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Report Highlights:

Brazil is the second-largest producer of biotech crops in the world with 115 events approved. Post forecasts the total area planted to GE crops reached over 56 million hectares during the recently completed crop year of 2020/2021. Adoption rates for soybeans reached 98 percent, 88 percent for corn, and 80 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.

AGRICULTURAL BIOTECHNOLOGY REPORT

EXECUTIVE SUMMARY

Brazil's grain and oilseed production during the 2020/2021 crop season (October 2020 through September 2021) was 252.3 million metric tons, down 1.8 percent from the previous crop year, according to CONAB, the National Supply Company of Brazil. The planted area reached 68.9 million hectares, an increase of 4.6 percent from the previous year, while productivity decreased by 6.1 percent on the account of inclement weather. According to the 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 genetically engineered (GE) seeds. The adoption rate of GE events during the 2019/20 crop season reached record levels for area planted in corn, soybeans, and cotton. Final data from CropLife Brasil shows an adoption rate of 98 percent for soybeans, 80 percent for cotton, and 88 percent for corn. The most common traits added to these crops are herbicide tolerance and insect resistance, separately or combined. The final data for the 2020/2021 crop season is currently being finalized and the outlook is for continued growth in the use of GE seeds. The government announced R$251.2 billion (about $461 million) in total funds available to support farmers for the current 2021/2022 crop season, an overall increase of 6.3 percent from the last Safra Plan. This includes R$73.44 billion for investments, which represents an increase of 29 percent from the 2020/2021 Safra Plan.

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. In July 2021, CTNBio published the Normative Resolution (RN) 32. This Resolution eliminates the requirement for the committee to evaluate combined events obtained from conventional breeding of single events that were previously approved by CTNBio.

Total agricultural trade between Brazil and the United States reached $6.385 billion in 2020, an increase of 1.26 percent from the previous year. Brazil exported to the United States $5.3 billion in agricultural commodities and related products, up 3.25 percent, and imported about $1.07 billion, down 7.5 percent. U.S. agricultural exports to Brazil in 2020 were primarily commodities required to meet local shortfalls, such as wheat, animal feed preparations, and rice. In 2020, ethanol exports to Brazil reached nearly $340.9 million, a decrease of 37.22 percent from the previous year. The United States and Brazil are competitors in third-country markets, such as China, which is the largest destination for Brazilian exports, mostly GE soybeans, and both countries also compete at the Chinese animal protein market. The United States is also a major destination for Brazilian exports. In 2020, the most exported product to the United States market from Brazil was coffee, followed by ethanol, beef, wood products, sugar, orange juice, and tobacco.

On November 11, 2021, CTNBio approved an Argentina-produced GE wheat variety that is drought tolerant and expresses the HaHB4 sunflower gene. This approval will allow for the world's first occurrence of trade and production of a GE wheat variety.

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CHAPTER1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

According to the International Service for the Acquisition of Agri-Biotech Applications (ISAAA), in 2019 Brazil was the second largest producer of biotech crops in the world, and the top developing country that planted biotech crops. 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.

On November 11, CTNBio approved a GE variety of wheat that is drought tolerant and expresses the HaHB4 sunflower gene. Brazil approved the wheat for food, feed, and processing, but not for cultivation. As the situation currently stands, the wheat is planted in Argentina, and will be imported to Brazil. The wheat was first given conditional approval in Argentina in October 2020, with the requirement that it must also be approved in Brazil before being fully commercialized, as Brazil is the main export market for Argentine wheat. Brazilian wheat and confectionary industry associations have pushed back against this approval and are threatening litigation and possible rejection of Argentine wheat imports.

On November 17 the Brazilian Wheat Industry Association, Abitrigo, sent an official letter to the Ministry of Agriculture asking the Ministry to convene the National Biosafety Council (CNBS) to review the decision of CTNBio - a body that reports to the council. CTNBio is responsible for the technical decision on biological risk, and their decision is definitive. However, the CNBS can revoke the decision based on social and economic factors, rather than biosafety reasons. If CTNBio decides to approve the commercial release of a new GE product, CNBS has 30 days to revoke the decision. If it is not revoked, the new product will then be evaluated by registration and enforcement agencies, such as the Ministries of Health, Agriculture, and Environment. If the approved product conforms to their standards, it may enter the market. If the approval remains in place, it will allow for the world's first occurrence of commercial trade and production of a GE wheat variety.

b) COMMERCIAL PRODUCTION

As of October 13, 2021, ISAA data shoes that there are 115 GE events approved for commercial cultivation in Brazil, of which 65 events are for corn, 23 for cotton, 19 for soybeans, one for dry edible beans, one for eucalyptus, and six for sugarcane.

The total area planted to GE crops during the last crop season (2019/20) reached 53.1 million hectares. For the 2020/2021 crop season, Post forecasts a 56.4 million hectares planted with GE traits, to be confirmed once final numbers are published. In the 2019/20 crop season, 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. Croplife Brasil estimates the following adoption rates for the first three crops:

- Soybeans: The adoption rate of GE soybean seeds in 2019/20 was 98 percent.
- Corn: The adoption rate of GE corn seeds in 2019/20 was 88 percent.
- Cotton: The adoption rate of GE cotton in 2019/20 was 80 percent.
- Dry Edible Beans: Approved in 2011 and first 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 GE soybeans, corn, and cotton. China is the main importer of Brazilian GE soybeans and cotton. Brazil also exports to the European Union. Corn exports are mainly bound for Iran, followed by Japan, as well as 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

The COVID-19 pandemic created significant disruption for the Brazilian economy, and the value of the domestic currency plummeted by 30 percent in the second quarter of 2020. The Brazilian real has struggled to regain ground since. As a result, Brazilian commodity exports saw significant expansion, leaving unmet demand on the domestic market, particularly for corn and soybeans: two crops used by the livestock industry for feed. Under pressure from the livestock and poultry sectors, the government of Brazil adopted numerous measures to facilitate imports of corn and soybeans into the country.

In a late April decision, the Executive Management Committee from the Foreign Trade Chamber (GECEX/CAMEX) zeroed out import tariffs for soybeans and corn for countries outside of Mercosur. The measure is in effect from April 27 to December 31, 2021 and is valid for the HS Codes: 1005.90.10, 1201.90.00, 1507.10.00, and 2304.00.10, without quotas. In June, the National Technical Commission on Biosecurity (CTNBIO) issued the Normative Instruction 32, simplifying the approval process for biotechnology traits in corn and soybean designated for human consumption and for animal feed, effectively guaranteeing that any imported corn from the United States would fit under this approved category.

