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Report Highlights:

Brazil is the second-largest producer of biotech crops in the world with a total of 107 events approved. The availability of subsidized credit for farmers, foreign investments from large biotechnology companies, and a sophisticated legal framework to approve biotech events, have supported the widespread adoption of biotech crops in Brazil. During the 2018/2019 crop season, total area planted with biotech corn, cotton, and soybeans is estimated at nearly 51.8 million hectares, with an adoption rate of 95.7 percent for soybeans, 89.8 percent for cotton, 90.7 percent for first-crop corn, and 84.8 percent for second-crop corn. Since 2018, a legislation, established by the National Technical Biosafety Commission (CTNBio), provides technical requirements for submitting requests for consultation to CTNBio on Innovative Techniques for Improvement of Precision Breeding.

SECTION I.

EXECUTIVE SUMMARY

Brazil's grain and oilseeds production during the 2018/2019 crop season set another record at 235 million metric tons, up 6.5% percent from the previous crop year. The planted area reached 60 million hectares, an increase of 2.5 percent from the previous year, while productivity increased by nearly 4 percent. During the 2018/2019 crop year, farmers had available R$194 billion (US$50 billion) in credit at subsidized interest rates to finance production, biotechnology inputs, and marketing during the crop season. This represented an increase of 2 percent over last crop year.

The increase of Brazilian crop productivity reflects the continued use of biotechnology seeds. The adoption rate of biotechnology during the 2018/19 crop season is likely to reach record levels for area planted in corn, soybeans, and cotton. Final data is not available, but the total area planted with biotech corn, cotton, and soybeans likely reached nearly 55 million hectares, with an adoption rate of 94 percent for soybeans, 95 percent for cotton, 88 percent for first-crop corn, and 78 percent for second-crop corn.

After the publication of Normative Resolution RN 16/2018, on October 4, 2018 the National Technical Biosafety Commission (CTNBio) received seven consultation letters under the terms of article two of the referred regulation regarding several products. CTNBio evaluated all these requests and determined that two varieties of yeast for production of bioethanol, one veterinary vaccine, two other varieties of yeast, one variety of waxy corn, tilapia and one bovine animal produced using Innovative Techniques for Improvement of Precision Breeding (TIMP, in Portuguese), did not fit the legal definition of Genetically Modified Organisms according to RN 16/2018 and Law number 11,105/2015.

Brazil is a major producer and exporter of a variety of agricultural products, including soybeans, cotton, sugar, cocoa, coffee, frozen concentrated orange juice, beef, poultry, pork, tobacco, hides and skins, fruits and nuts, fish products, and wood products. As a result, the United States and Brazil are sometimes competitors in third-country markets, such as China, which is the largest destination of Brazilian exports, mostly soybeans. In 2018, total Brazilian agricultural exports to China reached US$31 billion, of which US$27 billion were soybeans and products. The United States is also a major destination for Brazilian exports, mostly tropical products such as sugar, coffee, tobacco, orange juice, and wood products.

Bilateral agricultural trade between Brazil and the United States reached a record US$6 billion in 2018, up 2.5 percent from the previous year. Brazil exported to the United States US$4.5 billion in agricultural commodities and food products and imported US$1.4 billion. 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. However, in the past two years, ethanol exports to Brazil increased substantially. For 2019, January-October data shows a decline in U.S. agricultural and related products exports to Brazil by 20 percent and decline of agricultural imports from Brazil by 1.0 percent.

Section II.

Chapter 1: PLANT BIOTECHNOLOGY

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 approvals are not expected within the next five years.

b) Commercial Production

As of December 10, 2019, there are 107 GE events approved for commercial cultivation in Brazil, of which 60 events are for corn, 23 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 (2018/19) reached 51.8 million hectares. GE events with herbicide tolerance traits lead the 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 estimated for the 2019/2020 crop season.

- **Soybeans:** The adoption rate of GE soybean seeds in 2018/19 was 95.7% percent.
- **Corn:** The adoption rate of GE corn seeds in 2018/19 was 90.7 percent (first crop) and 84.8 percent (second crop).
- **Cotton:** The adoption rate of GE cotton in 2018/19 was 89.8 percent.
- **Dry Edible Beans**: Although approved in 2011, GE dry edible beans is now expected to be planted during the 2019/20 crop season.
- **Eucalyptus**. Although recently approved, GE eucalyptus is not ready to be commercially cultivated**.**
- **Sugarcane**. GE sugarcane planted area during 2018/19 was estimated at only 4,000 hectares, compared to over 10 million hectares planted with sugarcane 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 15 percent price premium barely covers the extra cost of production.

d) Imports

The National Technical Biosafety Commission (CTNBio) allows imports of GE events into the country on a case-by-case basis. The Agriculture Ministers of Argentina, Bolivia, Brazil, Chile, Paraguay, and Uruguay participated in the Southern Agricultural Council (CAS) meeting in late September 2018 and delivered another joint statement calling for the region to work together to reduce the asynchrony in the approvals of biotech events. No further action has been reported.

