework for the research and marketing of new GE crops in the country, has encouraged Brazil's federal government to embrace and protect new technologies that benefit agriculture. Multinational companies such as Bayer, Syngenta, Corteva, and BASF have licensing agreements with EMBRAPA, which is linked to MAPA to develop GE crops, mostly soybeans, corn, and cotton. In general, at the beginning of the new crop year, technology providers negotiate payment agreements for the collection of royalties with individual Brazilian states and farmer associations. Bayer also pursues an export-licensing scheme to collect royalties on shipments of soybeans and soybean products at ports of destination in countries where Bayer has a patent on the Roundup Ready soybean technology.

Update on Bayer court cases in Brazil:

There are no new developments in these legal cases.

In July 2019, Bayer (formerly Monsanto) was required to deposit in escrow the full amount of royalties paid by soybean producers (about US$69 million) for Intacta RR2 PRO seeds (patent PI0016460-7) as the result of a lawsuit filed by the Brazilian Association of Soybean Producers (APROSOJA). The lawsuit seeks to annul Bayer's patent for not meeting the requirements of Brazil's intellectual property laws. A hearing on this case was scheduled for the end of August 2019, but it was postponed.

On October 9, 2019, Bayer won an important decision in Brazil's Superior Court of Justice (STJ). The court found that the company could charge royalties to rural producers who plant its GE soybeans. This lawsuit against Bayer specifically deals with the company's Roundup Ready soybean and was filed collectively by unions of rural producers in the state of Rio Grande do Sul who were seeking protection to use harvested GE seeds for replanting and for selling soybeans as food or raw material without having to pay extra royalties. The plaintiffs argued that the issue should be analyzed from the perspective of Brazil's "Cultivars Law" rather than the country's intellectual property regulations.

According to the STJ ruling, Industrial Property Law # 9,279 of 1996 prohibits the patenting of parts of living beings found in nature. However, there is an exception for "GMOs" that meet requirements such as novelty and industrial application. According to the ruling, farmers are not obliged to buy GE soybean seeds, but they must bear the royalty costs if they choose to plant a specific variety. The STJ's precedent is important because it might have a bearing on the Aprosoja case.

l) Cartagena Protocol Ratification

On August 12, 2020, Brazil´s Official Gazette published Legislative Decree #136/2020, which ratifies Brazil´s participation in the Nagoya Protocol (an accessory to the Convention on Biological Diversity).

The treaty establishes rules for the division between countries of monetary and non-monetary benefits, resulting from genetic research with biodiversity (such as plants and animals) and the use of traditional knowledge from indigenous and local communities.

In November 2003, Brazil ratified the United Nations' Cartagena Protocol on Biosafety (under the UN Convention on Biological Diversity). With few exceptions, the Government of Brazil (GOB) is supportive of the positions advocated by the U.S. Government regarding the liability and redress provisions under the supplementary agreement to the Cartagena Biosafety Protocol. One notable exception is that the GOB considers the provisions regarding treatment of non-parties to be closed. The GOB is also opposed to strict liability but has agreed to use a narrow definition of damage and supports the idea of a limited narrow definition of an operator. The GOB is also opposed to the mandatory use of insurance or other financial instruments for the shipment of living modified organisms (LMOs).

m) International Treaties and Fora

During the last meeting of the U.S.-Brazil High Level Working Group in June 2020, Brazil reiterated that the country promotes science-based standards and definitions in international fora with an aim to remove unscientific sanitary and technical barriers to trade. Brazil also supports the labeling of GE plant products. Brazil's positions in these international fora are like those of the United States. Post does not have access to Brazil's statements or positions discussed at these international fora and is not aware of any Brazilian positions that have affected U.S. agricultural exports to Brazil.

n) Related Issues

Brazil continues to collaborate with the United States to conduct joint outreach in third countries. Global food security and the role of biotechnology therein is a driving force behind enhanced collaboration. Asynchronous approvals remain a relevant issue for biotech companies in Brazil. Although China has moved ahead with the approval of several new traits of interest to Brazilian soybean exporters, the European Union (EU) has not. The Ministry of Agriculture (MAPA) has been more vocal and engaged with the European Union to speed the approval process.

PART C: Marketing

a) Public/Private Opinions

There are no new developments in this area.

A poll conducted in the second quarter of 2016 regarding public perceptions of GE products concluded that 80 percent of Brazilians are concerned with the word "transgenic" and that 33 percent of Brazilians think that consuming these products can do harm. According to Brazilian analysts, the bad image of "transgenic" products is related to the high use of pesticides in Brazil. The poll also showed that most Brazilians do not know which GE plants are grown in Brazil.

