Required Report: Required - Public Distribution **Date:** December 08, 2023

Report Number: BR2023-0027

Report Name: Agricultural Biotechnology Annual

Country: Brazil

Post: Brasilia

Report Category: Biotechnology and Other New Production Technologies

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Report Highlights:

Brazil is the second-largest producer of biotech crops in the world with 105 events approved. For the 2022/2023 crop season, FAS Brasilia forecasts 68 million hectares planted with GE traits. Adoption rates for soybeans and cotton reached 99 percent and for corn, 95 percent. Continued use of biotechnology seeds has been a major contributor to yield growth in Brazil since its adoption. The National Technical Commission (CTNBio) is responsible in Brazil for assessing the safety of new technologies such as GE animal technology, genome editing including CRISPR technology, and microbial biotechnology. In addition to GE plants, this report provides updates on several aspects of these new technologies.

EXECUTIVE SUMMARY

Brazil is the second-largest producer of biotech crops in the world with 105 events approved between plants, animals, and microbial events, only behind the United States. This report is separated in three major sections: plant biotechnology, animal biotechnology, and microbial biotechnology. As of the 2022/2023 crop season, almost the entirety of the Brazilian soybeans, cotton, and corn productions were genetically engineered. These are major commodities exported by Brazil, and its participation in the global market on these commodities affect global food availability and prices. Brazil has domestic research and development of biotechnologies, and the Brazilian regulatory framework designates specific responsibilities for different governmental ministries and regulatory agencies. The National Technical Biosafety Commission (CTNBio) is a multidisciplinary collegiate body composed of scientists who perform the safety assessments of biotechnologies in Brazil. Brazil has a zero-tolerance for imports of unapproved events. Overall, market acceptance of biotechnology in Brazil is widespread, especially among producers.

In October 2023 Brazil, Argentina, Paraguay and Uruguay created an International Network for the biosafety of products derived from modern biotechnology, an initiative that will establish common procedures and harmonize standards for assessing the biosafety of products, reducing cost and time.

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) RESEARCH AND PRODUCT DEVELOPMENT

According to the International Service for the Acquisition of Agri-Biotech Applications (ISAAA), in 2022 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, 2021, CTNBio approved a GE variety of wheat that is drought tolerant and expresses the HB4 sunflower gene. This approval allowed for the world's first occurrence of commercial trade and production of a GE wheat variety. Brazil approved the import of this product in the form of flour, but it was not approved to be imported as unmilled grain or as seeds for cultivation. As the situation currently stands, the GE wheat is planted and milled in Argentina, and the wheat flour is imported into 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. Back then, Brazilian wheat and confectionary industry associations had pushed back against this approval and even threatened litigation and possible rejection of Argentine wheat imports.

On November 17, 2021, the Brazilian Wheat Industry Association, Abitrigo, sent an official letter to the Ministry of Agriculture asking it to convene the National Biosafety Council (CNBS) to review the decision of CTNBio – which reports to CNBS. CTNBio is responsible for the technical decision on biological risk, and their decision is definitive. However, CNBS can revoke the decision based on social and economic factors, rather than biosafety reasons. In late May 2022, media cited that MAPA had decided not to convene a CNBS meeting to discuss the approval of HB4 wheat. A December 2021 study showed that 70 percent of consumers accepted the consumption of this wheat variety (see more details in Part C: Marketing; section A) Public/Private Opinions). Despite this wide public acceptance, Abitrigo was still against the variety, according to the media.

Embrapa has planted close to 70 square meters of the HB4 wheat in Brasilia in a controlled trial in partnership with the Argentinean developer Bioceres. HB4 is a wheat seed genetically modified with HaHB4 gene, from the sunflower plant and resistant to drought and the pesticide *glufosinate ammonium*, an herbicide approved in Brazil that kills weeds when it is used at the beginning of planting. The wheat was planned to be harvested in August 2022 and other experiments should take place in following seasons, so Embrapa can evaluate the benefits and limitations of that GE wheat variety production in Brazil.

Before the Argentinean company had legal approval of HB4 wheat commercialization in Brazil, CTNBio was concerned about the access into the Brazilian market with lack of official procedures. On that occasion, the Commission proposed the Brazilian and Argentinean regulatory agencies to formally submit the mutual request to have CTNBio evaluate it, instead of assessing a third party without a clear method. The Commission then provided a technical opinion to officially authorize the use and marketing of the product. To meet the new demand in Brazil, therefore, the Argentinean company had to pass the Quality and Safety Certificate and create a National Registration Number of Legal Persons (CNPJ in Portuguese) in Brazil. The company combined efforts with the Argentinean National Institute of Agricultural Technology (INTA in Argentine) to come up with the ideal technology to use. This whole request by CTNBio to have mutual procedures between the regulatory agencies, in this case INTA and Embrapa, gave rise to have the method replicated at Mercosur level.

In early March 2023 Brazil approved the planting and sale of HB4, when Abitrigo published an official statement on the case, informing that the Association is in favor of innovative developments that will bring benefits to the health and food security of Brazilians. It emphasized that, since the approval of the import of TGM flour (HB4), they did not offer considerable demonstrations by Brazilian consumers regarding the use of GE. With regard to operational risks, the Association stated that there could be a regulatory conflict between the approval of the flour and the granting of HB4 use. However, the final statement was that approval of the planning, import and commercialization of transgenic wheat (HB4) in the Brazilian national territory by CTNBio reassures the different players in the market and that the final word will be with consumers. Consumers in Brazil are logical and rational, tied to price, especially due to budget constraints from Brazilian households.

The initial results of the research are likely to be available in three years. The Ministry of Agriculture is in the formal process of registering cultivars, seeds, and seedlings of genetically engineered wheat.

Brazil has been importing the flour with GE wheat for human consumption since November 2021, but now Brazilian farmers will be able to plant the GE wheat seed in their country. With this, Brazil became the second nation, after Argentina, to approve a variety for this purpose.

For human consumption only, food from HB4 wheat has already been approved for import either in the form of wheat flour or as finished products such as baked goods in Australia, New Zealand, Indonesia, South Africa, Colombia, Nigeria, and the United States. Those countries are not authorized to plant genetically engineered wheat.

Historically, Brazil has always depended on imports to be able to supply the domestic market with wheat. For this reason, national producers see in the release of HB4 an opportunity to increase Brazilian production. However, HB4 will take time to reach the field because of the tests being conducted by Embrapa, which will define whether the new seeds from Argentina have drought tolerance in the Brazilian environment.

CTNBio states that genetically engineered wheat is safe for the environment, human and animal health, based on data from the scientific literature and information from experts presented at a public hearing that the Commission held. The drought tolerance is crucial for planting in regions with excessive drought, which is the case in central-western Brazil. It withstands veranicles and allows wheat planting

to advance into less explored areas. Wheat from the Brazilian Midwest has been proven to be of good quality.

Despite the advances, Brazil still depends on imports to supply the domestic market. For 2023, CONAB predicts that Brazil should produce 10.5 million tons of wheat but will need to buy another 5.8 million tons to meet domestic consumption.

According to Abitrigo, Brazil imports 85 percent of Argentina's wheat. Until March 2023, only conventional wheat was purchased. The cultivated area of HB4 wheat was more than 50,000 hectares in Argentina in 2022 but has not yet reached commercial scale.

The expectation for the next Brazilian wheat harvest is that it will have very little planting of GE wheat, since the decisions took place after the definitions of seed purchases, according to analysts. However, according to reports, it is likely to pick up area in the coming years, as the GE wheat is more resilient and could bring greater stability in production.

If Embrapa's tests prove positive, the next phase will be seed multiplication and only then will the GE wheat reach the producer, who in turn will analyze whether it will be economically viable and less risky in the field. Embrapa estimated that it will take between three to five years for the new GE seed to produce results in Brazil.

Abimapi, the association that represents manufacturers of biscuits, pastas, breads and cakes in Brazil, stated that the approval of the cultivation and marketing of GE wheat in Brazil is positive because it potentially allows the increase of the domestic supply of the cereal, which could reduce the costs for the baking industry.

Once the tests reach their final stage, authorization will need to be granted by CTNBio for commercial scale production, and the GE seed developer will need to arrange for a system of royalties' payments.

b) COMMERCIAL PRODUCTION

As of October 3, 2022, CTNBio data shows that there are 105 GE events approved for commercial cultivation in Brazil, of which 55 events are for corn, 23 for cotton, 18 for soybeans, six for sugarcane, two for eucalyptus, and one for a virus resistant variety dry edible bean.

With 56 million hectares in 2021, Brazil accounts for 30.6 percent of the total cultivated area in the world. It is only behind the United States, and is followed by Argentina, Canada, India, and China. FAS Brasilia forecasts close to 68 million hectares planted with GE traits, to be confirmed once final numbers are published. The widespread adoption of GE events in Brazil has contributed to record soybean and corn crops in recent years, and the main traits are herbicide tolerance, and insect resistance. Biotec-LATAM[1] reports the following adoption rates in Brazil:

- Soybeans: The adoption rate of GE soybean seeds in 2022 was 99 percent.

[1] https://biotec-latam.com/en/

- Corn: The adoption rate of GE corn seeds in 2022 was 95 percent.
- Cotton: The adoption rate of GE cotton in 2022 was 99 percent.
- Sugarcane: The adoption rate of GE sugarcane in 2022 was 0.45 percent.
- Dry Edible Beans: the adoption rate of GE dry edible beans in 2022 was 0.17 percent.
- Eucalyptus: Although recently approved, GE eucalyptus is not yet commercially cultivated.