Additionally, on September 22, 2021, President Jair Bolsonaro issued the Provisional Measure 1071, zeroing all charges of PIS/Cofins (taxes) on the import of corn. The measure is in effective from September 29 to December 31, 2021 and is valid for HS Code: 1005. This will benefit the animal protein

sector producers who sell domestically. Producers who imported corn to feed animals that would be exported were already eligible for the PIS/Cofins exemption. Besides corn imports, some poultry and pork industries are considering substituting grains, moving to winter grains such as wheat and triticale as a way to reduce the costs of animal feed.

Despite the Brazilian government's engagement to promote imports from outside of Mercosur, 99.9 percent of corn imports last season came from Paraguay and Argentina. Post does not anticipate significant volumes of corn from outside Mercosur to enter the Brazilian market this season.

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 commodities of which there are no commercially available GE varieties.

f) TRADE BARRIERS

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

PART B: POLICY

a) REGULATORY FRAMEWORK

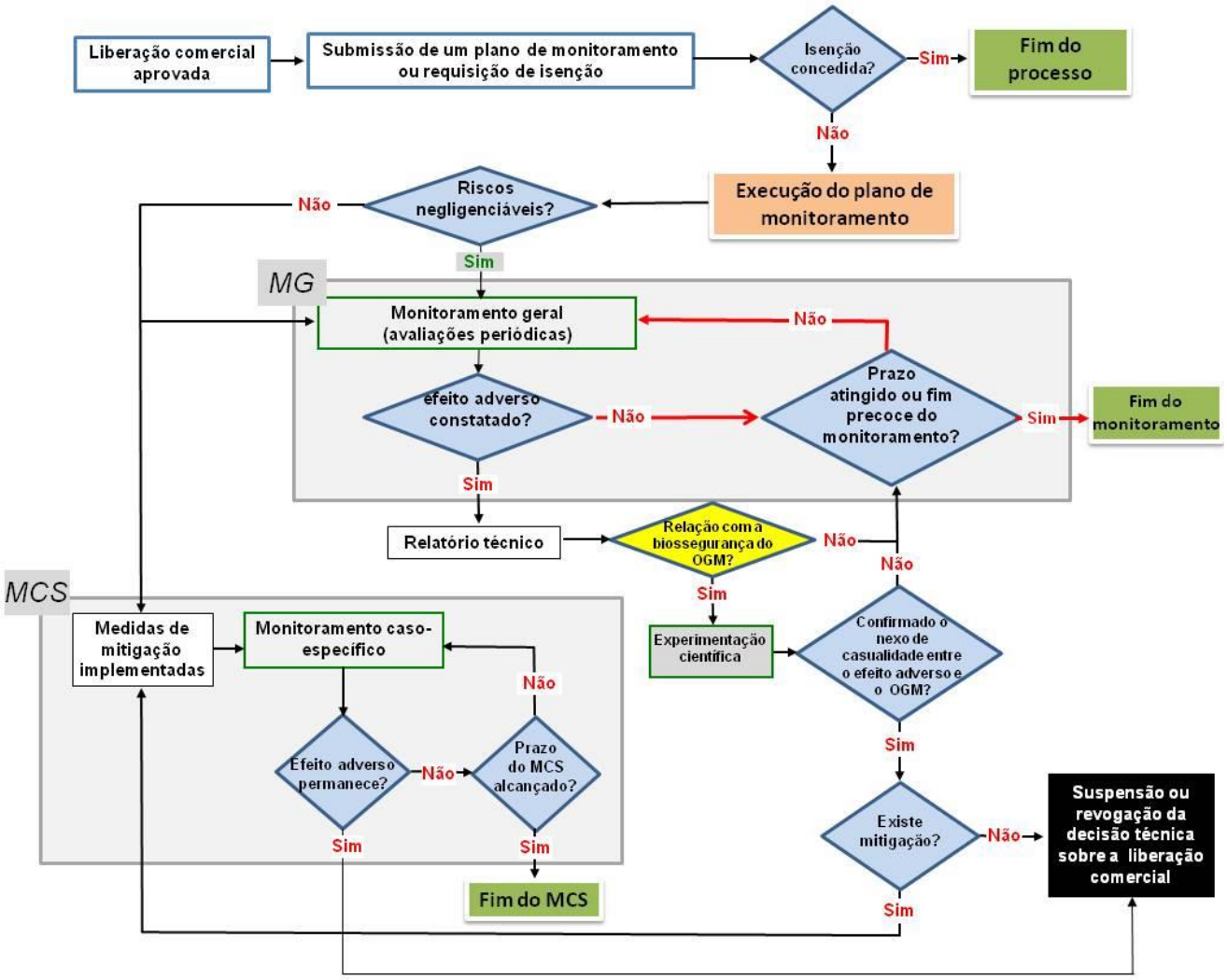
Law 11105 of March 25, 2005, outlines the regulatory framework for agricultural biotechnology in Brazil, but Law 11460 of 2007, and Decree 5591 of 2006, modified this law. There are two main governing bodies regulating agricultural biotechnology in Brazil:

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 #8974). 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: animal health, plant, environment, and human health (3 specialists from each area); and 6 specialists from other areas: consumer defense, human health, environment, biotechnology, family farming, and worker's health. 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 11460 of March 21, 2007, modified Article 11 of Law 11105 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



Source: CTNBIO

b) APPROVALS

Cotton

Crop - Year	Trait Category	Applicant	Event (Commercial Name)	Trait Description	Uses within Brazil

Cotton 2021	Insect Resistant	Syngenta Seeds Ltda	COT102	Insect Resistant	Not available
Cotton 2019	Herbicide Tolerant, Insect Resistant	BASF	GHB811 x T-304-40 x GHB119 x COT102 x COT102	Herbicide Tolerant, Insect Resistant	Textile Fibers Food and Feed
Cotton 2019	Herbicide Tolerant/Insect Resistant	Dow	DAS-21023-5 x DAS – 24236-5 x SYN-IR102-7 x DAS-81910-7	Herbicide Tolerant Insect resistant	Textile Fibers Food and Feed
Cotton 2018	Herbicide Tolerant Insect Resistant	Monsanto	COT102 x MON15985 x MON88913 x MON88701 (BGIIIRRFlexDGT)	Herbicide Tolerant, Insect Resistant	Textile Fibers Food and Feed
Cotton 2018	Herbicide Tolerant Insect Resistant	Monsanto	MON88913 x MON88701 (RRFlexDGT)	Herbicide Tolerant, Insect Resistant	Textile Fibers Food and Feed
Cotton 2018	Herbicide Tolerant Insect Resistant	BASF	T304-40 x GHB119 x COT102	Herbicide Tolerant, Insect Resistant	Textile Fibers Food and Feed
Cotton 2018	Herbicide Tolerant	Dow	DAS 81910 (Enlist)	Herbicide Tolerant	Textile Fibers Food and Feed
Cotton 2018	Insect Resistant	Dow	DAS-21023-5 x DAS24236-5 x SYN-IR102-7 (Widestrike 3)	Insect Resistant	Textile Fibers Food and Feed
Cotton 2017	Herbicide Tolerant Insect Resistant	Bayer	GHB614 x T304-40 x GHB119 x COT 102	Herbicide Tolerant Insect Resistant	Textile Fibers Food and Feed
Cotton 2017	Herbicide Tolerant	Monsanto	MON88701 (DGT)	Herbicide Tolerant	Textile Fibers Food and Feed
Cotton	Herbicide Tolerant Insect Resistant	Monsanto	COT102 x MON15985 x	Herbicide Tolerant Insect	Textile Fibers Food and Feed