The marketing campaign "Brazil Better without Transgenic" was launched in opposition to the use of GE crops in Brazil. The campaign was sponsored by Greenpeace and supported by certain environmental and consumer groups, including government officials within the Ministry of Environment, some political parties, the Catholic Church, and the Landless Movement. The campaign against GE plant and plant products in Brazil is more effective among large European retailers with investments in Brazil, food processors and exporters, mostly to the European Union, than among Brazilian consumers in general.

b) Market Acceptance and Studies

Acceptance of GE crops in Brazil is widespread among producers. According to the Brazilian Confederation of Agriculture (CNA), the latest full survey among Brazilian farmers, which covered the last three years, showed an 80 percent acceptance rate of GE crops.

However, meat processors, the food processing industry, and retailers are less receptive to biotechnology, especially the French-owned hypermarkets located throughout Brazil. These groups are concerned that a marketing campaign against their products could be spearheaded by environmental and consumer groups. However, tests conducted by these groups showed minimal biotech residues in several consumer-ready products.

According to the Brazilian Food Industry Association, 74 percent of Brazilian consumers have never heard of biotech products. In general, Brazilian consumers are disengaged from the biotechnology debate, as they are more concerned about price, quality, and the expiration date of their foods. However, a small number of consumers avoid GE plant products and their derivatives.

The following organizations offer articles regarding Brazil-specific studies on the marketing of GE plants and plant products. Nearly all studies are in Portuguese:

National Association of Biosecurity (Anbio): http://www.anbio.org.br/

Brazilian Food Industry Association (ABIA): http://www.abia.org.br/

Brazilian Agricultural Research Corporation (EMBRAPA): https://www.embrapa.br

CropLife Brasil (CLB): https://croplifebrasil.org/

Note: CropLife Brasil was launched in October 2019 to integrate the National Association for Plant Defense (ANDEF), the Brazilian Association of Biological Control Companies (ABCbio), the Association of Biotechnology Companies in Agriculture and Agroindustry (AgroBio), and the Biotechnology Information Council (CIB). The new entity has the support of CropLife International and is part of the global Culture Science Industry network, with a presence in 91 countries.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: Production and Trade

a) Product Development

While Brazil is the second-largest producer of GE plants in the world, research and application of animal biotechnology, including animal cloning and GE animals is nascent. EMBRAPA has been successful with GE dairy cattle, and research with recombinant proteins is in the pipeline. Two calves born in 2013 are part of this research. Another project focuses on the use of GE technology to improve the health of beef cattle and increase cattle weight. Additionally, two GE goats produced in the state of Ceará have high levels of a human antimicrobial proteins proven effective in treating diarrhea in young pigs. The research demonstrated the potential for food products from GE animals to benefit human health. This project was carried out in cooperation with the University of California at Davis.

Brazil has a well-developed research system for cloned animals under the national coordination of EMBRAPA. Cloning research started in the late 1990s in Brazil, mostly focused on cattle. In March 2001, Brazil was successful in cloning a Simmental heifer, named *"Vitor*ia." The second clone was born in 2003 from cells of a Holstein cow named "Lenda da EMBRAPA." The third clone was born in April 2005 from a native cow named *"Junque*ira" that is on an endangered species list.

b) Commercial Production

Commercial Somatic Cell Nuclear Transfer (SCNT) cloning in Brazil is carried out by a small number of companies, mostly through partnerships with EMBRAPA. These companies have cloned cattle for use as elite show and breeding animals. In May 2009, MAPA changed its regulation to allow the genetic registration of cloned cattle under the Brazilian Zebu Cattle Association (ABCZ), since this breed of animal (Brazilian Zebu, similar to the Brahman in the United States) represents about 90 percent of the cattle herd in Brazil.

On April 10, 2014, CTNBio approved the first commercial release of GE mosquitoes in Brazil. A British company, Oxitec, which was sold to U.S.-based Intrexon, produced the GE Aedes aegypti mosquitoes (OX513A). Despite commercial approval by CTNBio, Brazil's National Health Surveillance Agency (ANVISA), under the Ministry of Health, and equivalent to the Food and Drug Administration in the United States, has not approved the commercial use of OX513A in Brazil, but instead provided a Temporary Special Registry (RET, in Portuguese) for research use.

Brazil has 42 GE vaccines released by CTNBio for commercial use, 28 microorganisms, and one medication for the treatment of skin cancer.