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. This law was modified by Law #11,460 of 2007 and Decree #5,591 of 2006. 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 approval for commercial use of biotech products. No safety considerations are evaluated by CNBS. Under the presidency of 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 other specialists from other areas such as consumer defense and family farming. Members of CTNBio are elected for 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 are 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 votes is needed, out of 27 on CTNBio's board, 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 Law. 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, eliminates a major barrier for approval of biotech events in Brazil.

b) 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 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		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,	Insect Resistant	Monsanto	BCE 531	Lepidoptera Order	Textile Fibers

2005					Food and Feed

Corn

Crop - year	Trait Category	Applicant	Event	Trait Description	Uses within Brazil
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	87427xMON89034 x MIR162xMON874 11		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	Syngenta	Bt11xMIR162 xMON89034		Food, Feed, Imports

	Insect Resistant		xGA21		
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	Herbicide	Dow Agro	DAS 40278-9	Herbicide	Food, Feed, Imports

2015	Tolerant	Science		Tolerant	
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 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 (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 Tolerant 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 2009	Herbicide Tolerant Insect Resistant	Syngenta	BT 11 x GA 21	Glyphosate Tolerant Lepidoptera R.	Food, Feed, Imports
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	Insect Resistant	Monsanto	MON 810	Lepidoptera	Food and Feed

2007			Guardian	resistant	
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 2018		Du Pont	DP-305423-1x MON 04032-6		Food and Feed
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	Food and Feed

				Insect 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 and they are treated as new events. In Brazil, it is estimated that stacked events account for 20 percent of the total area in Brazil planted to GE crops.

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 CIBios are 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. However, there are other updates.

According to CTNBio, during the entire year of 2018, the National Technical Biosafety Commission (CTNBio) received ***seven*** consultation letters under the terms of article two of the referred regulation regarding several products. CTNBio evaluated all these requests and determined that two varieties of yeast for production of bioethanol, one vaccine, two other varieties of yeast, one variety of waxy corn, and one bovine animal produced using TIMP, did not fit the legal definition of Genetically Modified Organisms according to RN 16/2018 and Law number 11,105/2015. Tilapia has also been reported as reviewed, but not officially published.

The National Technical Biosafety Commission (CTNBio) published on January 15, 2018, Normative Resolution #16, which established the requirements to evaluate Precision Breeding Innovation, (TIMP, in Portuguese), which also encompasses the so-called New Breeding Technologies (NBTs). CTNBio regulates NBTs case-by-case and exempts them 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 can be exempt. Note: These 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 the manipulated genes or genetic elements function and whether the product has already been approved for marketing in other countries.

According to Normative Resolution (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.

U.S. based CORTEVA Agriscience and Brazil's Agricultural Research Corporation (EMBRAPA) recently signed a partnership agreement for research using CRISPR, a gene editing technique. 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 technique to develop drought tolerant and nematode resistant soybean varieties.

In July 2019, the EMBRAPA Genetic Resources and Biotechnology Center promoted the 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 the cooperation between Brazil, Argentina, Colombia, Paraguay and Uruguay.

f) Coexistence

Law #11,105 of March 2005 established the legal framework under which biotech crops can be produced and marketed in Brazil. Conventional or non-biotech 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, establishes the legal framework for registration of both biotech and non-biotech 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 biotech and non-biotech seeds. Normative Instruction #04/07 issued by CTNBio establishes rules specifically for biotech corn, regarding the coexistence of biotech and non-biotech crops in Brazil.

g) Labeling

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 4,680/2003). The new draft bill establishes that only products which 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 will likely continue pending there for another year or two. Currently Executive Order 4,680/2003 is in force as per information below.

On April 2, 2004, the Civil Cabinet of the Presidency published Normative Instruction Number 1, signed by 4 cabinet ministers (Civil Cabinet, Justice, Agriculture, and Health) that established the conditions by which Directive #2,658/03 will enforce the labeling of products containing biotech events above the 1-percent limit. In addition to the federal agencies, Normative Instruction #1 also authorizes state and municipal consumer defense officials to enforce the new labeling requirements.

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

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 through biotech events. The Executive Order declares that consumers need to be informed of the biotech nature of the product.

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.