2016			MON88913 (BGIIIRRFlex)	Resistant	
Cotton 2012	Herbicide Tolerant Insect Resistant	Bayer	GHB614 x T304-40x GHB119 (GlytoIxTwinLink)	Gossypium hirsutum L.	Textile Fibers Food and Feed
Cotton 2012	Herbicide Tolerant Insect Resistant	Monsanto	MON 15985 x MON 89913 (BGIIFlex)	Herbicide Tolerant Insect Resistant	Textile Fibers Food and Feed
Cotton 2012	Herbicide Tolerant	Bayer	GHB614 x LL Cotton 25 (GTxLL)	Gossypium hirsutum L.	Textile Fibers Food and Feed
Cotton 2011	Herbicide Tolerant	Monsanto	MON 88913	Gossypium hirsutum L.	Textile Fibers Food and Feed
Cotton 2011	Herbicide Tolerant Insect Resistant	Bayer	T 304-40 x GHB 119 (TwinLink)	Gossypium hirsutum L.	Textile Fibers Food and Feed
Cotton 2010	Herbicide Tolerant	Bayer	GHB 614 (GlyTol)	Gossypium hirsutumm L.	Textile Fibers Food and Feed
Cotton 2009	Herbicide Tolerant Insect Resistant	Monsanto	MON 531 x MON 1445 (Round Ready BGRR)	Gossypium hirsutum L. Glyphosate Herbicide	Textile Fibers Food and Feed
Cotton2009	Insect Resistant	Monsanto	MON 15985 (Bollgard II)	Gossypium hirsutum L.	Textile Fibers Food and Feed
Cotton 2009	Insect Resistant Herbicide Tolerant	Dow AgroScience	281-24-236 x 3006-210-23 (Widestrike)	Gossypium hirsutum L. Herbicide glufosinate ammonium	Food and Feed

Cotton 2008	Herbicide Tolerant	Bayer	LL Cotton 25 (Liberty Link)	Gossypium hirsutum L. Glyphosate Herbicide Ammonium	Textile Fibers Food and Feed
Cotton 2008	Herbicide Tolerant	Monsanto	MON 1445 (Roundup Ready)	Gossypium hirsutum L. Glyphosate Herbicide	Textile Fibers Food and Feed
Cotton 2005	Insect Resistant	Monsanto	MON 531 (Bollgard 1)	Lepidoptera Order	Textile Fibers Food and Feed

Source: CTNBio, updated September 26, 2021

Corn

Crop - Year	Trait Category	Applicant	Event (Commercial Name)	Trait Description	Uses within Brazil
Corn 2021	Herbicide Tolerant	Corteva	DAS-59122-7	Herbicide Tolerant	Food and Feed
Corn 2021	Herbicide Tolerant Insect Resistant	Corteva	DP4114-3	Herbicide Tolerant Insect Resistant	Food and Feed Import
Corn 2020	Insect Resistant	Monsanto	MON 95379	Insect Resistant	Not available
Corn 2020	Herbicide Tolerant Insect Resistant	Dow	MON-89034-3 x DAS-01507-1 x SYN-IR162-4 x MON-00630-6 x DAS 40278-9 (and undercombinations)	Herbicide Tolerant Insect Resistant	Food and Feed
Corn 2020	Herbicide Tolerant	DuPont	NK603 x T25 x DAS-40278	Herbicide Tolerant	Food and Feed

Corn 2019	Herbicide Tolerant	Monsanto	MON87427 x MON87419 x NK603 (and undercombinations)	Herbicide Tolerant	Food, Feed, Imports
Corn 2019	Herbicide Tolerant Insect Resistant	Dow	MON87427-7 x MON89034-3 x DAS01507-1 x MON87411-9 x DAS59122-7 x DAS40278-9	Herbicide Tolerant and Insect Resistant	Food, Feed, Imports
Corn 2018	Insect Resistant	Syngenta	MZIR 098	Approved only for human and animal food	Food, Feed Imports
Corn 2018	Insect Resistant Herbicide Tolerant	Dow	MON 89034 x TC1507 x MIR162 x NK603 x DAS40278-9 (PowerCore Ultra Enlist)	Insect Resistant Herbicide Tolerant	Food, Feed, Imports
Corn 2017	Herbicide Tolerant Insect Resistant	Dow	MON89034 x TC1507 x NK603 x MIR162 (PowerCore Ultra)	Herbicide Tolerant Insect Resistant	Food, Feed, Imports
Corn 2017	Insect Resistant	Syngenta	MIR162 x MON89034	Insect Resistant	Food, Feed, Imports
Corn 2017	Herbicide Tolerant Insect Resistant	Syngenta	Bt11 x MIR162 x MON89034	Herbicide Tolerant Insect	Food, Feed, Imports

			(VIP4)	Resistant	
Corn 2017	Herbicide Tolerant Insect Resistant	Syngenta	Bt11 x MIR162 x MON89034 x GA21 (VIP4TG)	Herbicide Tolerant Insect Resistant	Food, Feed, Imports
Corn 2016	Drought Stress	Monsanto	MON87460	Approved only for human and animal food	Food, Feed, Imports
Corn 2016	Amylase Thermostability Increase	Syngenta	3272 (Enogen)	Approved only for human and animal food	Food, Feed, Imports
Corn 2016	Herbicide Tolerant	Monsanto	MON87427	Herbicide Tolerant	Food, Feed, Imports
Corn 2016	Herbicide Tolerant Insect Resistant	Monsanto	MON97411	Herbicide Tolerant Insect Resistant	Food, Feed, Imports
Corn 2016	Herbicide Tolerant Insect Resistant	Dow AgroSciences	MON89034 x MON88017 x TC1507 x DAS59122-7 (SmartStax)	Herbicide Tolerant Insect Resistant	Food, Feed, Imports
Corn 2016	Herbicide Tolerant Insect Resistant	Dow AgroSciences	MON89034 x TC1507 x NK603 x DAS40278-9 (PowerCore Enlist)	Herbicide Tolerant Insect Resistant	Food, Feed, Imports
Corn	Fertility	Du Pont	SPT 32138	Fertility	Food, Feed, Imports