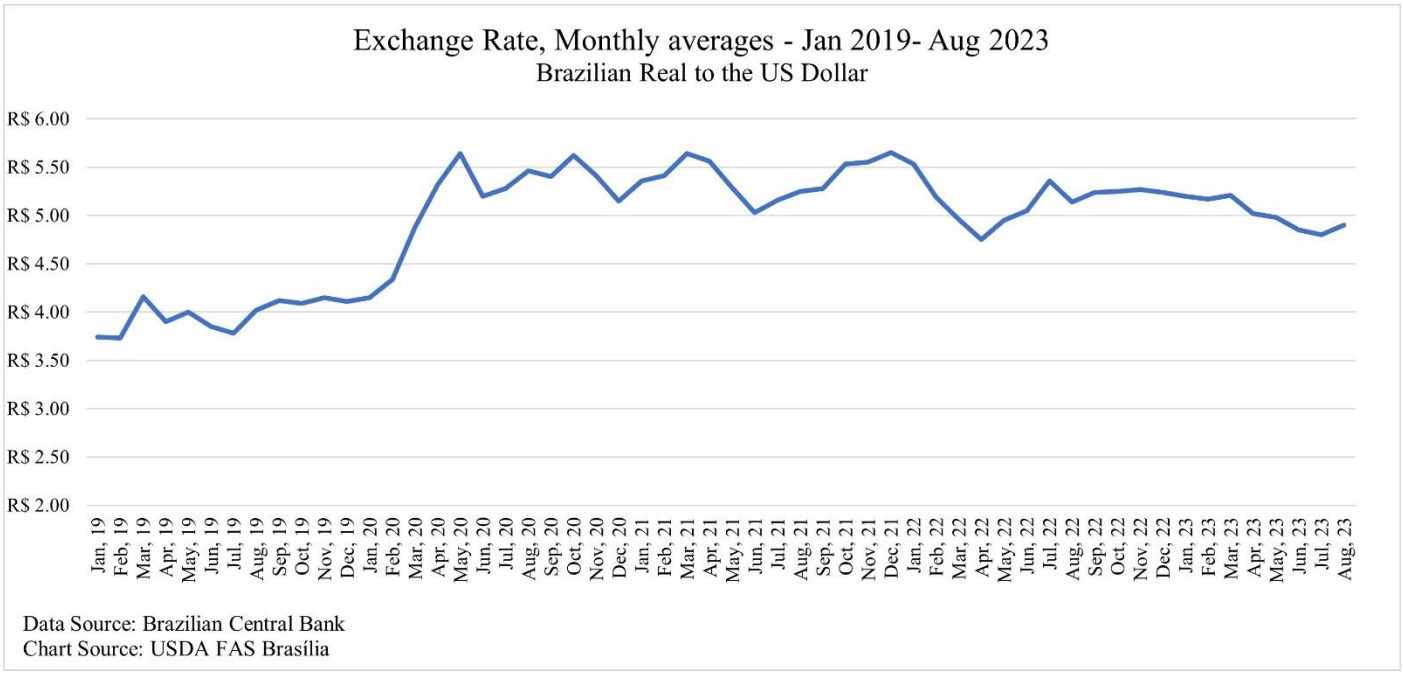
c) EXPORTS

Brazil's economy is still recovering from the negative impacts of the pandemic on its GDP growth, employment, and most sectors of the economy. For 2023, the Brazilian Central Bank (BCB) forecasts GDP to grow 2.64 percent due to a positive performance of agribusiness at the beginning of the year, BCB estimates the sector to grow ten percent.

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, as well as other Asian countries. Corn exports are mainly bound for Iran, followed by Egypt, Spain, Japan, and South Korea. Brazil is also an exporter of conventional soybeans, although these exports are expected to fall due to the declining production 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 in 2020. The Brazilian real has struggled to regain ground since, as noted on the following table.



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 a measure to facilitate imports of corn and wheat into the country.

In June 2021 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. This effectively guaranteed that any imported corn from the United States could be quickly approved for food and feed uses in Brazil.

Despite the Brazilian government's engagement to promote imports from outside of Mercosur, 99.16 percent of corn imports from January to August 2023 came from Paraguay. FAS Brasilia 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. In Brazil, food aid for humanitarian purposes is governed by Law 12429 of 2011, updated by Law 13001 of 2014. The 2011 law stipulates which countries can receive Brazilian food aid and which products can be sent, and limits of tonnage, per year. Per the law, the only countries that can receive Brazilian humanitarian food aid are: Bolivia, El Salvador, Guatemala, Haiti, Nicaragua, Zimbabwe, Cuba, country-members of the Community of Portuguese Language Countries, Palestine National Authority, Sudan, Ethiopia, Central African Republic, Democratic Republic of Congo, Somali, Niger, and North Korea. The products and annual limits as established by the laws are: rice (up to one million tons), dry edible beans and corn (up to one hundred thousand tons, each), powdered milk (up to ten thousand tons), and vegetable seeds (up to one ton). The Brazilian National Supply Company (CONAB) administers the program with the Brazilian Ministry of External Affairs. The Ministry works with the United Nations World Food Program and determines the amounts and destination of the donations. Brazil can also donate food aid as emergency assistance to people in vulnerabilities caused by migration fluxes caused by humanitarian crises, as established on Law 13684 of 2018.

From 2011 to 2022, CONAB has donated at the ports of origin in Brazil approximately 358,000 tons of basic foods, such as rice, corn grains and beans, to 45 countries. The guidelines for Purchase with Simultaneous Donation (CDS in Portuguese) operations of the Food Acquisition Program (PAA) were updated on September 11, 2023, through the manual that consolidates the normative provisions by CONAB and will guide the next actions related to donations.

f) TRADE BARRIERS

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

PART B: POLICY

a) REGULATORY FRAMEWORK

In Brazil, biotechnology is regulated by different governmental ministries and regulatory agencies, such as the Ministry of Environment (MMA), Ministry of Agriculture, Livestock, and Food Supply (MAPA), Ministry of Science, Technology, and Innovations (MCTI), and the Ministry of Health. Each of these ministries have different roles in the regulation of biotechnology in Brazil. Under the MCTI falls the National Technical Biosafety Commission (CTNBio), the multidisciplinary collegiate body that performs safety assessments of biotechnologies in Brazil. Under the Ministry of Health falls ANVISA, the Brazilian Health Regulatory Agency, whose role in biotechnology is to promote the protection of the population`s health, through sanitary control of production and consumption of all products destined for human use, including those approved by CTNBio for commercial release.

In 1995, Brazil published its first biosafety law, Law 8974/1995, governing "genetic engineering techniques" and the release into the environment of "genetically modified organisms". Ten years later, Law 11105 of March 25, 2005, revoked the first law and outlined the regulatory framework for agricultural biotechnology in Brazil. Law 11105 is still in place and is the overarching regulatory framework on biotechnologies. It is further regulated by Decree 5591 of November 22, 2005[2]. Minor amendments to the second biosafety law are present in Law 11460 of 2007. The most up-to-date version of Law 11105/2005 is available in Portuguese in this link[3], and compiles all changes made to it after its publication.

There are several other pieces of legislation that compose the entire regulatory framework for biotechnologies in Brazil. All legislation related to biotechnology is compiled by CTNBio at the Norms and Laws link on their website[4] and is available in Portuguese. Some of the legislation on that link is also available in English by changing the language on the top right corner of the website to English. Prior to its use, the product needs to abide by all applicable regulations by the different governmental bodies.

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 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 government bodies and needs a minimum quorum of six members to approve any relevant issue.
2. The National Technical Biosafety Commission (CTNBio) was initially established in 1995 under the first Brazilian biosafety law (Law 8974/1995). However, under the

[2] English version available at CTNBio`s website at http://ctnbio.mctic.gov.br/en/decretos/-/asset_publisher/fV9lwZYqwou5/content/decreto-presidencial-n-5-591-de-22-11-2005
[3] http://www.planalto.gov.br/ccivil_03/_Ato2004-2006/2005/Lei/L11105.htm#art42
[4] http://ctnbio.mctic.gov.br/normas-e-leis

current law, CTNBio was expanded from 18 to 27 primary members to include official representatives from 9 bodies 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 six specialists from other areas: consumer defense, human health, environment, biotechnology, family farming, and worker's health. All members have an alternate, therefore, CTNBio in total has 54 members, which 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, Technology, and Innovations. 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 primary board members is needed to approve new biotechnology products.

In a June-18-2008 meeting, 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 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.

Brazilian legislation makes distinctions between GE plant products containing DNA in the final form of the product and those products of GE plants that do not. It also makes a distinction between GE plant products considered living (able to increase in size or number) versus non-living. Article 3 of the Biosafety Law of 2005 states the definitions of what Brazil considers as "genetically modified organism", and a "genetically modified organism" by-product. It defines "GMO" as "an organism the genetic material of which – DNA/RNA has been modified by any genetic engineering technique", and a by-product is "a product obtained from a GMO and that is not capable of autonomously replicating, or that does not contain a feasible GMO form".

Paragraphs 1 and 2 of this article also bring relevant information on what is not considered a "GMO" or a "GMO" by-product, as below:

> "Paragraph 1 It is not considered a GMO that which results from direct introduction techniques into an organism, provided this does not entail the use of recombinant DNA/RNA molecules or GMOs, including in vitro fecundation, conjugation, transduction, transformation, polyploid induction and any other natural process.
>
> Paragraph 2. It is not considered a GMO by-product a chemically defined pure substance obtained from biological processes that do not contain GMOs, heterologous protein nor recombinant DNA."