LIVE VACCINES AND DERIVED PRODUCTS FROM GENETICALLY MODIFIED ORGANISMS APPROVED COMMERCIALLY IN BRAZIL FOR HUMAN/ANIMAL CLINICAL USE

Product	**Characteristics**	**Company**	**DOCUMENT/DATE**
Recombitek	Cães/Viroses	Merial	Com 38/98
Vaxxitek MD/IBD	Aves/Marek-Gumboro	Merial	Com 99/04
Suvaxyn PCV2	Suinos/Circovirose	Fort Dodge	1300/2008
Ingelvac	Suinos/Circovirose	Boehringer	1427/2008
P. Circumvent	Suinos/Circovirose	Intervet	1591/2008
Poulvac	Aves/E. coli	Fort Dodge	2146/2009
Vectormune FP-MG	Aves/Roup-Micoplasma	Ceva	2214/2009
Vectormune FP-MG+AE	Aves/Roup-Encefalomielite	Ceva	2226/2009
Vectormune HVT-IBD	Aves/Marek-Gumboro	Ceva	2280/2010
Vectormune HVT-NDV	Aves/Marek-Newcastle	Ceva	2279/2010
PouvacSt	Aves/Salmonelose	Fort Dodge	2741/2010
Vectormune FP-LT	bouba aviária e laringotraqueíte aviária	Ceva	2957/2011
Vectormune FP-LT-AE	bouba aviária, laringotraqueíte aviária e encefalomielite aviária	Ceva	2958/2011
INNOVAX ILT	Aves/Marek e Laringotraqueíte	Intervet	2872/2011
InnovaxND	Aves/Marek e Newcastle	Intervet	3265/2012
ProteqFlu TE	Influenza e tétano equino	Merial	3636/2013
ProteqFlu	Influenza equina	Merial	3637/2013
Vectormune HVT-LT	laringotraqueíte aviária e Doença de Marek, Sorotipo 3	Ceva	4304/2014
PRO-VAC Circomaster	Circovirose Suína	Vencofarma	4090/2014
B058	Circovirose Suína	Ourofino	4202/2014
Bovela	Diarreia bovina	Boehringer	4594/2015
Vacina Dengue 1,2,3,4	Vacina contra Dengue	Inst. Butantan	4673/2015
Dengvaxia	Vacina Contra a Dengue	Sanofi Aventis	4759/2015
Bay98	Imunoestimulante	Bayer	4915/2016
HIPRABOVIS IBR MARKER LIVE	Vacina contra Hespes Bovina	Hipra	5005/2016
OncoVEXGM-CSF	Tratamento melanomas	Lab. Bergamo	5099/2016

Vacina Biotech Vac Salmonella	Vacina contra salmonelose aviária	Vetanco do Brasil Importação e Exportação Ltda	5331/2017
Vacina PUREVAX RAIVA	Vacina contra a raiva para felinos	Merial	5407/2017
PROTEQFLU	Vacina contra a influenza de equinos	Merial	5486/2017
Purevax Felv	Vacina viva contra o vírus da Leucemia Felina	Merial	5935/2018
INNOVAX ND-IBD	Vacina recombinante viva, contra as doenças de Marek, Newcastle e Gumboro	Merial	5836/18
Newxxitek HVT+ND	Vacina viva contra Doença de Marek e Doença de Newcastle – Vírus da Doença de Marek como vetor, Sorotipo 3	Merial	5861/2018
Ingelvac Provenza	Vacina vírus vivo modificado contra Influenza Suína	Boehringer	6062/2018
Vacina Recombinante Aviária Código 1062.R0	contra Doença de Marek e Influenza Aviária	Ceva	5997/2018
Trovac-NDV	Vacina vírus vivo recombinante contra a Doença de Newcastle e Bouba Aviária	Merial Saude Animal LTDA	6055/2018
Vacina Recombinante contra Circovirus porcino tipo 2	Vacina contra Doença de Marek e Influenza Aviária	Ourofino Saúde Animal Ltda	6056/2018
Prevexxion RN	Vacina contra a Doença de Marek em aves	Merial Saúde Animal Ltda	6162/2018
Avipro Megan VAC 1	Vacina viva contra Salmonella em frangos de corte	Elanco Saúde Animal	6220/2018
Fostera Gold PCV MH	Vacina Inativada contra Circovirus Suíno e Mycoplasma hyopneumoniae	Zoetis Industria de Produtos Veterinários	6221/2018
Luxturna (voretigene neparvovec)	Terapia gênica LUXTURNA (voretigene neparvovec) que é indicada para o tratamento de pacientes adultos e pediátricos com perda de visão à distrofia hereditária de retina por mutações bialéticas de gene RPE65	Novartis Biociências S.A.	6849/2020

MHYOSPHERE PCV ID	Liberação comercial de uma vacina inativada. A substância ativa de MHYOSPHERE PCV ID consiste em uma cepa recombinante inativada de Mycoplasma hyopneumoniae	Hipra Saúde	6910/2020
INNOVAX ND – ILT	Liberação Comercial da Vacina Recombinante Viva contra Doença de Marek, Newcastle e Laringotraquíte Infecciosa, derivada de OGM (INNOVAX ND-ILT)	Merck Sharp & Dohme Saúde Animal Ltda	6923/2020

Source: CTNBio

c) Biotechnology Exports

None for commercial use.

d) Biotechnology Imports

None for commercial use.

e) Trade Barriers

Post is not aware of any restrictions on imports from the United States of live animals, reproductive material or livestock products. Brazil is a significant importer of U.S. animal genetics, mostly cattle semen.