2015	Restauration		(32138 Mantenedor SPT)	Restauration	
Corn 2015	Herbicide Tolerant Insect Resistant	Syngenta	BT11 x MIR162 (VIP2)	Herbicide Tolerant Insect Resistant	Food, Feed, Imports
Corn 2015	Insect Resistant	Syngenta	5307 (Agrisure Duracade)	Insect Resistant	Food, Feed, Imports
Corn 2015	Herbicide Tolerant Insect Resistant	Syngenta	BT11 x MIR162 x MIR604 x TC1507 X 5307 x GA21 (Agrisure Duracade 5222)	Herbicide Tolerant Insect Resistant	Food, Feed, Imports
Corn 2015	Herbicide Tolerant	Dow AgroSciences	DAS40278-9 x NK603 (Enlist RR)	Herbicide Tolerant	Food, Feed, Imports
Corn 2015	Herbicide Tolerant Insect Resistant	Du Pont	TC1507 x MON810 x MIR162 Undercombinations approved and already referred previously	Herbicide Tolerant Insect Resistant	Food, Feed, Imports
Corn 2015	Insect Resistant	Du Pont (RN15)	MON 810 x MIR162	Insect Resistant	Food, Feed, Imports
Corn 2015	Herbicide Tolerant Insect Resistant	Du Pont (RN15)	MIR162 x NK603	Herbicide Tolerant Insect Resistant	Food, Feed, Imports
Corn 2015	Herbicide Tolerant Insect Resistant	Du Pont (RN15)	TC1507 x MIR162	Herbicide Tolerant	Food, Feed, Imports

				Insect Resistant	
Corn 2015	Herbicide Tolerant Insect Resistant	DuPont (RN15)	TC1507 x MON 810 x MIR 162 x NK603	Herbicide Tolerant	Food, Feed, Imports
Corn 2015	Herbicide Tolerant Insect Resistant	DuPont (RN15)	TC1507 x MON810 x MIR162 x NK603 (Leptra)	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 (Enlist)	Herbicide Tolerant	Food, Feed, Imports
Corn 2014	Insect Resistant	Syngenta	MIR 604	Insect Resistant	Food, Feed, Imports
Corn 2014	Herbicide Tolerant Insect Resistant	Syngenta	Bt11 x MIR162 x MIR604 x GA21 (Viptera4)	Glyphosate Tolerant Glufosinate Ammonium	Food, Feed, Imports
Corn 2013	Herbicide Tolerant Insect Resistant	DuPont and Dow AgroSciences	MON89034 x MON88017 x DAS-01507-1 (Herculex XTRA maize)	Glyphosate Herbicide Ammonium	Food, Feed, Imports
Corn 2011	Herbicide Tolerant Insect Resistant	Monsanto	MON 89034 x MON 88017	Glyphosate Herbicide	Food, Feed, Imports
Corn 2011	Herbicide Tolerant Insect Resistant	DuPont	TC1507 x MON 810	Glyphosate Herbicide Ammonium	Food, Feed, Imports
Corn	Herbicide Tolerant	DuPont	MON 810 x TC	Glyphosate	Food, Feed, Imports

2011	Insect Resistant		1507 x NK 603 (Optimum Intrasect)	Herbicide Lepidoptera R.	
Corn 2010	Herbicide Tolerant Insect Resistant	Monsanto and Dow Agrosciences	MON 89034 x TC 1507 x NK 603 (Power Core PW/Dow)	Glyphosate Herbicide Ammonium	Food, Feed, Imports
Corn 2010	Herbicide Tolerant Insect Resistant	Monsanto	MON 88017 (Yield Guard VT)	Glyphosate Herbicide Ammonium	Food, Feed, Imports
Corn 2010	Herbicide Tolerant Insect Resistant	Monsanto	MON 89034 x NK 603 (PRO2)	Glyphosate Herbicide Ammonium	Food, Feed, Imports
Corn 2010	Herbicide Tolerant Insect Resistant	Syngenta	BT 11 x MIR 162 x GA 21 (TL TG Viptera)	Glyphosate Herbicide Ammonium	Food, Feed, Imports
Corn 2009	Insect Resistant	Monsanto	MON 89034 (Pro)	Lepidoptera Resistant	Food, Feed, Imports
Corn 2009	Herbicide Tolerant Insect Resistant	DuPont	TC1507 x NK603 (HR Herculex/RR2)	Glyphosate T olerant Insect Resistant	Food, Feed, Imports
Corn 2009	Insect Resistant	Syngenta	MIR162 (Viptera-MIR162)	Lepidoptera Resistant	Food, feed, Imports
Corn 2009	Herbicide Tolerant Insect Resistant	Syngenta	BT 11 x GA 21 (TL/TG)	Glyphosate Tolerant Lepidoptera R.	Food, Feed, Imports
Corn 2009	Herbicide Tolerant Insect Resistant	Monsanto	NK603 x MON810 (YGRR2)	Glyphosate Tolerant Lepidoptera R.	Food, Feed, Imports
Corn 2008	Herbicide Tolerant Insect Resistant	Dupont and Dow AgroScience	TC1507 (Herculex)	Glyphosate ammonium Herbicide Tolerant	Food and Feed

Corn 2008	Herbicide Tolerant	Syngenta	GA 21 (TG)	Glyphosate Tolerant	Food and Feed
Corn 2008	Herbicide Tolerant	Monsanto	NK 603 (Roundup Ready 2)	Glyphosate Tolerant	Food and Feed
Corn 2008	Insect Resistant Herbicide Tolerant	Syngenta	Bt 11 (TL)	Lepidoptera resistant	Food and Feed
Corn 2007	Herbicide Tolerant	Bayer	T 25 (Liberty Link)	Ammonium Glyphosate tolerant	Food and Feed
Corn 2007	Insect Resistant	Monsanto	MON 810 (Yield Guard)	Lepidoptera resistant	Food and Feed

Source: CTNBio, updated September 26, 2021

Soybeans

Crop - Year	Trait Category	Applicant	Event (Commercial Name)	Trait Description	Uses within Brazil
Soybeans 2021	Herbicide Tolerant	BASF	GMB151	Nematode resistance and selectivity to HPPD-inhibiting herbicides	
Soybeans 2019		TMG	HB4 and HB4 x RR	Herbicide and Drought Tolerant	Food and Feed
Soybeans 2018	Herbicide Tolerant Insect Resistant	Monsanto	MON87751 x MON 97708 x MON87701 x MON89788	Herbicide Tolerant Insect Resistant	Food and Feed
Soybeans	GM-HRA; GM-FAS2-1 (partial	Du Pont	DP-305423-1 x	GM-HRA; GM-FAS2-1	Food and Feed