In regard to regulatory approval/authorization treatment for different types of applications, when the applicant submits the documentation for CTNBio`s risk analysis evaluation, it is up to them to define which will be the applications of the product being submitted for evaluation. For each type of

application request, the applicant needs to provide supporting data to the safety of the product fort that specific application. It is common for GE plants commercialized as seeds to have a statement similar to this in the application: “Commercial release for cultivation, production, manipulation, transportation, transfer, commercialization, import, export, storage, release, and disposal of this ‘genetically modified organism (GMO)` and its by-products, as well as its progenies and exemption of a post-commercial release monitoring plan”. The evaluation period for plants can vary from two to six meetings, depending on the complexity of the process and the rapporteur`s time availability. Other factors that can influence the timeline for approvals/authorization for a product are: the quality of the documentation provided, the CTNBio meetings schedule, restrictions related to confidential data, etc. Commercial plant approvals do not have an expiration date, nor re-registration is required. However, it is important to note that although approvals do not have expiration dates, they can be reviewed shall a new scientific data is reported by the applicant or by scientific literature. In these cases, CTNBio will evaluate if the new information has an impact in the biosafety of the product and if it remains safe or not.

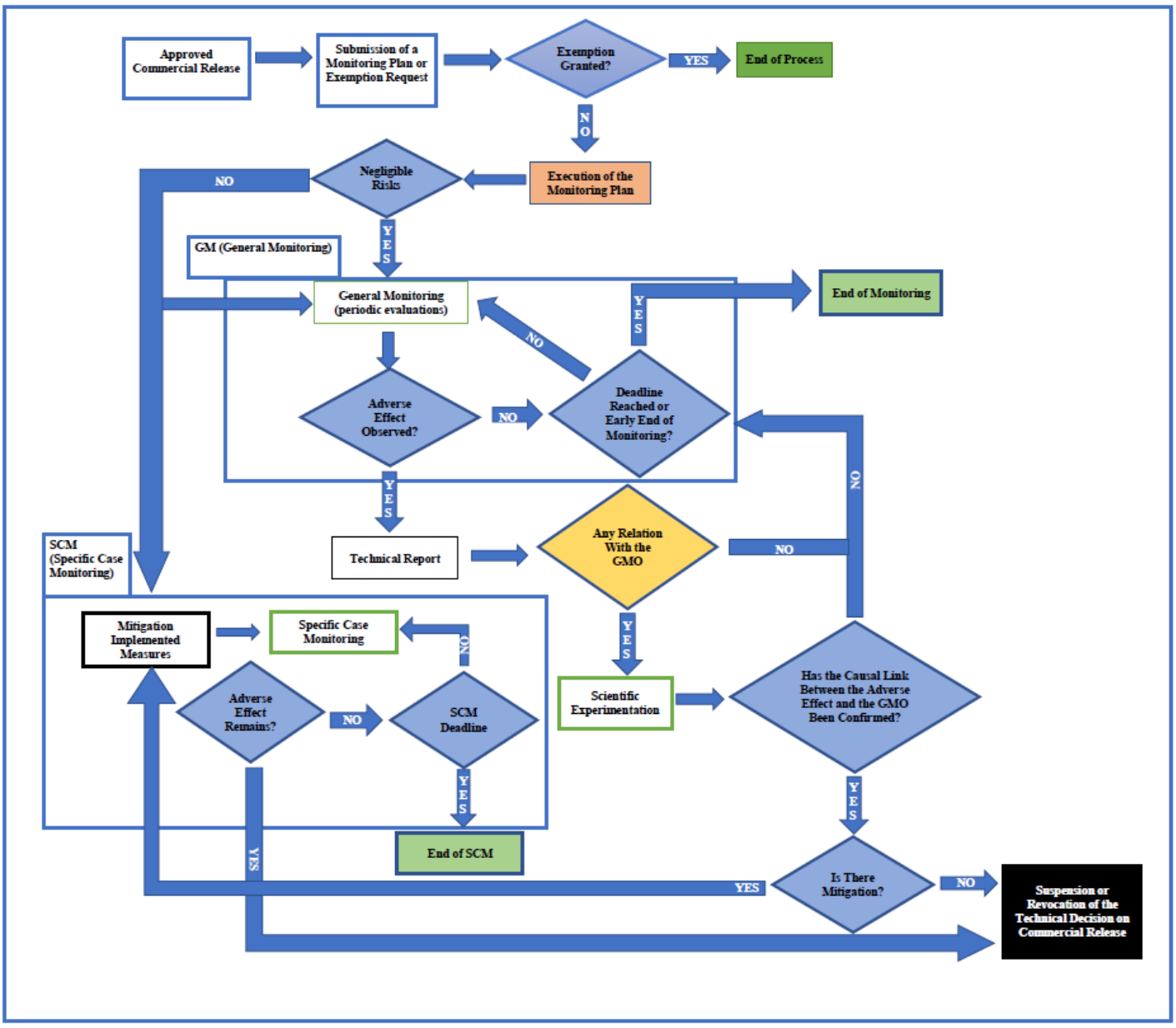
In 2020 the Ministers of Science and Technology of Brazil and Argentina and the Minister of Education and Culture of Uruguay signed a Memorandum of Understanding to create the Latin American Center for Biotechnology (CABBIO) to support research and trainings. By using the research infrastructure of the three countries, the goal is to maintain a knowledge-generating pole, including the participation of the private sector and the exchange between biotechnology companies and scientific and technical teams. Since its creation, CABBIO has offered webinars, short and graduate courses.

On August 22, 2023, the Brazilian Federal Supreme Court decided, by majority of eight to three votes, to maintain the competence of the CTNBio to approve the commercialization of genetically engineered organisms. The trial took place in a virtual plenary and validates parts of the Biosafety Law, which covers the supervision, creation and study of genetically engineered organisms and genetically altered foods. The action was initiated in 2005 (Law 11105/2005[5]) by the Attorney General's Office (PGR) and was approved in the same year.

In 18 years of operation, the commission approved 260 “GMOs” for use in the Brazilian market, with no detection of environmental, human, or animal health issues. Considering those approved materials, 45 percent are plants, mainly soybean, corn, and cotton seeds, but also beans, sugarcane, eucalyptus, and wheat. The flow of products from other areas, such as vaccines, therapies, and medicines, has been increasing.

[5]Available in Portuguese at https://www.planalto.gov.br/ccivil_03/_Ato2004-2006/2005/Lei/L11105.htm

Brazil´s Review Process for GE Products



Source: CTNBIO, adapted to English by FAS Brasilia.

i. Legal terms Table

The following legal terms table is by no means exhaustive of all legal framework involving biotechnologies in Brazil. It is organized by alphabetical order of the legal term in English.

Legal Term (in Portuguese)	Legal Term (in English)	Laws and Regulations where term is used	Legal Definition (in English)
Agroinfiltração/ Agroinfecção	Agroinfiltration/ agroinfection	CTNBio Normative Resolution 16/2018	Foliage (or other somatic tissue) infiltrated with Agrobacterium sp. or gene constructs containing the gene of interest to obtain a 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.
Requerente	Applicant	CTNBio Normative Resolution 32/2021	Any legal entity, holder of a Quality Certificate in Biosafety – CQB, which intends to conduct a commercial release, according to this Normative Resolution.
Embriões congelados disponíveis	Available frozen embryo	Decree 5591/2005	An embryo frozen on or before March 28, 2005, after three years from the date of its freezing have elapsed genitor.
Clonagem	Cloning	Law 11105/2005; Decree 5591/2005	An asexual reproduction process, artificially produced, based on a sole genetic patrimony, by using or not genetic engineering techniques.
Clonagem para fins reprodutivos	Cloning for reproductive means	Law 11105/2005	Cloning the end purpose of which is to make an individual.
Liberação Planejada no Meio Ambiente	Commercial release in the environment	CTNBio Normative Resolution 35/2021	Commercial release in the environment of a GMO and its derivatives, for experimental evaluations under monitoring, in accordance with the dispositions of this Normative Resolution.
Dano	Damage	CTNBio Normative Resolution 32/2021	Harm to the environment and/or human, animal, and plant health.
Perigo	Danger	CTNBio Normative Resolution 32/2021	Any chemical, physical or biological component that causes potential damage.

Ácido desoxirribonucléico - ADN, ácido ribonucléico - ARN	Deoxyribonucleic acid - DNA, ribonucleic acid - RNA	Law 11105/2005; Decree 5591/2005	Genetic material which contains determining information about transmissible hereditary characters to progeny.
Organismo doador	Donor organism	CTNBio Normative Resolution 32/2021	Organism which donates one DNA or RNA sequence to the genetic transformation of the receptive organism or those whose original DNA or RNA sequences are modified in vitro or synthetized before the insertion in the receptive organism.
Células-tronco embrionárias	Embryonic stem cells	Law 11105/2005; Decree 5591/2005	Embryonic cells that are capable of modifying the cells of any organism tissue.
Elemento regulador da expressão gênica	Gene expression regulating element	CTNBio Normative Resolution 21/2018	DNA/RNA sequences involved in the gene expression regulation, such as those responsible for the codification of the transcription factors, micro RNAs and other elements scientifically known as related to the gene expression regulation.
Técnica de silenciamento gênico	Gene silencing technique	CTNBio Normative Resolution 21/2018	Genetic engineering technique by which the expression of a gene is negatively regulated.
Construção genética	Genetic construct	CTNBio Normative Resolution 32/2021	Genetic sequence containing one or more codifying regions and the genetic elements needed for its transcriptional regulation.
Engenharia genética	Genetic engineering	Law 11105/2005; Decree 5591/2005; CTNBio Normative Resolution 32/2021	The activity of manipulating DNA/RNA recombinant molecules.
Transformação genética	Genetic transformation	CTNBio Normative Resolution 32/2021	Activity of modifying, in a controlled manner, the genetic material present in an organism through the integration of an exogenous DNA.