Update on DICAMBA use in Brazil:

The Ministry of Agriculture, Livestock and Food Supply (MAPA) confirmed in mid-August 2019 the release for use and marketing of soybean seeds resistant to the dicamba herbicide in Brazil. The seed bearing the trade name Intacta 2Xtend will be marketed by Bayer and is expected to hit the market in 2021. The Brazilian Association of Soy Producers (Aprosoja) Association considers this release as "premature and risky".

Bayer also announced recently during the event *Future of Farming Dialogue* in Germany that Brazil should receive a new formulation of Dicamba with less drift. In addition, the company's new herbicide molecules will be tested in Brazil soon.

i) Low Level Presence Policy

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

j) Additional Regulatory Requirements

An event approved by the CTNBio requires no further review.

k) Intellectual Property Rights (IPR)

This section has been updated.

The current Biosafety Law, which provides a clear regulatory framework for the research and marketing of new biotechnology crops in the country, has encouraged Brazil's federal government to embrace and protect new technologies that benefit agriculture. Multinational companies such as Bayer (including the former Monsanto), Syngenta and BASF, have licensing agreements with the Brazilian Agriculture and Livestock Research Enterprise (EMBRAPA), which is linked to MAPA to develop plant biotech crops, mostly for soybeans, corn and cotton. In general, at the beginning of the new crop year, technology providers negotiate payment agreements with individual Brazilian states and farmer associations for the collection of royalties. Monsanto also pursues an export-licensing scheme to collect royalties on soybean and product shipments at ports of destination in countries where Bayer has a patent on the Roundup Ready (RR) soybean technology.

Update on Monsanto-Bayer court cases in Brazil.

On July 2019, Bayer (formerly Monsanto) was required to deposit the full amount of royalties from Intacta RR2Pro (patent PI0016460-7), paid by soybean producers. This is a result of a lawsuit in which the Association of Corn and Soybean Producers of the state of Mato Grosso (APROSOJA) seeks to annul the patent for not meeting the requirements under the intellectual Property Law. The decision also sets a daily fine in case of non-compliance by Bayer. The rule reinforced the injunction that had already been granted by the same court on July 3, 2018 determining the escrow deposits of amounts that each associated Aprosoja farmer paid as royalties for the acquisition of Intacta RR2Pro. 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 dispute in the Superior Court of Justice (STJ). The court found that the multinational can charge royalties to rural producers who purchase the transgenic soybeans it develops. This lawsuit against Bayer specifically deals with the Round-up Ready soybean. The lawsuit was filed collectively by unions of rural producers in the state of Rio Grande do Sul who argued that the issue would have to be analyzed from the perspective of the Cultivars Law and not the Patent Law. This would allow them to use the seeds for replanting and also for selling soybeans as food or raw material without having to pay extra.

According to the court ruling, the Industrial Property Law # 9,279 of 1996 does not allow parts of living beings found in nature to be patented. There is an exception, however, for GMOs that meet requirements such as novelty and industrial application. According to the ruling, farmers are not obliged to buy transgenic soybean seeds, they can rely on conventional ones. But if they have chosen the specific variety, they must bear the costs.

The understanding of the STJ is important because another similar lawsuit is being filed in the judiciary by the Brazilian Association of Soy Producers (APROSOJA) from the state of Mato Grosso (see above). The discussion, however, is about another technology, INTACTA RR2 Pro, resistant to the herbicide glyphosate and to the four caterpillars that attack the soybean crop.

l) Cartagena Protocol Ratification

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 agrees 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

Like the United States, Brazil promotes science-based standards and definitions in international fora with an aim to remove unscientific sanitary and technical barriers to trade. Brazil supports labeling of GE plant products in international fora.

n) Related Issues

Brazil continues to be a partner with the United States in conducting joint outreach in third countries. Global food security and the role of biotechnology therein, is a driving force behind enhanced collaboration.

During the meeting of the U.S. – Brazil Consultative Committee on Agriculture (CCA), on September 11, 2019 in Brasilia, Brazil, a read-out was given of the video conference call of the U.S. Brazil High Level Biotech Working Group (HLBWG), held on September 5, 2019. The United States stressed the importance of this group and the continued support from Brazil in international fora to minimize trade disruptions in biotech products and collaboration on third country markets. The United States and Brazil agreed that the group should meet every 6 months.

PART C: Marketing

a) Public/Private Opinions

There are no changes to this section.

A poll conducted in the second quarter of 2016 regarding public perception of biotech 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 biotech plants are grown in Brazil.