2018	sequence); cp4 epsps (aroA:CP4)		MON 04032-6 (Plenish x Plenish; Plenish RR1)	(partial sequence); cp4 epsps (aroA:CP4)	
Soybeans 2017	Herbicide Tolerant Insect Resistant	Dow	DAS 44406-6 x DAS 81419-2 (Conkest Enlist E3)	Herbicide Tolerant Insect Resistant	Food and Feed
Soybeans 2017	Herbicide Tolerant	Monsanto	MON 87708 x MON 89788 (Xtend)	Herbicide Tolerant	Food and Feed
Soybeans 2017	Insect Resistant	Monsanto	MON 87751	Insect Resistant	Food and Feed
Soybeans 2016	Herbicide Tolerant	Monsanto	MON 87708	Herbicide Tolerant	Food and Feed
Soybeans 2016	Herbicide Tolerant Insect Resistant	Dow Agro Science	DAS 81419-2 (Conkesta)	Herbicide Tolerant Insect Resistant	Food and Feed
Soybeans 2015	Herbicide Tolerant	Bayer	FG72 x A5547-127	Herbicide Tolerant	Food and Feed
Soybeans 2015	Herbicide Tolerant	Dow Agro Science	DAS 44406-6 (Enlist E3)	Herbicide Tolerant	Food and Feed
Soybeans 2015	Herbicide Tolerant	Bayer	FG72	Herbicide Tolerant	Food and Feed
Soybeans 2015	Herbicide Tolerant	Dow Agro Science	DAS 68416-4 (Enlist)	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 Resistant	Food and Feed
Soybeans 2010	Herbicide Tolerant	Bayer	A2704-12 (Liberty Link)	Gluphosinate ammonium	Food and Feed
Soybeans 2010	Herbicide Tolerant	Bayer	A5547-127 (Liberty Link)	Herbicide Tolerant	Food and Feed
Soybeans 2009	Herbicide Tolerant	BASF Embrapa	BPS-CV 127-9 (Cultivance)	Herbicide Tolerant Imidazolinone class	Food and Feed
Soybeans 1998	Herbicide Tolerant	Monsanto	GTS-40-3-2 (Roundup Ready)	Glyphosate Herbicide Tolerant	Food and Feed

Source: CTNBio, updated September 26, 2021

c) STACKED or PYRAMIDED 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 stacked 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.

In July 2021, CTNBio published the Normative Resolution 32. This Resolution establishes that for food and feed, CTNBio no longer will need to evaluate combined events obtained from conventional breeding of single events that were previously approved by CTNB. Translation of the article related to this change is below:

Art. 13. For the exclusive purposes of human and animal consumption, the technical opinions for the commercial release of risk class 1 transformation events and their derivatives contemplate the food safety assessment of isolated and combined events.

Single paragraph. The isolated and combined events referred to in the caput may be used commercially for food and feed alone, in mechanical mixtures and in products combined with other transformation 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 genome edited products. CTNBio regulates genome edited products 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 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 "GMO" regulatory assessment. However, since Brazil's previous provisions consisted of "GMO" regulation heavily triggered by the genetic engineering procedures used, NR 16 contains an annex with a list of genetic engineering 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 approved its 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). The Brazilian agricultural research service (EMBRAPA) is developing 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 2020, the National Technical Biosafety Commission (CTNBio) received ten consultation letters (versus six in 2019) under the terms of article two of the referred regulation regarding several products (not listed by CTNBio). Nine consultation letters were approved for TIMP and the other one 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 genome editing and precision agriculture. The areas of genome 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.

U.S.-based Corteva Agriscience and EMBRAPA signed in 2020 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.

EMBRAPA Genetic Resources and Biotechnology Center is intensifying partnerships with the private sector. In the first semester of 2021, it signed 13 new contracts, and 10 more are being negotiated. EMBRAPA and Agrocinco, for instance, are working together on a folic-acid enriched lettuce and on a tomato resistant to the spotted wilt virus. EMBRAPA has also opened a public call in September 2021 for partnerships in the production of Castor Oil Plant (*Ricinus communis*) without the ricin toxin to be used in animal feed.

f) COEXISTENCE

There are no new developments in this area.

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 and TRACEABILITY

There are no new developments regarding the approval by Brazil's lower house of Congress of Draft 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 Draft Bill 4148/2008 by a margin of 320 to 135, to amend the current GE-labeling legislation (Executive Order 4680/2003). The new bill establishes that only products that have more than one 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 the last movements on it were in 2015, therefore, Post believes it is likely to continue pending there for the foreseeable future. Executive Order 4680/2003 remains in force, per the information below.

On April 24, 2003, the President of Brazil published in Brazil's Federal Register ("Diário Oficial") Executive Order 4680/03, establishing a tolerance limit of one 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 2658/03, 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 one 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 2658/03 enforced the labeling of products containing biotech events above the one 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. Its obligations are also to 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 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.

DICAMBA

As of October, 2020 BASF and Bayer were expected to launch in the market 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).

As of October, 2021, Bayer's XtendiMax had not yet been launched. A company representative was quoted on the news in May stating that there was no forecast for when the product would be launched but promised "the largest launch for Bayer in five years for Latin America."

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 2020/2021 harvest. Producers had different deadlines for the use of the remaining stocks depending on the crop. The last deadline for the use of Paraquat was July 31, 2021.

i) LOW LEVEL PRESENCE (LLP) 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. In Brazil, intellectual property rights for biotechnology are covered under the Industrial Property Law, Law 9279, from 1996, which safeguards the rights to collect royalties on the use of seeds which contain valid intellectual property. Multinational companies such as Bayer, Syngenta, Corteva, and BASF have licensing agreements with EMBRAPA 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.

In 2021, BASF, Bayer, Corteva, and Syngenta created the project "*Cultive Biotec*" (Cultivate Biotech), an initiative to promote a collective management model for the recognition of intellectual property, open to any companies that provide biotechnology products protected by intellectual property rights, and which have the intention of commercializing their products in the Brazilian market. The goal is to develop a collective industry solution, and with that, create a structured environment for the recognition of intellectual property rights, which will allow new soybeans biotechnologies to enter the Brazilian market. The model envisions that at the points of delivery for the grains, there will be testing done and the producers will be able to pay the royalties (if they haven't already done so) at the point of delivery. All royalties will be paid for within this system, which reduces the bureaucracy for the producers who plant different technologies. Producers now will no longer need to go into different systems to pay for the royalties, segregate production at the farms, at the silos, or deliver different technologies at different locations. This system will allow for companies to benefit from their royalties being properly paid, regardless of whether the seeds had been purchased that year or saved from the previous crop, assuring the maintenance of investment in innovation and new technologies entering the market. As this system will be used by major big biotech companies, the Brazilian anti-trust body, Cade, had to evaluate the request in order to make sure this was in the best interest of the population. *Cultive Biotec* received Cade's approval on August 5, 2021. More information on this project, can be found at their website, available in Portuguese.