Microrganismo geneticamente modificado - MGM	"Genetically Modified Microorganism - GMM"	CTNBio Normative Resolution 21/2018	Microorganism whose genetic material - DNA/RNA has been modified by any genetic engineering technique.
Organismo geneticamente modificado - OGM	"Genetically modified organism - GMO"	Law 11105/2005; Decree 5591/2005; CTNBio Normative Resolution 32/2021	An organism the genetic material of which – DNA/RNA has been modified by any genetic engineering technique.
Genitores	Genitors	Decree 5591/2005	The final users of in vitro fertilization.
Derivado de MGM	"GMM" by-product	CTNBio Normative Resolution 21/2018	A product obtained from a "GMM" and that is not capable of autonomously replicating, or that does not contain a feasible "GMM" form.
Atividade de uso comercial de OGM e seus derivados	"GMO" and "GMO" derivatives commercial use activity	Decree 5591/2005	Any activity not included as research, and involving cultivation, production, manipulation, transport, transfer, marketing, import, export, storage, consumption, disposal and discarding of "GMO" and its derivatives for commercial purposes.
Derivado de OGM	"GMO" by-product	Law 11105/2005; Decree 5591/2005; CTNBio Normative Resolution 32/2021	A product obtained from a "GMO" and that is not capable of autonomously replicating, or that does not contain a feasible "GMO" form.
Célula germinal humana	Human germinal cell	Law 11105/2005; Decree 5591/2005	The mother cell responsible for forming gametes which are found in the female and male sexual glands and their direct progeny in any ploid degree.
Construção genética idêntica	Identical genetic construct	CTNBio Normative Resolution 35/2021	Genetic construct which contains the same genes and promotors that result in the same expression product inside the same species.

Fertilização in vitro	In vitro fertilization	Decree 5591/2005	The fusion of gametes conducted by any technique of extracorporeal fertilization.
Tecnologias genéticas de restrição do uso	Limited use genetic technologies	Decree 5591/2005	Any process of human intervention to generate or multiply plants "genetically modified" to produce sterile reproductive structures, as well as any form of genetic manipulation with the purpose of activating or deactivating genes related to plant fertility by external chemical inductors.
Microrganismo	Microorganism	CTNBio Normative Resolution 21/2018	All microscopic biological entity, uni or pluricellular capable of reproducing or transferring genetic material, including virus and other classes that come to be known.
Plano de monitoramento pós-liberação comercial	Monitoring plan after commercial release	CTNBio Normative Resolution 32/2021	Pool of procedures to monitor the effects derived from the commercial release of the GMO and its derivatives on the environment and to the human and animal health.
Risco negligenciável	Negligible risk	CTNBio Normative Resolution 32/2021	Risk associated to a reduced damage with negligible likelihood to take place over the probable term of the GMO commercial use.
Embriões inviáveis	Non-viable embryo	Decree 5591/2005	An embryo with genetic alterations evidenced by preimplant diagnosis, according to the Ministry of Health specific rules, whose development has been interrupted by spontaneous absence of cleavage for a period exceeding twenty-four hours from the in vitro fertilization, or an embryo with morphologic alteration that adversely affects its full development.

Mutagênese direcionada por oligonucleotídeo	Oligonucleotide Directed Mutagenesis	CTNBio Normative Resolution 16/2018	A synthesized oligonucleotide containing one or a few nucleotide alterations complementary to the targeted sequence, on being introduced into the cell, may cause substitution, insertion or deletion in the target sequence through the cellular repair mechanism (microorganisms, plants, animals, and human cells).
Organismo	Organism	Law 11105/2005; Decree 5591/2005; CTNBio Normative Resolution 32/2021	Each and every biological entity that is capable of reproducing or transferring genetic material, including virus and other classes that may be made known.
Responsável legal	Person legally in charge	CTNBio Normative Resolution 32/2021	Individual responsible for conducting the commercial release, according to CTNBio norms.
Responsável legal	Person legally in charge	CTNBio Normative Resolution 35/2021	Individual responsible for conducting the commercial release in the environment, according to CTNBio norms.
Técnicas Inovadoras de Melhoramento de Precisão	Precision breeding innovation techniques	CTNBio Normative Resolution 16/2018	Are based on a set of new methodologies and approaches that differ from the transgenic genetic engineering strategy that results in the absence of recombinant DNA/RNA in the final product.
Florescimento Precoce	Precocious flowering	CTNBio Normative Resolution 16/2018	Silencing and/or super-expression of genes related to flowering by inserting genetic modification into the genome and subsequent separation or through transient expression by viral vector.
Organismo receptor	Receptive organism	CTNBio Normative Resolution 32/2021	Organism that will receive the DNA sequence.

Moléculas de ADN/ARN recombinante	Recombinant DNA/RNA molecules	Law 11105/2005; Decree 5591/2005; CTNBio Normative Resolution 32/2021	Molecules manipulated outside live cells through changes made to natural or synthetic DNA/RNA segments that can multiply in a live cell, or yet, DNA/RNA molecules resulting from this multiplication; DNA/RNA synthetic segments equivalent to natural DNA/RNA are also considered.
Atividade de pesquisa	Research activity	Decree 5591/2005	Any activity conducted in a laboratory, under field containment, as part of the process of obtaining a GMO and its derivatives, or assessment of the GMO and its derivatives biosafety involving, in the experimental context, construction, cultivation, manipulation, transport, transfer, import, export, storage, disposal to the environment and discarding of GMO and its derivatives.
Melhoramento Reverso	Reverse breeding	CTNBio Normative Resolution 16/2018	Inhibiting meiotic recombination in heterozygous plants selected for the trait of interest in order to produce homozygous parental lines.
Risco	Risk	CTNBio Normative Resolution 32/2021	Probability of the occurrence of damage, and its likely consequences, due to the exposure to the danger.
Risco	Risk	CTNBio Normative Resolution 35/2021	Probability of an adverse event.
Avaliação de risco	Risk assessment	CTNBio Normative Resolution 32/2021	Combination of procedures or methods, by which it is identified and evaluated, on a case-by-case basis, the risk. The risk assessment must include steps to identify and classify the risk; estimation of its occurrence; evaluation of its consequences and determination of the risk estimate.

Metilação do DNA dependente do RNA	RNA-dependent DNA methylation	CTNBio Normative Resolution 16/2018	Methylation driven by RNA interference (“RNAi”) in RNAi homologous promoter regions in order to inhibit target gene transcription in live beings.
Tecnologia para produção de sementes	Seed producing technology	CTNBio Normative Resolution 16/2018	Inserting fertility-restoring genetic modification in naturally malesterile lines in order to multiply these lines maintaining the male-sterile condition but not transmitting the genetic modification to descendants.
Risco não negligenciável	Significant risk	CTNBio Normative Resolution 32/2021	Risk associated to any damage with actual likelihood to take place over the probable term of the GMO commercial use.
Construção genética similar	Similar genetic construct	CTNBio Normative Resolution 32/2021	Non-identical genetic construct whose differences do not result in identity alterations the expression products.
Mutagênese sítio dirigida	Site-Directed Mutagenesis	CTNBio Normative Resolution 16/2018	Methylation driven by RNA interference (“RNAi”) in RNAi homologous promoter regions in order to inhibit target gene transcription in live beings.
Produto combinado	Stacked product	CTNBio Normative Resolution 32/2021; CTNBio Resolution 35/2021	"Genetically modified organism" which contains more than one transformation event.
Clonagem terapêutica	Therapeutic cloning	Law 11105/2005	Cloning the end purpose of which is to produce embryonic stem cells for therapeutic purposes.
RNAi uso tópico/sistêmico	Topical/systemic use RNAi	CTNBio Normative Resolution 16/2018	Use of double-stranded RNA (“dsRNA”) with targeted-gene homologous sequence specifically silencing this gene or genes. Engineered dsRNA molecules may be introduced/absorbed into the cell from the environment.