PART E: Policy

a) Regulatory Framework

GE animals and GE vaccines are governed by the same legislation as GE plants and are subject to the approval of CTNBio. See Regulatory Framework, under Chapter 1, Part B (Policy) in this report.

However, animal cloning and their products, although approved and permitted by the same legal framework referred above, do not have a specific regulatory framework approved in Brazil either at federal or state levels. A bill (#73, dated March 7, 2007) passed the Senate and on February 20, 2013, was sent to the Chamber of Deputies with a new identification (PL # 5010/73). Since then, it has remained under review by various committees. Bill #5010/73 proposes to regulate the cloning of animals, including wild animals and their offspring. It also proposes to make the Ministry of Agriculture, Livestock, and Food Supply (MAPA) responsible for the registration of all institutions, both private and public, that conduct research on cloned animals, including the authorization for commercial sales and imports of cloned animals for genetic or food purposes.

Since there is no regulation in place for cloned animals and their products, MAPA cannot authorize any imports to Brazil of cloned animals or their derived products, such as meat or dairy. The same applies for the progeny of cloned animals and their products. Under bill #5010/73, the authorization for imports of cloned animals and their products will be provided within 60 days after MAPA receives all documentation from the exporting company, such as origin of the animal, characteristics of the animal, destination of the animal in Brazil, and the purpose of imports (genetic or food).

The proposed legislation also differentiates between two types of authorizations for imports of cloned animals and their products:

a) Pharmaceutical or therapeutic use will require authorization under ANVISA in the Ministry of Health.
b) Cloned animals and their products involving genetically modified organisms will require authorization from CTNBio, under the Ministry of Science and Technology.

Bill #1056/73 does not refer to labeling of products derived from cloned animals. However, political analysts expect strong pressure from anti-biotech groups in Brazil to apply the same principles of Brazil's biotech legislation and use Brazil's Consumer Defense Code to pressure the government for a specific label for cloned animals and their products.

b) Approvals

Please see above table listing vaccines and derived products approved by CTNBio.

c) Innovative Biotechnologies

On October 4, 2018, CTNBio determined that the genome-edited hornless cow produced by the U.S. company Recombinetics to be a conventional animal. Brazil made this determination based on

Normative Resolution #16. Moreover, there is no inventory of animal traits "in the pipeline." The Ministry of Agriculture, Livestock, and Food Supply (MAPA) has not issued any notification or regulation about this decision by CTNBio.

Animal biotechnology has been evolving vigorously in Brazil. The 1980s were marked by pro-nuclear microinjections of embryos to produce transgenic animals, whose efficiency was very low. Nuclear transfer cloning dominated the 1990s, with the birth of Dolly the sheep in Scotland, and in Brazil with the birth of Victoria, an EMBRAPA-produced cow. In the 2000s, other techniques were incorporated into the scientific toolkit. Since 2010, the CRISPR technology has come to dominate the area of animal reproduction biotechnology in Brazil.

The focus of Brazilian research today is the prevention and curing of animal diseases, which are the major problem of producers. For instance, ticks cause damage to Brazilian livestock, costing producers more than R$5 billion a year. But there are other problems, like the horn fly. The CRISPR technology can be a tool in the search for solutions to these production irritants, either through the production of medicines in animal milk or to cure diseases that afflict the herds. EMBRAPA's Genetic Resources and Biotechnology Center is in the process of mastering and establishing the methodology to edit of bovine genomes.

d) Labeling and Traceability

The same regulations and laws as described under Chapter 1, Part B (Policy), Section (g) apply to GE animals, although some specific requirements such as labeling and traceability have not yet been developed for GE animals. As described above, the regulatory framework for animal cloning is under review by the Brazilian Congress and will likely fall under the authority of MAPA. There are no specifics in the draft legislation for animal cloning regarding labeling and traceability for products of animal cloning. Brazilian consumer laws apply to all products of GE plants, GE animals, or animal cloning in terms of basic and general information about the product for the consumer.

e) Additional Regulatory Requirements

Post is not aware of any additional regulatory requirements.

f) Intellectual Property Rights (IPR)

The Brazilian Biosafety Law, which provides a clear regulatory framework for the research and marketing of new biotechnology crops in the country, has encouraged the GOB to embrace and protect

new technologies that benefit agriculture. Since there are no commercial releases of GE animals and products, this area of IPR has not been tested.

g) International Treaties and Fora

Brazil is a member of both the Codex Alimentarius (CODEX) and the World Organization for Animal Health (OIE). Post is not aware of any official statements by Brazilian officials at these international fora related to animal biotechnology. However, several Brazilian scientists participate in international seminars or workshops related to this theme, including those sponsored by USDA.

h) Related Issues

Post is not aware of any related issues.