The marketing campaign "Brazil Better without Transgenic" is against the use of GE crops in Brazil. The campaign is 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 retailers and food processors than among Brazilian consumers in general.

b) Market Acceptance

Acceptance of biotech crops in Brazil is widespread among producers. According to the Brazilian Farm Bureau (CNA), the latest full survey among Brazilian farmers, which covers the last three years, showed an 80 percent acceptance rate of biotech 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 a minimum of biotech residues in several consumer ready products,

The Brazilian Food Industry Association indicated that 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.

c) Marketing Studies

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

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

Biotechnology Information Council (CIB): http://www.cbio.org.br/

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

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

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: Production and Trade

a) Biotechnology Product Development

Brazil is the second largest producer of GE plants in the world, but 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 is GE technology to improve the health of beef cattle and increase cattle weight. The state of Ceará produced two GE goats that yield higher levels of a human antimicrobial protein 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 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 "Vitoria." The second clone was born in 2003 from cells of a Holstein cow named "Lenda da EMBRAPA." The third clone was obtained in April 2005 from a native cow named “Junqueira” that is on an endangered species list.

b) Commercial production

Commercial Somatic Cell Nuclear Transfer (SCNT) cloning in Brazil is practiced by a small number of companies, mostly under a partnership with EMBRAPA. These companies have cloned cattle for use as elite show and breeding animals. Since 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 base 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 INTREXON from the United States, produced the GM Aedes aegypti mosquitoes (OX513A). Despite the commercial approval by CTNBio, Brazil’s National Health Surveillance Agency (ANVISA), under the Ministry of Health (MS), and equivalent to the Food and Drug Administration in the United States, has not approved the commercial use in Brazil of OX513A, but provides a Temporary Special Registry (RET, in Portuguese) for research use.

Brazil has 28 GE vaccines released by CTNBio for commercial use, 14 microorganisms, and one medication for the treatment of skin cancer.

BRAZIL: 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	Vacina contra salmonelose aviária	Vetanco do Brasil Importação e	*5331/2017*

Salmonella		Exportação Ltda	
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	*Aguarda publicação*
Vacina Recombinante Aviária Código 1062.R0	*contra Doença de Marek e Influenza Aviária*	*Ceva*	*Aguarda publicação*

Source: CTNBio

c) Biotechnology Exports

None for commercial use.

d) Biotechnology Imports

None for commercial use.

PART E: Policy

a) Regulatory Framework

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

Animal cloning and their products do not have a regulatory framework approved in Brazil either at federal or state levels. A draft bill (#73, dated March 7, 2007) is still before Brazil's Senate that proposes to regulate the cloning of animals, including wild animals and their offspring.

The draft bill 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 of cloned animals or their products (meat or dairy products) to Brazil. The same applies for the progeny of cloned animals and their products.

Under the Draft Bill #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 authorization for imports of cloned animals and their products:

a) Pharmaceutical or therapeutic use will require authorization under ANVISA, Ministry of Health and,

b) Cloned animals and their products involving genetically modified organisms will require authorization from CTNBio, under the Ministry of Science and Technology.

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

b) Innovative Biotechnologies

On October 4, 2018, CTNBio determined 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 for this first genome-edited animal.

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. The 1990s were dominated by nuclear transfer cloning, with the birth of the Dolly sheep in Scotland and Victoria, an Embrapa cow in Brazil. In the 2000s, other techniques were incorporated into the scientific toolkit. Since 2010, CRISPR technology has come to dominate the area of animal reproduction biotechnology.

The focus of research today in Brazil is on the cure and prevention of animal diseases, which are the major problem of producers. For instance, tick causes damage to Brazilian livestock exceeding R$ 5

billion a year. But there are other problems, like the horn fly. In this scenario, 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 Genetic Resources and Biotechnology is in the process of mastering and establishing the methodology with the construction of vectors for the editing of bovine genomes.

c) Labeling and Traceability

The same regulations and laws as described under Section II, Part B, (g) apply to GE animals, although some specific requirements such as labeling and traceability have not yet been developed for GE animals.

The regulatory framework for animal cloning is under review in 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 law** applies to all products of GE plants, GE animals or animal cloning in terms of basic and general information about the product for the consumer.

d) 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.

e) International Treaties and Fora

Brazil is a member of both the Codex Alimentarius (CODEX) and the World Organization for Animal Health (OIE). Brazil is also a signatory to parts of the Cartagena Protocol.

PART F: Marketing

a) Public/Private Opinions

Brazilian cattle producers are strong advocates of this new technology and support the approval of animal cloning regulation in Congress and that the authority for this new area fall under the auspices of MAPA.

b) Market Acceptance

This area has not been tested in terms of consumer and retailer acceptance or rejection. However, Brazilian cattle producers are enthusiastic about the potential use of genome editing.

c) Market Studies

Most market studies can be found on the home page of EMBRAPA: http://www.embrapa.br/

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