Evento de transformação	Transformation event	CTNBio Normative Resolution 32/2021; CTNBio Resolution 35/2021	Event with one or multiple insertions of one (same) genetic construct inserted in the receptive organism genome, as a result of the genetic transformation.
Vetor viral	Viral Vector	CTNBio Normative Resolution 16/2018	Inoculation of live beings with recombinant viruses (DNA or RNA) expressing the genetic modification and amplification of the gene of interest through viral replication mechanisms without host genome modification.

b) APPROVALS/AUTHORIZATIONS

Cotton

Crop - Year	Trait Category	Applicant	Event (Commercial Name)	Trait Description	Document Number/Uses within Brazil
Cotton 2023	Herbicide Tolerant	BASF	LLCotton25 x GBH811 (GLI)	Herbicide tolerance to glyphosate base and inhibitory herbicides	8540/2023 Release into the environment of the cotton variety; commercial use
Cotton 2022	Insects and pests resistant	Monsanto	MON 15985	Resistant to certain Insects and pests	8038/2022 Commercial Release of MON 15947 cotton, obtained through the segregation and selection of MON 15985 cotton
Cotton 2021	Insect Resistant	Syngenta Seeds Ltda	COT102	Insect Resistant	RN32 Not available
Cotton 2019	Herbicide Tolerant, Insect Resistant	BASF	GHB811 x T-304-40 x GHB119 x COT102 x COT102	Herbicide Tolerant, Insect Resistant	6405/2019 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	6657/2019 Textile Fibers Food and Feed

Cotton 2018	Herbicide Tolerant Insect Resistant	Monsanto	COT102 x MON15985 x MON88913 x MON88701 (BGIIIRRFlexDGT)	Herbicide Tolerant, Insect Resistant	6139/2018 Textile Fibers Food and Feed
Cotton 2018	Herbicide Tolerant Insect Resistant	Monsanto	MON88913 x MON88701 (RRFlexDGT)	Herbicide Tolerant, Insect Resistant	6139/18 Textile Fibers Food and Feed
Cotton 2018	Herbicide Tolerant Insect Resistant	BASF	T304-40 x GHB119 x COT102	Herbicide Tolerant, Insect Resistant	6130/18 Textile Fibers Food and Feed
Cotton 2018	Herbicide Tolerant	Dow	DAS 81910 (Enlist)	Herbicide Tolerant	6107/18 Textile Fibers Food and Feed
Cotton 2018	Insect Resistant	Dow	DAS-21023-5 x DAS24236-5 x SYN-IR102-7 (Widestrike 3)	Insect Resistant	5955/18 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	5400/17 Textile Fibers Food and Feed
Cotton 2017	Herbicide Tolerant	Monsanto	MON88701 (DGT)	Herbicide Tolerant	5429/17 Textile Fibers Food and Feed
Cotton 2016	Herbicide Tolerant Insect Resistant	Monsanto	COT102 x MON15985 x MON88913 (BGIIIRRFlex)	Herbicide Tolerant Insect Resistant	5155/16 Textile Fibers Food and Feed
Cotton 2012	Herbicide Tolerant Insect Resistant	Bayer	GHB614 x T304-40x GHB119 (GlytoIxTwinLink)	Gossypium hirsutum L.	3286/12 Textile Fibers Food and Feed
Cotton 2012	Herbicide Tolerant Insect Resistant	Monsanto	MON 15985 x MON 88913 (BGIIFlex)	Herbicide Tolerant Insect Resistant	3365/12 Textile Fibers Food and Feed
Cotton 2012	Herbicide Tolerant	Bayer	GHB614 x LL Cotton 25 (GTxLL)	Gossypium hirsutum L.	3290/12 Textile Fibers Food and Feed
Cotton 2011	Herbicide Tolerant	Monsanto	MON 88913	Gossypium hirsutum L.	2956/11 Textile Fibers Food and Feed
Cotton	Herbicide Tolerant	Bayer	T 304-40 x GHB	Gossypium	2795/11

2011	Insect Resistant		119 (TwinLink)	hirsutum L.	Textile Fibers Food and Feed
Cotton 2010	Herbicide Tolerant	Bayer	GHB 614 (GlyTol)	Gossypium hirsutumm L.	2754/10 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	2051/09 Textile Fibers Food and Feed
Cotton 2009	Insect Resistant	Monsanto	MON 15985 (Bollgard II)	Gossypium hirsutum L.	1832/09 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	1757/09 Food and Feed
Cotton 2008	Herbicide Tolerant	Bayer	LL Cotton 25 (Liberty Link)	Gossypium hirsutum L. Glyphosate Herbicide Ammonium	1521/08 Textile Fibers Food and Feed
Cotton 2008	Herbicide Tolerant	Monsanto	MON 1445 (Roundup Ready)	Gossypium hirsutum L. Glyphosate Herbicide	1598/08 Textile Fibers Food and Feed
Cotton 2005	Insect Resistant	Monsanto	MON 531 (Bollgard 1)	Lepidoptera Order	513/05 Textile Fibers Food and Feed

Source: CTNBio, updated on June 21, 2023

Corn

Crop - Year	Trait Category	Applicant	Event (Commercial Name)	Trait Description	Document Number/ Uses within Brazil
Corn 2023	Insect Resistant	Monsanto	MON 95275	Insect Resistant	Not available Post-commercial release monitoring plan
Corn 2023	Herbicide Tolerant	Syngenta	Bt11 x MIR162 x NK603 (Zea mays L.)	Herbicide Tolerant	8405/2023 Cultivation, production, handling,

					transport, transfer, marketing, import, export, storage, release, and disposal
Corn 2022	Insect Resistant	Syngenta	3272	Insect Resistant	7891/2022 Cultivation and exemption from monitoring plan
Corn 2022	Insect Resistant	Helix Semenentes e Mudas	EH913	Resistance to lepidoptera insect	8064/2022 Commercial use, planned release into the environment
Corn 2022	Herbicide Tolerant	Monsanto	MON87429	Herbicide Tolerant	8035/2022 Exemption from post- commercial release monitoring
Corn 2022	Herbicide Tolerant Insect Resistant	Syngenta Seeds Ltda	3272 x Bt11 x MIR162 x GA21	Herbicide Tolerant Insect Resistant	7897/2022 Cultivation, production, handling, transport, transfer, marketing, import, export, storage, release, and disposal
Corn 2021	Herbicide Tolerant Insect Resistant	Corteva	DP4114-3	Herbicide Tolerant Insect Resistant	7501/2021 Food and Feed Import
Corn 2021	Herbicide Tolerant Insect Resistant	Monsanto	MON 87427 × MON 95379 × MON 87411	Herbicide Tolerant Insect Resistant	7429/2021 Release into the environment, commercial use and any other activities
Corn 2020	Insect Resistant	Monsanto	MON 95379	Insect Resistant	7222/2020 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	6862/2020 Food and Feed
Corn	Herbicide Tolerant	DuPont	NK603 x T25 x	Herbicide	6797/2020

2020			DAS-40278	Tolerant	Food and Feed
Corn 2019	Herbicide Tolerant	Monsanto	MON 87427 x MON 89034 x MIR162 x NK603 (and undercombinations)	Herbicide Tolerant	6519/2019 Food, Feed, Imports
Corn 2019	Herbicide Tolerant Insect Resistant	Monsanto	MON 87427 × MON 87419 × NK603	Herbicide Tolerant Insect Resistant	6448/2019 Not available
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	6363/2019 Food, Feed, Imports
Corn 2018	Insect Resistant	Syngenta	MZIR 098	Approved only for human and animal food	6115/18 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	6035/18 Food, Feed, Imports
Corn 2017	Herbicide Tolerant Insect Resistant	Dow	MON89034 x TC1507 x NK603 x MIR162 (PowerCore Ultra)	Herbicide Tolerant Insect Resistant	5425/17 Food, Feed, Imports
Corn 2017	Insect Resistant	Syngenta	MIR162 x MON89034	Insect Resistant	5412/17 e 6310/2019 Food, Feed, Imports
Corn 2017	Herbicide Tolerant Insect Resistant	Syngenta	Bt11 x MIR162 x MON89034 (VIP4)	Herbicide Tolerant Insect Resistant	5412/17 Food, Feed, Imports
Corn 2017	Herbicide Tolerant Insect Resistant	Syngenta	Bt11 x MIR162 x MON89034 x GA21 (VIP4TG)	Herbicide Tolerant Insect Resistant	5412/17 Food, Feed, Imports

Corn 2016	Drought Stress	Monsanto	MON87460	Approved only for human and animal food	5224/16 Food, Feed, Imports
Corn 2016	Amylase Thermostability Increase	Syngenta	3272 (Enogen)	Approved only for human and animal food	5226/2016 e 7891/2022 Food, Feed, Imports
Corn 2016	Herbicide Tolerant	Monsanto	MON87427	Herbicide Tolerant	5221/16 Food, Feed, Imports
Corn 2016	Herbicide Tolerant Insect Resistant	Monsanto	MON97411	Herbicide Tolerant Insect Resistant	5162/2016 Food, Feed, Imports
Corn 2016	Herbicide Tolerant Insect Resistant	Dow AgroSciences	MON89034 x MON88017 x TC1507 x DAS59122-7 (SmartStax)	Herbicide Tolerant Insect Resistant	5128/16 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	4949/16 Food, Feed, Imports
Corn 2015	Fertility Restauration	Du Pont	SPT 32138 (32138 Mantenedor SPT)	Fertility Restauration	4865/15 Food, Feed, Imports
Corn 2015	Herbicide Tolerant Insect Resistant	Syngenta	BT11 x MIR162 (VIP2)	Herbicide Tolerant Insect Resistant	4764/15 Food, Feed, Imports
Corn 2015	Insect Resistant	Syngenta	5307 (Agrisure Duracade)	Insect Resistant	4764/15 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	4764/15 Food, Feed, Imports
Corn 2015	Herbicide Tolerant	Dow AgroSciences	DAS40278-9 x NK603 (Enlist RR)	Herbicide Tolerant	4763/15 Food, Feed, Imports
Corn 2015	Herbicide Tolerant Insect Resistant	Du Pont	TC1507 x MON810 x	Herbicide Tolerant	4465/15 Food, Feed,