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 $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 9279 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 obligated 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, 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)."

Brazil sends delegations to the COP-MOP meetings and serves at the Cartagena Protocol on Biosafety Ad-Hoc Technical Expert Groups (CBD AHTEGs).

m) INTERNATIONAL TREATIES and FORUMS

During the last meeting of the U.S.-Brazil High Level Working Group in April 2021, 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 is a member of the International Plant Protection Convention (IPPC), in which it is represented by the MAPA Head of the Plant Health and Agricultural Inputs Department. Brazil is also an active member of the Codex Alimentarius, which it joined in 1968, and is represented by the Ministry of External Relations at the body. Locally, the GoB has created a coordination body, called "Brazil Codex Alimentarius Coordination," composed of several government stakeholders, such as MAPA, the Ministry of Economy, ANVISA, Ministry of Science and Technology, and sector specific confederations such as the industry and agriculture federations.

Brazil's positions in these international fora are similar to 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 are a relevant issue for biotech companies in Brazil. It is important to note, however, that at this point, with the recent approvals by CTNBio, Post understands that there is no asynchrony between corn events approved in the United States and in Brazil, which could facilitate trade. Although China has moved ahead with the approval of several new traits of interest to Brazilian soybean exporters, the European Union (EU) has not. MAPA has been more vocal and engaged with the EU to speed up 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 EU, than among Brazilian consumers in general.

b) MARKET ACCEPTANCE/STUDIES

There are no new developments in this area.

Acceptance of GE crops in Brazil is widespread among producers. A Brazilian Confederation of Agriculture (CNA) survey showed an 80 percent acceptance rate of GE crops among Brazilian farmers.

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:

Brazilian Food Industry Association (ABIA)

Brazilian Agricultural Research Corporation (EMBRAPA)**Error! Hyperlink reference not valid.**

CropLife Brasil (CLB)**Error! Hyperlink reference not valid.**

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 successfully bred 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 *"Vitória*" (Victory). The second clone was born in 2003 from cells of a Holstein cow named "*Lenda da EMBRAPA*" (EMBRAPA's legend). The third clone, Porã, was born in April 2005 from a native cow named *"Junque*ira" that is on an endangered species list. The fourth clone, called Piatã, was born in August 2010, also from the *Junqueira* cow breed. All these clones had off springs, which demonstrates the good reproductive potential and motherly abilities of the animals used in the process.

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) is very important 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.

In June 2021, the Massachusetts-based company AquaBounty Technologies received CTNBio's approval for the commercial release of its GE Atlantic salmon in Brazil. ISAAA notes that CTNBio assessed AquaBounty's application to ensure that it met the relevant standards and regulatory

requirements and concluded that the sale and consumption of AquaBounty's GE salmon is safe for the environment and human health. CTNBio's approval followed approvals by the U.S. Food and Drug Administration and Health Canada, making AquaBounty the first and only company in the world to have its GE Atlantic salmon approved in these three major markets.

Brazil has 54 GE vaccines released by CTNBio for commercial use, 41 microorganisms, and four GE animals.

c) EXPORTS

None for commercial use.

d) 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 draft bill (PLS 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 5010/13). Bill #5010/73 proposes to regulate the cloning of animals, including wild animals and their offspring. It also proposes to make 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 Draft Bill 5010/13, 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.

This draft bill had remained under review by various committees since 2013, with no movement until April 2021, when the rapporteur voted to reject the draft bill as he "is against the cloning of domestic animals with a zootechnical interest, as well as [cloning] of wildlife native to Brazil," and finalized his remarks by request assistance from the other Congressmen in rejecting the draft bill.

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

GENETICALLY ENGINEERED ANIMALS APPROVED COMMERCIALLY IN BRAZIL

Product	**Animal**	**Company**	**Document/Year**
Aedes aegypti, lineage OX513A	Mosquito	Oxitec	3964/2014
Aedes aegypti, second generation lineage of OX5034	Mosquito	Oxitec	6946/2020
Moth *Spodoptera frugiperda*, lineage OX5382G	Fall Armyworm moth	Oxitec	7350/2021
Atlantic Salmon (Salmo salar), transgenic for growth hormone	Fish	Aquabounty	7450/2021

Source: CTNBio, updated on September 26, 2021.

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

Product	**Characteristics**	**Company**	*Document/Year*
Recombitek	Dogs/Viruses	Merial	*Com 38/98*
Vaxxitek MD/IBD	Birds/Marek-Gumboro	Merial	*Com 99/04*
Suvaxyn PCV2	Swine/Circovirus	Fort Dodge	*1300/2008*
Ingelvac	Swine/Circovirus	Boehringer	*1427/2008*
P. Circumvent	Swine/Circovirus	Intervet	*1591/2008*
Poulvac	Birds/*E. coli*	Fort Dodge	*2146/2009*
Vectormune FP-MG	Birds/Roup-Mycoplasma	Ceva	*2214/2009*
Vectormune **FP-MG+AE**	Birds/Roup-Encephalomyelitis	Ceva	*2226/2009*
Vectormune HVT-IBD	Birds/Marek-Gumboro	Ceva	*2280/2010*
Vectormune HVT-NDV	Birds/Marek-Newcastle	Ceva	*2279/2010*
PouvacSt	Birds/Salmonellosis	Fort Dodge	*2741/2010*
Vectormune FP-LT	**Avian yaws and avian laryngotracheitis**	Ceva	*2957/2011*
Vectormune FP-LT-AE	**Avian yaws, avian laryngotracheitis and Avian encephalomyelitis**	Ceva	*2958/2011*
INNOVAX ILT	Birds/Marek and Laryngotracheitis	Intervet	*2872/2011*
InnovaxND	Birds/Marek and Newcastle	Intervet	*3265/2012*
ProteqFlu TE	Equine Influenza and tetanus	Merial	*3636/2013*
ProteqFlu	Equine Influenza	Merial	*3637/2013*
Vectormune HVT-LT	Avian Laryngotracheitis Marek Disease, Serotype 3	Ceva	*4304/2014*
PRO-VAC Circomaster	Swine Circovirus	Vencofarma	*4090/2014*
B058	Swine Circovirus	Ourofino	*4202/2014*
Bovela	Bovine Diarrhea	Boehringer	*4594/2015*
Dengue Vaccine 1,2,3,4	Dengue Vaccine	Inst. Butantan	*4673/2015*
Dengvaxia	Dengue Vaccine	Sanofi Aventis	*4759/2015*
Bay98	Immunostimulant	Bayer	*4915/2016*
HIPRABOVIS IBR MARKER LIVE	Bovine Herpes Vaccine	Hipra	*5005/2016*
OncoVEXGM-CSF	Melanomas Treatment	Lab. Bergamo	*5099/2016*
Biotech Vac	Avian Salmonellosis	Vetanco do Brasil	*5331/2017*