Part F: Marketing

a) Public/Private Opinions

Only specialized rural TV programs have shown reports on cloned animals but nothing on gene editing to date. Post is not aware of any public studies about producer or consumer acceptance of these new technologies.

b) Market Acceptance/Studies

Post is not aware of any market studies or surveys related to consumer acceptance of these new technologies.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: Production and Trade

a) Commercial Production

Although Brazil is the second-largest producer of GE plants in the world, with 20 years of successful adoption of biotech plant events, research and application of microbial biotechnology is more recent, only dating back to 2010. CTNBio has approved several food ingredients and other products derived from microbial biotechnology, which are listed below.

b) Exports

Brazil exports several products that contain microbial biotech-derived food ingredients such as yeast and alkaline protease. Post does not have a list of specific products, quantities, or values exported. Post is also not aware of specific export documentation for such products.

c) Imports

Brazil imports enzymes and other products that contain microbial biotech-derived food ingredients, but CTNBio must approve any request for imports on a case-by-case basis.

d) Trade Barriers

Post is not aware of any trade barriers for these products.

PART H: POLICY

a) Regulatory Framework

Microbial biotechnology is governed by the same legislation as GE plants, animals, and vaccines, and is subject to analysis and approval by CTNBio. See Regulatory Framework, under Chapter 1, Part B (Policy) of this report.

b) Approvals

MICROORGANISMS GENETICALLY MODIFIED AND DERIVED PRODUCTS APPROVED COMMERCIALLY IN BRAZIL FOR INDUSTRIAL USE

PRODUCT	CHARACTERISTICS	INSTITUTION	DOCUMENT/DATE
Y1979	Liberação comercial de Levedura (Saccharomyces cerevisiae) geneticamente modificada para produção de Farneseno	Amyris do Brasil	2281/2010
Y5056	Liberaçãoo comercial de Levedura (Saccharomyces cerevisiae) geneticamente modificada para produção de Farneseno	Amyris do Brasil	3287/2012
S2014	Liberação comercial de Prototheca moriformis para produção de triglicerídeos e bioprodutos	Solazyme Brasil Óleos Renováveis e Bioprodutos Ltda	3775/2013
RN1016	Liberação comercial de Levedura (Saccharomyces cerevisiae) linhagem geneticamente modificada para produção de etanol	Bio Celere Agroindustrial Ltda	3877/2013
Bioproduto S5223	Libração comercial de derivado do micro-organismo Prototheca moriformis	Solazyme Brasil Óleos Renováveis e Bioprodutos Ltda	4203/2014
Celere-2L	Liberação comercial do micro-organismo geneticamente modificado e seus derivados da classe de risco biológico I	Bio Celere Agroindustrial Ltda	4526/2015
S5223	Liberação comercial de Prototheca moriformis linhagem S5223 para produção de triglicerídeos e bioprodutos	Solazyme Brasil Óleos Renováveis e Bioprodutos Ltda	4675/2015

S6697	Liberação comercial para produção de triglicerídeos e bioprodutos comercialização com micro-organismos Prototheca moriformis.	Solazyme Brasil Óleos Renováveis e Bioprodutos Ltda	4768/2015
Derivado	Liberação comercial para importação de protease alcalina	Du Pont do Brasil	5153/2016
S8695	Liberação comercial do micro organismo Prototheca moriformis	Solazyme Brasil Óleos Renováveis e Bioprodutos Ltda	5238/2016
M10682	Liberação comercial da levedura Saccharomyces cerevisae	Lallemand Brasil Ltda	5285/2016
S8885	Liberação comercial do micro-organismo Prototheca moriformis	Solazyme Brasil Óleos Renováveis e Bioprodutos Ltda	5286/2016
S1260	Liberação comercial de Saccharomyces cerevisae (S1260) para produção comercial de etanol.	Novozymes Latin America Ltda	5333/2017
GICC03299	Liberação comercial de derivado OGM a-amilase	Du Pont do Brasil	5496/2017
A-glucosidase	Liberação comercial de derivado de OGM (alfa-glucosidase)	Du Pont do Brasil	5797/2018
Hemicelulase	Liberação comercial de derivado de OGM-Hemicelulase	Du Pont do Brasil	5798/2018
Y22021	Liberação comercial da levedura Saccharomyces cerevisae geneticamente modificada (cepa Y22021) e seus derivados	Amyris do Brasil	5827/2018
B licheniformis	Liberação comercial de alfa amilase de Cytophaga sp expressa em Bacillus lichenifromis	Du Pont do Brasil	6152/2018
Alfa-amilase (GICC03469)	Liberação comercial de de derivado de OGM: alfa-amilase (GICC03469)	Danisco	6063/2018
Corynebacterium glutamicum cepa DM24.60	Micro-organismo geneticamente modificado da bactéria Corynebacterium glutamicum cepa DM24.60 e seu derivado para uso em fermentação industrial e seu derivado pra alimentação animal como aditivo em ração	Evonik Degussa do Brasil	6476/2019
S. cerevisiae (SCY011)	Micro-organismo Saccaromyces cerevisae para emprego na produção comercial de etanol – Linhagem SCY011	Novozymes Latin America Ltda	6507/2019
S. cerevisae	Liberação comercial da levedura	Amyris	6592/2019