			MIR162 Undercombinations approved and already referred previously	Insect Resistant	Imports
Corn 2015	Insect Resistant	Du Pont (RN15)	MON 810 x MIR162	Insect Resistant	4409/15 Food, Feed, Imports
Corn 2015	Herbicide Tolerant Insect Resistant	Du Pont (RN15)	MIR162 x NK603	Herbicide Tolerant Insect Resistant	4409/15 Food, Feed, Imports
Corn 2015	Herbicide Tolerant Insect Resistant	Du Pont (RN15)	TC1507 x MIR162	Herbicide Tolerant Insect Resistant	4409/15 Food, Feed, Imports
Corn 2015	Herbicide Tolerant Insect Resistant	DuPont (RN15)	TC1507 x MON 810 x MIR 162 x NK603	Herbicide Tolerant	4409/15 Food, Feed, Imports
Corn 2015	Herbicide Tolerant Insect Resistant	DuPont (RN15)	TC1507 x MIR162 x NK603	Herbicide Tolerant Insect Resistant	4409/15 Food, Feed, Imports
Corn 2015	Herbicide Tolerant	Monsanto	NK603 x T25	Glyphosate and Glufosinate Herbicides	4407/15 Food, Feed, Imports
Corn 2015	Herbicide Tolerant	Dow Agro Science	DAS 40278-9 (Enlist)	Herbicide Tolerant	4406/15 Food, Feed, Imports
Corn 2014	Insect Resistant	Syngenta	MIR 604	Insect Resistant	4207/14 Food, Feed, Imports
Corn 2014	Herbicide Tolerant Insect Resistant	Syngenta	Bt11 x MIR162 x MIR604 x GA21 (Viptera4)	Glyphosate Tolerant Glufosinate Ammonium	4207/14 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	3674/13 and 7467/2021 Food, Feed, Imports
Corn 2011	Herbicide Tolerant Insect Resistant	Monsanto	MON 89034 x MON 88017	Glyphosate Herbicide	3045/11 Food, Feed,

					Imports
Corn 2011	Herbicide Tolerant Insect Resistant	DuPont	TC1507 x MON 810	Glyphosate Herbicide Ammonium	3021/11 Food, Feed, Imports
Corn 2011	Herbicide Tolerant Insect Resistant	DuPont	MON 810 x TC 1507 x NK 603 (Optimum Intrasect)	Glyphosate Herbicide Lepidoptera R.	2955/11 Food, Feed, Imports
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	2753/10 Food, Feed, Imports
Corn 2010	Herbicide Tolerant Insect Resistant	Monsanto	MON 88017 (Yield Guard VT)	Glyphosate Herbicide Ammonium	2761/10 Food, Feed, Imports
Corn 2010	Herbicide Tolerant Insect Resistant	Monsanto	MON 89034 x NK 603 (PRO2)	Glyphosate Herbicide Ammonium	2725/10 Food, Feed, Imports
Corn 2010	Herbicide Tolerant Insect Resistant	Syngenta	BT 11 x MIR 162 x GA 21 (TL TG Viptera)	Glyphosate Herbicide Ammonium	2722/10 Food, Feed, Imports
Corn 2009	Insect Resistant	Monsanto	MON 89034 (Pro)	Lepidoptera Resistant	2052/09 Food, Feed, Imports
Corn 2009	Herbicide Tolerant Insect Resistant	DuPont	TC1507 x NK603 (HR Herculex/RR2)	Glyphosate Tolerant Insect Resistant	2053/09 Food, Feed, Imports
Corn 2009	Insect Resistant	Syngenta	MIR162 (Viptera-MIR162)	Lepidoptera Resistant	2042/09 Food, feed, Imports
Corn 2009	Herbicide Tolerant Insect Resistant	Syngenta	BT 11 x GA 21 (TL/TG)	Glyphosate Tolerant Lepidoptera R.	2040/09 Food, Feed, Imports
Corn 2009	Herbicide Tolerant Insect Resistant	Monsanto	NK603 x MON810 (YGRR2)	Glyphosate Tolerant Lepidoptera R.	2041/09 Food, Feed, Imports
Corn 2008	Herbicide Tolerant Insect Resistant	Dupont and Dow AgroScience	TC1507 (Herculex)	Glyphosate ammonium Herbicide Tolerant	1679/08 Food and Feed
Corn 2008	Herbicide Tolerant	Syngenta	GA 21 (TG)	Glyphosate Tolerant	1597/08 Food and Feed

Corn 2008	Herbicide Tolerant	Monsanto	NK 603 (Roundup Ready 2)	Glyphosate Tolerant	1596/08 Food and Feed
Corn 2008	Insect Resistant Herbicide Tolerant	Syngenta	Bt 11 (TL)	Lepidoptera resistant	1255/08 Food and Feed
Corn 2007	Herbicide Tolerant	Bayer	T 25 (Liberty Link)	Ammonium Glyphosate tolerant	987/07 Food and Feed
Corn 2007	Insect Resistant	Monsanto	MON 810 (Yield Guard)	Lepidoptera resistant	1100/07 Food and Feed

Source: CTNBio, updated on June 21, 2023

Soybeans

Crop - Year	Trait Category	Applicant	Event (Commercial Name)	Trait Description	Document Number/Uses within Brazil
Soybeans 2023	Glyphosate herbicide resistance	GDM	GTS 40- 3-2 x A5547-127 (Roundup Ready)	Glysophate and ammonium glusophinate herbicide tolerant	8565/2023 Release for free registration, use, testing, sowing, transportation, storage, marketing, consumption, importation, and disposal
Soybeans 2021	Herbicide Tolerant	BASF	GMB151	Nematode resistance and selectivity to HPPD-inhibiting herbicides	7306/2021 Commercial use
Soybeans 2019	Herbicide Tolerant	TMG	HB4 and HB4 x RR	Herbicide and Drought Tolerant	6540/2019 Food and Feed
Soybeans 2018	Herbicide Tolerant Insect Resistant	Monsanto	MON87751 x MON87708 x MON87701 x MON89788	Herbicide Tolerant Insect Resistant	5832/18 Food and Feed
Soybeans 2018	GM-HRA; GM-FAS2-1 (partial sequence); cp4 epsps (aroA:CP4)	Du Pont	DP-305423-1 x MON 04032-6 (Plenish x Plenish; Plenish RR1)	GM-HRA; GM-FAS2-1 (partial sequence); cp4 epsps (aroA:CP4)	5821/18 Food and Feed
Soybeans 2017	Herbicide Tolerant	Dow	DAS 44406-6 x DAS 81419-2	Herbicide Tolerant	5500/2017 Food and Feed

	Insect Resistant		(Conkesta Enlist E3)	Insect Resistant	
Soybeans 2017	Herbicide Tolerant	Monsanto	MON 87708 x MON 89788 (Xtend)	Herbicide Tolerant	5392/17 Food and Feed
Soybeans 2017	Insect Resistant	Monsanto	MON 87751	Insect Resistant	5398/17 Food and Feed
Soybeans 2016	Herbicide Tolerant	Monsanto	MON 87708	Herbicide Tolerant	5330/17 Food and Feed
Soybeans 2016	Herbicide Tolerant Insect Resistant	Dow Agro Science	DAS 81419-2 (Conkesta)	Herbicide Tolerant Insect Resistant	5148/16 Food and Feed
Soybeans 2015	Herbicide Tolerant	Bayer	FG72 x A5547-127	Herbicide Tolerant	4866/15 Food and Feed
Soybeans 2015	Herbicide Tolerant	Dow Agro Science	DAS 44406-6 (Enlist E3)	Herbicide Tolerant	4867/15 Food and Feed
Soybeans 2015	Herbicide Tolerant	Bayer	FG72	Herbicide Tolerant	4750/15 Food and Feed
Soybeans 2015	Herbicide Tolerant	Dow Agro Science	DAS 68416-4 (Enlist)	Herbicide Tolerant Gluphosinate ammonium	4410/15 Food and Feed
Soybeans 2010	Herbicide Tolerant Insect Tolerant	Monsanto	MON 87701 x MON 89788 (Intacta RR2 PRO)	Glyphosate Herbicide Tolerant Insect Resistant	2542/10 e 7245/2020 Food and Feed
Soybeans 2010	Herbicide Tolerant	Bayer	A2704-12 (Liberty Link)	Gluphosinate ammonium	2286/10 Food and Feed
Soybeans 2010	Herbicide Tolerant	Bayer	A5547-127 (Liberty Link)	Herbicide Tolerant	2273/10 Food and Feed
Soybeans 2009	Herbicide Tolerant	BASF Embrapa	BPS-CV 127-9 (Cultivance)	Herbicide Tolerant Imidazolinone class	2236/09 Food and Feed
Soybeans 1998	Herbicide Tolerant	Monsanto	GTS-40-3-2 (Roundup Ready)	Glyphosate Herbicide Tolerant	Com 54/98 Food and Feed

Source: CTNBio, updated on June 21, 2023

Bean

Crop - Year	Trait Category	Applicant	Event (Commercial Name)	Trait Description
Bean 2011	Disease Resistant	Embrapa	Embrapa 5.1	Resistant to Bean Golden Mosaic Virus

Source: CTNBio, updated on June 21, 2023

Eucalyptus

Crop - Year	Trait Category/Description	Applicant	Event (Commercial Name)	Document number
Eucalyptus 2023	Antibiotic Tolerant	Suzano	1521K059	8093/2023
Eucalyptus 2023	Herbicide Tolerant	Suzano	955P082	8396/2023
Eucalyptus 2023	Herbicide Tolerant	Suzano	955S024	8352/2023
Eucalyptus 2022	Herbicide Tolerant	Suzano	751K022	8281/2022
Eucalyptus 2022	Herbicide Tolerant	Suzano	955S019	8072/2022
Eucalyptus 2021 (pending CNBS decision)	Herbicide Tolerant	Suzano	751K032	7788/2021
Eucalyptus 2015	Growth Increase Increases wood volume	Futuragene	H421	4408/15

Source: CTNBio, updated on June 21, 2023

Sugarcane

Crop - Year	Trait Category	Applicant	Event (Commercial Name)	Document Number
Sugarcane 2022	Insect Resistant	CTC	CTC-92015-7	7988/2022
Sugarcane 2021	Insect Resistant	CTC	CTC95019-5	7482/2021
Sugarcane 2020	Insect Resistant	CTC	CTC79005-2	7246/2020
Sugarcane 2020	Insect Resistant	CTC	CTC75064-3	6827/2020
Sugarcane 2019	Insect Resistant	CTC	CTC93209-4	7140/2020
Sugarcane 2018	Insect Resistant	CTC	CTC91087-6	6235/18
Sugarcan 2017	Insect Resistant	CTC	CTB141175/01-A	5483/17 and 6974/2020

Source: CTNBio, updated on June 21, 2023

Wheat Flour

Crop - Year	Trait Category	Applicant	Event (Commercial Name)	Document Number
Wheat Flour 2023	Herbicide Tolerant	TMG	IND-00412-7	8407/2023
Wheat Flour 2021	Drought Resistance Herbicide Tolerant	TMG	IND-00412-7	7795/2021

Source: CTNBio, updated on June 21, 2023

c) STACKED OR PYRAMIDED EVENT APPROVALS/AUTHORIZATIONS

Stacked events follow the same approval process as single events, as they are treated as new events. In early 2020, CTNBio published Normative Resolution 24, which changed the approval process for stacked events. The resolution aimed 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 could take 2-3 years.