Salmonella Vaccine	Vaccine	Importação e Exportação Ltda	
PUREVAX RAIVA Vaccine	Feline Raibes Vaccine	Merial	*5407/2017*
PROTEQFLU	Equine Influenza Vaccine	Merial	*5486/2017*
Purevax Felv	Feline Leukemia Live Vaccine	Merial	**5935/2018**
INNOVAX ND-IBD	Live Recombinant Vaccine for Marek Disease, Newscastle Disease and Gumboro Disease	Merial	*5836/18*
Newxxitek HVT+ND	Live Vaccine for Marek Disease, Newscastle Disease – Marek Diases as vector, Serotype 3	Merial	***5861/2018***
Ingelvac Provenza	Swine Influenza Live Modified Virus Vaccine	Boehringer	*6062/2018*
Trovac-NDV	Live Recombinant Virus Vaccine for Newcastle Disease and Avian Yaws	*Merial Saude Animal LTDA*	*6055/2018*
Recombinant Vaccine Against Pork Circovirus type 2	*Marek Disease and Avian Influenza*	*Ourofino Saúde Animal Ltda*	*6056/2018*
Avian Recombinant Vaccine Code 1062.R0	*Against Marek Disease and Avian Influenza*	*Ceva*	*5997/2018*
PREVEXXION RN	*Vaccine for Marek Diseas in Birds*	*Merial Saúde Animal Ltda*	*6162/2018*
Avipro Megan VAC 1	*Live Vaccine against Salmonella in Broiler chicken*	*Elanco Saúde Animal*	*6220/2018*
Fostera Gold PCV MH	*Innactivated Vaccne Against Pork and Mycoplasma hyopneumoniae*	*Zoetis Industria de Produtos Veterinários*	*6221/2018*
LUXTURNA *(voretigene neparvovec)*	*Genetic Therapy LUXTURNA (voretigene neparvovec) which is indicated for the treatment of adult and pediatric patients with eyesight loss due to hereditary retinal dystrophy caused by bialletic RPE65 gene mutations*	*Novartis Biociências S.A.*	*6849/2020*
MHYOSPHERE PCV ID	*Commercialization of an innactivated vaccine. The*	*Hipra Saúde*	*6910/2020*

	active substance MHYOSPHERE PCV ID is a inactivated recombinant strain of Mycoplasma hyopneumoniae		
(INNOVAX ND – ILT)	*Commercialization of a Recombinant Live Vaccine against Marek Disease, Newcastle Disease, Infectiou Laryngotracheitis, derived from a GMO (INNOVAX ND-ILT)*	*Merck Sharp & Dohme Saúde Animal Ltda*	*6923/2020*
Zolgesma	*Commercialization of Live Recombinant Vaccine for pediatric patients with Spinal Muscular Atrophy (SMA)*	*Novartis Biociência S.A.*	*6495/2020*
Avian Recombinant Vaccine Code 1A89.R0	*Avian Vaccine for the Prevention against Marek Disease, Newcastle Disease and Gumboro Diseas*	*Ceva Saúde Animal LTDA*	*7055/2020*
Lamzede	*LAMZEDE, commercial name of active component alfavelmannase, which is a human recombinant alpha-mannosidase, indicated for treatment of adult and pediatric patients who suffer from lysosomal alpha-mannosidade enzyme deficiency*	*Chiesi Farmacêutica Ltda*	*7201/2020*
CIRCO/MYCOGARD	*Recombinant Vaccine against Swine Circovirus and Mycoplasma hyopneumoniae*	*Eco Animal Health do Brasil, Comércio de Produtos Veterinários Ltda*	*7239*2020*
Poulvac Procerta HV-ND	*Poulvac Procerta HV-ND Vaccine – Vectorized live frozen vaccine against Marek and Newcastle diseases*	*Zoetis Indústria de Produtos Veterinários Ltda*	*7249/2020*
G608 Vaccine	*Vaccine against Edema Disease in piglets, inactivated*	*Ceva Saúde Animal*	*7340/2021*
CIRCOGARD	*Vaccine against Swine*	*Eco Animal*	*7449/2021*

Recombinant Vaccine	*Circovirus Type 2 (PCV2)*	*Health do Brasil, Comércio de Produtos Veterinários Ltda*	
FVAX-20SA01 Vaccine	*Specific Vaccine against Strepstococcus for captive-bred tilapia*	*Tevah Consultoria Empresarial, Regulatória, Governamental e Engenharia Ltda.*	*7480/2021*
Covid-19 Vaccine	*Commercialization of the recombinant Covid-19 vaccine based on microorganism of Risk Class 1 (ChAdOx1+nCoV19)*	*Instituto de Tecnologia em Imunobiológicos-Bio Manguinhos (FIOCRUZ)*	*7292/2021*
Covid-19 Vaccine	*Commercialization of the Covid-19 vaccine (Ad26.COV2.S1 – recombinant and incompetent replicant), indicated for the active immunization in prevention of the disease caused by severe acute respiratory syndrome Ccoronavirus type 2 (SARSCoV-2)*	*Janssen-Cilag Farmacêutica Ltda*	*7400/2021*
Covid-19 Vaccine	*Commercialization of the GAM-COV-VAC (SPUTNIK V) Vaccine, against SARS-CoV-2, developed by the Gamaleya Institute (Russia)*	*União Química Farmacêutica Nacional S.A*	*7440/2021*
Kymriah	*KYMRIAH, tisagenlecleucel (CTL019) treatment for Refractory acute B-cell lymphoblastic leukemia and in post-transplant relapse, in second relapse or in later relapse*	*Novartis Biociências S.A.*	*7502/2021*

Source: CTNBio, updated on August 26, 2021

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. 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, which 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 Vitória, 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 FORUMS

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 television 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, dating back only 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