(Y47220)	Saccharomyces Cerevisae para produção de esteviol		
Substilisina	Derivado de microorganismo geneticamente modificado – Substilisina (GICC03528)	Danisco do Brasill Ltda.	6592/2019
Treonima	Liberação comercial de Derivado de Micro-organismo geneticamente modificado – Treonina granulada THR Pro (L-Treonina 75%)	CJ do Brasil Industria e Comercio de Produtos Alimentícios Ltda	6623/2019
S. cerevisiae (GICC03506)	Liberação comercial de levedura para produção de etanol combustível para fermentação etanólica a partir do processamento de carboidratos e grãos	Danisco Brasil Ltda	6729/2019
Triptofano Granulado TRP Pro	Liberação comercial de derivado de micro-organismo geneticamente modificado, Triptofano Granulado TRP Pro (LTriptofano 60%)	CJ do Brasil Industria e Comercio de Produtos Alimentícios Ltda	
Saccharomyces cerevisae (Y63348)	Liberação comercial de Saccharomyces cerevisae geneticamente modificada (Cepa Y63348) e seus derivados	Amyris do Brasil Ltda	
Derivado do microoranismo geneticamento modificado (MGM Corynebacterium Glutamicum	Liberação comercial do produto derivado de OGM VALPro Granulada, composto por L-Valina 70% para uso na alimentação animal	CJ do Brasil Ind. E Com. De Produtos Alimentícios Ltda	6925/2020

Source: CTNBio

c) Labeling and Traceability

Post is not aware of any specific regulation for labeling of microbial biotechnology products. However, Brazilian consumer laws apply to all GE products sold to consumers. In addition, according to Executive Order #4,680/2003, products that contain more than 1 percent GE material in their final composition must be labeled.

d) Monitoring and Testing

CTNBio's obligations are, among others, to conduct case-by-case risk assessments of activities and projects concerning GE microbial biotechnology products and their by-products, to authorize GE microbial research activities, and to identify activities and products resulting from the use of GE microbial technology and their by-products that could potentially cause environmental degradation or endanger human health. CTNBio issues final decisions about cases in which the activity is a potential or effective cause for environmental degradation, as well as about the need for environmental permits. CTNBio's decision binds other Brazilian government agencies as to the biosafety aspects of GE microbial biotechnology and their by-products.

e) Additional Regulatory Requirements

Post is not aware of any additional regulatory requirements aside from the laws and regulations described above, which also apply to other GE products.

f) Intellectual Property Rights (IPR)

The current biosafety laws, which provide a clear regulatory framework for the research and marketing of biotechnology crops and related products, as well as for innovative technologies, have encouraged Brazil's federal government to embrace and protect these technologies that benefit agriculture. Post is not aware of any IPR laws or regulations specific to microbial biotechnology products.

g) Related Issues

Post is not aware of any related issues.

PART I: MARKETING

a) Public/Private Opinions

Post is not aware of any public concern about microbial biotechnology since it is a recent innovation and mainly applied to food. The Brazilian public has little knowledge or awareness about this type of GE product.

b) Market Acceptance/Studies

There are no specific studies regarding market acceptance of microbial biotechnology products and derived products. However, a recent survey conducted in several South American countries sponsored by a large U.S.-based company working in the area of plant-based proteins and food ingredients, showed that 90 percent of Brazilians are willing to try plant-based products. In South America, this percentage was second only to Colombia, where it reached 93 percent. According to the surveyed consumers, the main reasons that they want to try these products are related to the perceived healthfulness (56 percent), nutrition (28 percent), and new flavors (16 percent). In addition, according to the survey, Brazilian consumers consider it important that brands disclose the origin of the ingredients of the plant-based products.