In June 2021, CTNBio revoked this norm by publishing the Normative Resolution 32[6], which is currently in force. For stacked events which have an event that is yet unapproved, the norm remains the same previously explained in Normative Instruction 24. 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 CTNBio. Translation of the articles 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.*

[6] Available in Portuguese at http://ctnbio.mctic.gov.br/resolucoes-normativas/-/asset_publisher/OgW431Rs9dQ6/content/resolucao-normativa-n%C2%BA-32-de-15-de-junho-de-2021?redirect=http%3A%2F%2Fctnbio.mctic.gov.br%2Fresolucoes-normativas%3Fp_p_id%3D101_INSTANCE_OgW431Rs9dQ6%26p_p_lifecycle%3D0%26p_p_state%3Dnormal%26p_p_mode%3Dview%26p_p_col_id%3Dcolumn-2%26p_p_col_count%3D3%26_101_INSTANCE_OgW431Rs9dQ6_advancedSearch%3Dfalse%26_101_INSTANCE_OgW431Rs9dQ6_keywords%3D%26_101_INSTANCE_OgW431Rs9dQ6_delta%3D15%26p_r_p_564233524_resetCur%3Dfalse%26_101_INSTANCE_OgW431Rs9dQ6_cur%3D1%26_101_INSTANCE_OgW431Rs9dQ6_andOperator%3Dtrue

Art. 14. For plant and animal production purposes, CTNBio, under consultation and based in technical criteria, can dispense the analysis and issuance of a new technical opinion of stacked products in which the transformation events that compose it have been previously approved for commercial release by CTNBio (...).

d) FIELD TESTING

In accordance with article 14 of the Law 11105/2005, CTNBio is responsible for granting prior approval for all field trials in Brazil. The technology provider must obtain a Certificate of Quality in Bio Safety (CQBs) from CTNBio 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.

On January 15, 2018, CTNBio published Normative Resolution (NR) 16[7], 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.

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". The list includes the following techniques: 1. Precocious

[7] Available in Portuguese at: http://ctnbio.mctic.gov.br/en/resolucoes-normativas/-/asset_publisher/OgW431Rs9dQ6/content/resolucao-normativa-n%C2%BA-16-de-15-de-janeiro-de-2018?redirect=http%3A%2F%2Fctnbio.mctic.gov.br%2Fen%2Fresolucoes-normativas%3Fp_p_id%3D101_INSTANCE_OgW431Rs9dQ6%26p_p_lifecycle%3D0%26p_p_state%3Dnormal%26p_p_mode%3Dview%26p_p_col_id%3Dcolumn-2%26p_p_col_count%3D3%26_101_INSTANCE_OgW431Rs9dQ6_advancedSearch%3Dfalse%26_101_INSTANCE_OgW431Rs9dQ6_keywords%3D%26_101_INSTANCE_OgW431Rs9dQ6_delta%3D15%26p_r_p_564233524_resetCur%3Dfalse%26_101_INSTANCE_OgW431Rs9dQ6_cur%3D2%26_101_INSTANCE_OgW431Rs9dQ6_andOperator%3Dtrue

flowering; 2. Seed producing technology; 3. Reverse breeding; 4. RNA-dependent DNA methylation; 5.Site-Directed Mutagenesis; 6. Oligonucleotide Directed Mutagenesis; 7. Agroinfiltration/ agroinfection; 8. Topical/systemic use RNAi; and, 9. Viral Vector. 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.

On September 1st, 2022, in a CTNBio meeting, the Commission considered that the editing of the soybean genome, conducted by Embrapa with the CRISPR technique to deactivate some anti-nutritional factors, results in conventional (non-transgenic or not-"genetically modified") soybeans, allowing it to be exempt from biotechnology regulations. More details about this case can be found in this EMBRAPA article[8], available in English. FAS Brasilia has no further information about developments for the other crops.

According to CTNBio Annual Report 2021[9], during the entire year of 2021, the National Technical Biosafety Commission (CTNBio) received 13 consultation letters (versus ten in 2020) under the terms of article two of the referred regulation regarding several products (not listed by CTNBio).

f) COEXISTENCE

There are no new developments in this area.

Law 11105 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 9456 of April 25, 1997[10], 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

[8] https://www.embrapa.br/en/busca-de-noticias/-/noticia/73468020/gene-edited-to-reduce-anti-nutritional-factors-soybeans-get-green-light

[9] Available in Portuguese at; http://ctnbio.mctic.gov.br/en/c/document_library/find_file_entry?p_l_id=583965&noSuchEntryRedirect=http%3A%2F%2Fctnbio.mctic.gov.br%2Fen%2Frelatorios-anuais%2F-%2Fasset_publisher%2FDeibhjOs37Q0%2Fdocument%2Fid%2F2306922%3Fredirect%3Dhttp%253A%252F%252Fctnbio.mctic.gov.br%252Fen%252Frelatorios-anuais%253Fp_p_id%253D101_INSTANCE_DeibhjOs37Q0%2526p_p_lifecycle%253D0%2526p_p_state%253Dnormal%2526p_p_mode%253Dview%2526p_p_col_id%253Dcolumn-2%2526p_p_col_count%253D1&fileEntryId=2306920&redirect=http%3A%2F%2Fctnbio.mctic.gov.br%2Fen%2Frelatorios-anuais%3Fp_p_id%3D101_INSTANCE_DeibhjOs37Q0%26p_p_lifecycle%3D0%26p_p_state%3Dnormal%26p_p_mode%3Dview%26p_p_col_id%3Dcolumn-2%26p_p_col_count%3D1

[10] Available in Portuguese at: http://www.planalto.gov.br/ccivil_03/leis/l9456.htm

2366 of November 5, 1997[11], 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 Resolution 04/07[12], issued by CTNBio, established rules specifically for GE corn, regarding the coexistence of GE and non-GE crops in Brazil.

g) LABELING AND TRACEABILITY

On April 29, 2015, Brazil's House of Representatives approved Draft Bill 4148/2008 to amend the current GE-labeling legislation (Decree 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. Decree 4680/2003[13] remains in force, per the information below.

On April 24, 2003, the President of Brazil published in Brazil's Federal Register ("Diário Oficial") Decree 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 Decree declared that consumers need to be informed of the biotech nature of the product. It applies to bulk shipments, raw material, packaged food, feed, or other products derived from and/or containing ingredients from GE plants.

On December 26, 2003, the Ministry of Justice published Ordinance 2658/03[14], approving the regulations for the use of the transgenic "T" logo, see below.

[11] Available in Portuguese at: http://www.planalto.gov.br/ccivil_03/decreto/1997/d2366.htm
[12] Available in English at: http://ctnbio.mctic.gov.br/en/resolucoes-normativas/-/asset_publisher/OgW431Rs9dQ6/content/resolucao-normativa-n%C2%BA-4-de-16-de-agosto-de-2007?redirect=http%3A%2F%2Fctnbio.mctic.gov.br%2Fen%2Fresolucoes-normativas%3Fp_p_id%3D101_INSTANCE_OgW431Rs9dQ6%26p_p_lifecycle%3D0%26p_p_state%3Dnormal%26p_p_mode%3Dview%26p_p_col_id%3Dcolumn-2%26p_p_col_count%3D3%26_101_INSTANCE_OgW431Rs9dQ6_advancedSearch%3Dfalse%26_101_INSTANCE_OgW431Rs9dQ6_keywords%3D%26_101_INSTANCE_OgW431Rs9dQ6_delta%3D15%26p_r_p_564233524_resetCur%3Dfalse%26_101_INSTANCE_OgW431Rs9dQ6_cur%3D3%26_101_INSTANCE_OgW431Rs9dQ6_andOperator%3Dtrue
[13] Available in Portuguese at: http://www.planalto.gov.br/ccivil_03/decreto/2003/d4680.htm
[14] Available in Portuguese at: https://www.gov.br/agricultura/pt-br/assuntos/insumos-agropecuarios/insumos-pecuarios/alimentacao-animal/arquivos-alimentacao-animal/legislacao/portaria-no-2-658-de-22-de-dezembro-de-2003.pdf/view

Source: Reproduction, Senate

It applies to biotech products for either human or animal consumption, with content above one percent, and does not differentiate between products containing DNA and those that do not. The requirement became effective on February 27, 2004. On April 2, 2004, the Civil Cabinet of the Presidency published Interministerial Normative Instruction 1[15], signed by four cabinet ministers (Civil Cabinet, Justice, Agriculture, and Health), establishing the conditions by which Ordinance 2658/03 enforced the labeling of products containing biotech events above the one percent limit. In addition to the Brazilian Health Regulatory Agency (ANVISA), MAPA, Ministry of Justice, 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

[15] Available in Portuguese at: https://www.gov.br/agricultura/pt-br/assuntos/insumos-agropecuarios/insumos-pecuarios/alimentacao-animal/arquivos-alimentacao-animal/legislacao/instrucao-normativa-interministerial-no-1-de-1o-de-abril-de-2004.pdf

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.

i) LOW LEVEL PRESENCE (LLP) POLICY

Brazil has a zero-tolerance policy for imports of 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[16], 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

[16] Available in Portuguese at: https://www.planalto.gov.br/ccivil_03/leis/l9279.htm

Cade's approval on August 5, 2021. More information on this project, can be found at their website[17], available in Portuguese.