GENETICALY ENGINEERED MICROORGANISMS AND DERIVED PRODUCTS APPROVED COMMERCIALLY IN BRAZIL FOR INDUSTRIAL USE

Product	**Characteristics**	**Company**	**Document/Year**
Y1979	Yeast (*Saccharomyces cerevisiae*) genetically engineered for the production of Farnesene	Amyris do Brasil	2281/2010
Y5056	Yeast (*Saccharomyces cerevisiae*) genetically engineered for the production of Farnesene	Amyris do Brasil	3287/2012
S2014	*Prototheca moriformis* for the production of triglycerides and bioproducts	Solazyme Brasil Óleos Renováveis e Bioprodutos Ltda	3775/2013
RN1016	Yeast (*Saccharomyces cerevisiae*) lineage genetically engineered for the production of ethanol	Bio Celere Agroindustrial Ltda	3877/2013
Bioproduct S5223	*Prototheca moriformis* microorganism derivative	Solazyme Brasil Óleos Renováveis e Bioprodutos Ltda	4203/2014
Celere-2L	Genetically engineered microorganisms and its derivatives of the biological risk class I	Bio Celere Agroindustrial Ltda	4526/2015
S5223	*Prototheca moriformis* lineage S5223 for the production of triglycerides and bioproducts	Solazyme Brasil Óleos Renováveis e Bioprodutos Ltda	4675/2015
S6697	*Prototheca moriformis* microorganisms for the production of triglycerides e bioproducts.	Solazyme Brasil Óleos Renováveis e Bioprodutos Ltda	4768/2015
Derivative	Import of alcaline protease	Du Pont do Brasil	5153/2016
S8695	*Prototheca moriformis* microorganism	Solazyme Brasil Óleos Renováveis e Bioprodutos Ltda	5238/2016
M10682	*Saccharomyces cerevisae* Yeast	Lallemand Brasil Ltda	5285/2016
S8885	*Prototheca moriformis* microorganism	Solazyme Brasil Óleos Renováveis e Bioprodutos Ltda	5286/2016
S1260	*Saccharomyces cerevisae* (S1260) for the comercial production of ethanol.	Novozymes Latin America Ltda	5333/2017
GICC03299	"GMO" derivative of a-amylase	Du Pont do Brasil	5496/2017
A-glucosidase	"GMO" derivative of alpha glucosidase	Du Pont do Brasil	5797/2018
Hemicellulase	"GMO" derivative of Hemicellulase	Du Pont do Brasil	5798/2018

Y22021	*Saccharomyces cerevisae* Yeast genetically engineered (strain Y22021) and its derivatives	Amyris do Brasil	5827/2018
B licheniformis	Alpha amylase of *Cytophaga sp* expressed in *Bacillus lichenifromis*	Du Pont do Brasil	6152/2018
Alpha amylase (GICC03469)	"GMO" derivative of alpha amylase (GICC03469)	Danisco	6063/2018
Corynebacterium glutamicum strain DM24.60	Genetically engineered microorganism of the bacteria *Corynebacterium glutamicum* strain DM24.60 and its derivative for the use in industrial yeast and its derivative for animal feed as feed aditive	Evonik Degussa do Brasil	6476/2019
S. cerevisiae (SCY011)	*Saccaromyces cerevisae* microorganism to be used in the commercial production of ethanol – Lineage SCY011	Novozymes Latin America Ltda	6507/2019
S. cerevisae (Y47220)	*Saccharomyces Cerevisae* Yeast for the production of steviol	Amyris	6592/2019
Substilisin	Derivative of genetically engineered microorganism Substilisin (GICC03528)	Danisco do Brasill Ltda.	6592/2019
Threonym	Derivative ofgenetically engineered microorganism – Granulated Threonym THR Pro (L-Treonina 75%)	CJ do Brasil Industria e Comercio de Produtos Alimentícios Ltda	6623/2019
S. cerevisiae (GICC03506)	Yeast for the production of ethanol fuel for the ethanolic fermentation from carbohydrates and grains processing	Danisco Brasil Ltda	6729/2019
Granulated Tryptophan TRP Pro	Derivative of genetically engineered microorganism, Granulated Tryptophan TRP Pro (LTriptofano 60%)	CJ do Brasil Industria e Comercio de Produtos Alimentícios Ltda	Waiting for publication
Saccharomyces cerevisae (Y63348)	*Saccharomyces cerevisae* genetically engineered (Strain Y63348) and its derivatives	Amyris do Brasil Ltda	Waiting for publication
Derivative of genetically engineered microorganism *Corynebacterium Glutamicum*	Product derivative from the genetically engineered organism Granulated VALPro, composto por L-Valine 70% for animal feed use	CJ do Brasil Ind. E Com. De Produtos Alimentícios Ltda	6925/2020
Derivative of	Product derivative from the genetically	Danisco Brasil	7002/2020

alpha amylase enzyme microorganism (GICC03556)	engineered organism alpha amylase enzyme (GICC03556) destined for the formulation of washing machine and dish washer soaps to assist in the removal of starch origin stains	Ltda	
Saccharomyces serevisae M15419	Industrial Production of Corn-based Ethanol fuel	Lallemand Brasil Ltda	7059/2020
Soy Leghemoglobin produced by the genetically engineered Picchia pastoris	The derivate is destined for adding in analogous products of ground beef for human consumption	Jomakol Representações e Serviços Ltda	7060/2020
L-Lysine (BestAmino)	Additive for feed preparation for animals such as birds and swine	CJ do Brasil Indústria e Comércio de Produtos Alimentícios Ltda	7056/2020
Prototheca moriformis Strain S9120	Strain S9120 of the microorganism *Prototheca moriformis*	Corbion Produtos Renováveis Ltda	7205/2020
Alpha Amylase enzyme (GICC03561)	Alpha Amylase enzyme (GICC03561)	Danisco Brasil Ltda	7250/2020
Saccharomyces cerevisae Strains (SCY015 and SCY016)	SCY015 contains a glucoamylase gene distinct organisms and a alpha amylase gene of another genetically engineered microorganism. Lineage SCY016 contains a glucoamylase gene of a distinct organism, a alpha amylase gene	Novozymes Latin American LTDA	7398/2021
Saccharomyces cerevisae – CelluXTM 4	Yeast for ethanol production	BioSpringer do Brasil Indústria de Alimentos S.A.	7481/2021
Saccharomyces cerevisae M24296	Yeast for corn-based ethanol production	Lallemand Brasil Ltda	7561/2021
S.cerevisae (GICC03578 and GICC03588)	Yeast for ethanol production	Danisco Brasil LTDA	7643/2021
Saccharomyc	*Saccharomyces cerevisae* M23541 to be	Lallemand Brasil	7661/2021

es cerevisae M23541	used in corn-based ethanol production	LTDA	
Saccharomyces cerevisae (SCY017)	*Saccharomyces cerevisae* SCY017 to be used in ethanol production	Novozymes Latin America LTDA	7662/2021
Saccharomyces cerevisae (strain Y67383)	*Saccharomyces cerevisae* (Strain Y67383) genetically engineered for steviol glycoside Reb-M production	Amyris Biotecnologia do Brasil LTDA	7663/2021

Source: CTNBio, updated on October 8, 2021.

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 4680/2003, products that contain more than one 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, MARFRIG, and a U.S.-based ingredient company formed a joint venture in May of 2020 and created PlantPlus Foods, which began operation in late October 2020 for the production of plant-burgers targeted at Brazil and South America markets. The production of plant-burger in Brazil will incorporate microbial ingredients from the United States. The plant-burgers started being commercialized in May 2021.

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 11105 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. 11105 of March 24, 2005;

Considering that Law 11105 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 11105 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 11105 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 11105 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 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