The second-largest meat packer in Brazil and a U.S.-based ingredient company formed a joint venture in May of 2020 and created PlantPlus Foods, which is expected to begin operation later this year for the production of plant-burgers, targeted at Brazil and South America markets. Microbial ingredients for this operation will come from the United States for the production of plant-burger in Brazil.

APPENDIX

Normative Resolution No. 16, of January 15, 2018 (Informal Translation)

Establishes the technical requirements for submitting a request for consultation to CTNBio on Innovative Techniques for Improvement of Precision Breeding

THE NATIONAL TECHNICAL BIOSAFETY COMMISSION - CTNBio, in the use of its legal and regulatory authority and in compliance with the provisions contained in items XV and XVI of article 14 of Law 11,105 of March 24, 2005;

CONSIDERING the need to evaluate the Innovative Precision Breeding Technique (**TIMP,** in Portuguese) which also encompasses the so-called New Breeding Technologies -NBTs, considering the precepts provided for in Law No. 11,105 of March 24, 2005;

Considering that Law No. 11,105 of 2005 defines recombinant DNA/RNA molecules, genetic engineering and genetically modified organisms - GMOs in items III, IV and V of its article three, respectively;

Whereas TIMPs encompass a set of new methodologies and approaches differ from the genetic engineering strategy by transgene, as it results in the absence of recombinant DNA/RNA in the final product;

Whereas TIMPs can introduce innovative uses of molecular biology tools, which can result in:

1. In the precise editing of genomes, by induction of specific mutations, generating or modifying wild and/or mutated alleles without transgene insertion(s);

2. In genetic transformation and/or control of gene expression (activation/inactivation);

3. In epigenetic regulation of the expression of genes by natural mechanisms without genetic modification in the individual;

4. In genetic transformation and/or control of gene expression with genes of sexually compatible species;

5. In temporary and non-inheritable genetic transformation of cells and tissues;

6. On permanent or non-host infection of genetically modified viral elements;

7. In the creation of alleles with autonomous inheritance and potential of recombination with the possibility of altering a whole population (gene drive); and

8. In the construction of heterologous genes or new copies of homologous genes.

Resolve:

Article 1. Examples of Innovative Techniques for Improvement of Precision (TIMP), but not limited to these, are the technologies described in Annex I that are part of this Normative Resolution, which may originate a product not considered as a Genetically Modified Organism (GMO) and derivatives, as defined in Law No. 11,105 of March 24, 2005.

Paragraph one. The product referred to in the heading of this article is defined as the offspring, lineage or product of a process that uses Innovative Precision Improvement Techniques in one of its development stages.

Paragraph two. The cases to be classified are not limited to the technologies described in Annex I, since the rapid and continuous advancement of different technologies may provide new products, to which the provisions of this Normative Resolution will also apply.

Paragraph three. The products referred to in the main paragraph of this article imply at least one of the following characteristics:

I - product with proven absence of recombinant DNA/RNA, obtained by a technique employing GMOs as a parent;

II - product obtained by technique using DNA/RNA that will not multiply in a living cell;

III - product obtained by a technique that introduces targeted site mutations, generating gain or loss of gene function, with the proven absence of recombinant DNA/RNA in the product;

IV - a product obtained by a technique where there is a temporary or permanent expression of recombinant DNA/RNA molecules, without the presence or introgression of these molecules in the product; and

V - A product where techniques employing DNA/RNA molecules are used which, whether absorbed or not systemically, do not cause permanent modification of the genome.

Sole paragraph. In the case of a product obtained from a GMO with the favorable opinion of CTNBio for commercial release, the conditions described will apply only to the characteristic introduced by TIMP.

Article 2. In order to determine whether the product obtained by TIMP will be considered as a GMO and its derivatives, pursuant to article three of Law 11,105 of 2005, the applicant must submit a request to CTNBio.

Paragraph one. The consultation shall be instructed with the information contained in Annex II of this Normative Resolution.

Paragraph two. Once the consultation with CTNBio has been filed, its extract will be published in the Official Gazette of the Union and distributed to one of the members, titular or alternate, to report and prepare a final opinion.

Paragraph three. The final opinion of the member shall be based on a case-by-case analysis of the proof of compliance at least one of the conditions described in § three of article One of this Normative Resolution.

Paragraph four. For the products and technologies obtained using the techniques exemplified in Annex I, CTNBio's decision will observe compliance with one or more of the conditions described in § 3 of article one of this Normative Resolution and will be conclusive regarding the application of the definitions of articles three and four of Law 11,105 of 2005.

Article 3. The final opinion referred to in paragraph 2 of art. Two of this Normative Resolution shall be submitted to at least one of the Standing Sectoral Subcommittees, in agreement with the parental

organism and the proposed use of the technique submitted for consultation and, after its approval, shall be referred to the CTNBio plenary for deliberation.

Sole paragraph. The Subcommittees will have a deadline of up to ninety days for analysis and elaboration of opinions and may be extended for the same period by decision of the CTNBio plenary.

Article 4. CTNBio may, because of consultation and with due scientific justifications, request additional information or studies.

Article 5. The situations not foreseen in this Normative Resolution will be evaluated and defined, case by case, by CTNBio.

Article 6. This Normative Resolution comes into force on the date of its publication.

ANNEX I: Examples of Innovative Precision Improvement Techniques (TIMP)

1. TECHNIQUE: Early Flowering.

    1.1 SUMMARY OF THE TECHNIQUE: Silencing and/or overexpression of genes related to flowering by insertion of genetic modification into the genome and subsequent segregation or by temporary expression by viral vector.

2. TECHNIQUE: Technology for Seed Production.

    2.1 TECHNICAL SUMMARY: Insertion of genetic modification for restoration of fertility in naturally male-sterile lines in order to multiply these lines maintaining the male-sterility condition, without, however, transmitting the genetic modification to the offspring.

3. TECHNIQUE: Reverse improvement.

    3.1 SUMMARY OF THE TECHNIQUE: Inhibition of meiotic recombination in selected heterozygous plants for the characteristic of interest in order to produce homozygous parental lines.

4. TECHNIQUE: Methylation of RNA-Dependent DNA.

    4.1 TECHNICAL SUMMARY: Methylation directed by interfering RNAs ("RNAi") in promoter regions homologous to RNAi with the objective of inhibiting the transcription of the target gene in living beings.

5. TECHNIQUE: Mutagenesis Target Site.

5.1 TECHNICAL SUMMARY: Protein or riboprotein complexes capable of causing site-directed mutagenesis in microorganisms, plants, animals and human cells.

6. TECHNIQUE: Oligonucleotide Directed Mutagenesis.

6.1 TECHNICAL SUMMARY: Introduction into the cell of an oligonucleotide synthesized complementary to the target sequence, containing one or a few nucleotide changes, which may cause substitution, insertion or deletion in the target sequence through the cell repair mechanism (microorganisms, plants, animals and human cells).

7. TECHNIQUE: Agro infiltration/Agro infection.

7.1 TECHNICAL SUMMARY: Leaves (or other somatic tissue) infiltrated with Agrobacterium sp. or gene constructs containing the gene of interest to obtain temporary expression at high levels located in the infiltrated area or with viral vector for systemic expression, without the modification being transmitted to subsequent generations.

8. TECHNIQUE: RNAi topical/systemic use.

8.1 TECHNICAL SUMMARY: Use of double stranded RNA ("dsRNA") sequence homologous to the target gene(s) for specific silencing of such gene(s). The engineered dsRNA molecules can be introduced/absorbed by the cell from the environment.

9. TECHNIQUE: Viral Vector.

9.1 SUMMARY OF THE TECHNIQUE: Inoculation of living organisms with recombinant virus (DNA or RNA) expressing the genetic modification and amplification of the gene of interest through the mechanisms of viral replication, without modification of the host genome.

ANNEX II:

1. Regarding the original organism (Parental), inform:

1. The identification of the genetic technology, purpose and intended use of the resulting organism and its derivatives;

2. The taxonomic classification, from family, to the most detailed level of the organism to be released, including, where appropriate, subspecies, cultivar, pathovar, strain and serotype;

3. The risk classification of the genetically modified organism in accordance with Normative Resolution No. 2 of November 27, 2006;

4. The gene(s) and/or genetic element(s) handled, the organism(s) of origin and their specific functions, where applicable;

5. The genetic strategy (ies) used to produce the desired modification(s); the genetic map(s) of the building(s) used in the process indicating, with all genetic elements present;

6. Molecular characterization of the result of manipulation in the recipient organism (parent and product), where applicable, providing information related to: (1) number of manipulated copies (e.g. number of genomic sequences, number of alleles, etc.); (2) location in the genome of the manipulated region, where possible; (3) identify the presence of unintentional genetic modifications (off-target), when applicable.

7. The product of expression of the manipulated genomic region(s), described in detail, where applicable.

2. Regarding the product (offspring, lineage or final product) inform):

1. Proof of the absence of recombinant DNA/RNA molecules, using molecular methods.

2. Whether the product containing DNA/RNA molecules for topical/systemic use has the recombinant ability to enter into target species and/or non-target species.

3. Whether the product covered by the application is commercially approved in other countries.

4. If the product uses the gene drive principle that may allow the phenotypic change conferred to have the potential to spread throughout the recipient organism population, explain the care to monitor the organism using at least two strategies.

5. How the possibility of potential unintentional (off-target) effects of the technology that may be present in the product has been assessed.

Attachments:

No Attachments