Update on Bayer court cases in Brazil:

In July 2019, Bayer (formerly Monsanto) was required to deposit, in escrow, the full amount of royalties paid by soybean producers 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.

In August 2022, a Mato Grosso judge issued an injunction that Bayer needs to deposit in escrow a third of the total amount it has received in royalties since 2018 for the technology RR2 PRO. The total amount is reaching R$ 2.5 billion (about 470 million dollars). According to Aprosoja, R$ 1.3 billion is owed due to the patent that expired in 2018. However, there is a second patent, expired in December 2020, which – per the Association – would be valued at R$ 1.2 billion. In total, there are three patents that include the Intacta technology.

l) CARTAGENA PROTOCOL RATIFICATION

On August 12, 2020, Brazil´s Official Gazette published Legislative Decree 136[18], 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). Brazil sends delegations to the COP-MOP meetings and serves at the Cartagena Protocol on Biosafety Ad-Hoc Technical Expert Groups (CBD AHTEGs).

[17] https://www.cultivebiotec.com.br/

[18] Available in Portuguese at: https://www2.camara.leg.br/legin/fed/decleg/2020/decretolegislativo-136-11-agosto-2020-790527-norma-pl.html

m) INTERNATIONAL TREATIES AND FORUMS

During a 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. In 2022 and 2023, the working group has not held any meetings.

Brazil is a member of the International Plant Protection Convention (IPPC), where 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 (MRE) at the body. Locally, the GoB has created a coordination body, called "Brazil Codex Alimentarius Coordination," headed by the National Institute of Metrology Standardization and Industrial Quality (Inmetro), and is composed of several government stakeholders, such as MRE, MAPA, the Ministry of Economy, ANVISA, Ministry of Science, Technology, and Innovations, Ministry of Justice, and sector specific confederations such as the industry, the agriculture, and the commerce federations.

Brazil's positions in these international fora are similar to those of the United States. FAS Brasilia 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.

In October 2023, during an official trip to Argentina, the Minister of Science, Technology and Innovation, Luciana Santos, signed a Memorandum of Understanding between Brazil, Argentina, Paraguay and Uruguay, creating the International Network for the Biosafety of Products Derived from Modern Biotechnology, ABRE-Bio. The joint action initiative establishes procedures to reduce cost and time, including GE risk assessment. Moreover, it requires the determination of the regulatory status of products derived from New Breeding Technologies (NBTs) and other products of modern biotechnology. In addition to the MCTI, the network has the participation of Argentina's Ministry of Economy and the Ministries of Agriculture and Livestock of Paraguay and Uruguay.

This scientific-technological cooperation is a pioneering action in the risk assessment of modern biotechnology products, defining a model that can be mirrored in other markets while also benefiting small entrepreneurs.

A Memorandum of Understanding was also signed between Finep, MINCyT and the Argentine agency R+D+i to finance research and development projects of common interest. The MoU also aims to exchange best practices and promote joint activities to improve collaboration between organizations in both countries in RD&I.

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. 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

Public perception regarding GE plants in the country varies by audience. As the second-largest adopter of biotechnology in the world, Brazilian farmers' and ranchers' acceptance of these techniques is very well established throughout the entire country. In 1998, when the first plant approval took place in Brazil – for soybeans – there was a movement against "transgenic" plants. The resistance was stronger from the consumers, which were boosted by campaigns against "genetically modified organisms".

As time passed, acceptance increased, although some concern remains on the consumer side. For instance, 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. FAS Brasilia was unable to find newer research covering biotechnologies acceptance broadly for 2022.

In 2021, Brazil approved the GE drought-resistant wheat in Brazil. In May 2022, the Brazilian Association of Biscuits, Pasta, and Industrialized Breads and Cakes (Abimapi, in its Portuguese acronym) published the results of a December 2021 research conducted to analyze acceptance (or not) to this new variety of wheat amongst consumers. The research showed that 72 percent of the 3135 consumers interviewed said they did not have any major concerns about eating food products produced from the GE wheat. This result was paradigmatic, as it was believed that consumers would not accept it. This result made Abimapi, which originally opposed the approval, to accept it, as the consumers polled in 12 state capitals have demonstrated to be in favor of the product.

From those polled by the research, 1790 people said they know what a transgenic food is and from those, 75.5 percent said they are aware they consume "genetically modified" food (as almost the entirety of soybeans and corn in Brazil is genetically engineered). A small percentage of people said they were unaware they consume genetically engineered food, but once informed, the majority said they would not have a problem with it. From the 1345 consumers who answered they did not know what a transgenic food is, 71.4 percent of them said they would consume it after receiving information. Specifically related to the genetically engineered wheat flour, 71.8 percent of the overall polled consumers said they would not have any restrictions to it being added to food products such as bread, biscuits, pasta, and cakes.

In the past, there were cases of biotechnology industries and research institutions being invaded by opposers in Brazil, such as the 2015 case in which the Landless Movement invaded a research institute and destroyed GE-eucalyptus research plants. This same group also invaded a Bayer site in Jacareí – SP on June 10, 2022 to protest against agrochemicals – but was not able to enter the compound, and only vandalized the exterior of the site. The Brazilian Consumer Defense Institute (IDEC, in its Portuguese acronym) still campaigns against genetically engineered foods, such as in the "No to Transgenic wheat on our bread", which included a petition for signature.

The results of the Abimapi research, however, may indicate that overall consumers perception of genetically engineered plants may be evolving and shifting to a more favorable perspective to biotechnologies.

b) MARKET ACCEPTANCE/STUDIES

There are no new developments in this area.

Acceptance of GE crops in Brazil is widespread among producers. Farmers and ranchers are in favor of biotechnology and understand the benefits associated with the adoption on these new agricultural techniques, such as increased yields, reduced use of crop protection products, and reduced losses due to diseases. In Brazil, 67 percent of GE crop area is used for soybeans, 31 percent is used for corn, 2 percent is used for cotton, and less than one percent of crop area is used for both sugarcane and beans. That number represents 31 percent of the total area of GE crops harvested in the world, according to CropLife Brazil.

The following organizations offer articles/data regarding Brazil-specific studies on the marketing of GE plants and plant products. Nearly all studies are in Portuguese, however, Embrapa has material also available in English:

Brazilian Food Industry Association (ABIA)[19]

Brazilian Agricultural Research Corporation (EMBRAPA)[20]**Error! Hyperlink reference not valid.**

CropLife Brasil (CLB)[21]

Biotec-LATAM[22]**Error! Hyperlink reference not valid.**

[19] https://www.abia.org.br/
[20] https://www.embrapa.br/en/international
[21] https://croplifebrasil.org/
[22] https://biotec-latam.com/en/

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) RESEARCH AND PRODUCT DEVELOPMENT

EMBRAPA has successfully bred GE dairy cattle and has research on recombinant proteins. Two calves born in 2013 are part of this research. Other project focused 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. EMBRAPA Genetic Resources and Biotechnology unit is responsible for animal reproduction, one of the areas most advanced in EMBRAPA in biotechnology. They have developed several techniques and introduced them in the productive sector, such as in vitro fertilization (IVF), transfer, and embryo sexing, amongst others. One of the key areas the unit devotes attention to is cloning by nuclear transfer. 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 deceased Holstein cow and was named "*Lenda da EMBRAPA*" (EMBRAPA's legend). The third clone, Porã, was born in April 2005 from the native cow breed *"Junqu*eira" that is on an endangered species list. The fourth clone, called Piatã, was born in August 2010, is an offspring of Porã, and also from the *Junqueira* cow breed. All these clones had offspring, which demonstrates the good reproductive potential and motherly abilities of the animals used in the process. In 2016, the biotechnology animal reproduction team of the EMBRAPA unit developed a technology called Intrafollicular Transfer of Immature Oocytes (TIFOI, in its Portuguese acronym). This is a biotechnique that resembles IVF but has the additional benefit that it does not need to be performed at a laboratory, so farmers and ranchers can receive the embryos with the same agility as IVF at the comfort of their farms.

EMBRAPA Genetic Resources and Biotechnology unit also works on genetic resources conservation of domestic animals such as cattle, swine, goats, horses, donkeys, and sheep. The conservation is targeted to preserve native species found in Brazil at the time of colonization, to avoid the extinction of species. EMBRAPA started the conservation program in 1983 and has been building the program since. More recently, the unit began conserving wild vertebrate species from Brazil.

b) COMMERCIAL PRODUCTION

In regard to genome edited cattle, CTNBio has evaluated three cases to date (2022) for commercial production. The first case was the 2018 polled bull, from the semen of a Holstein crossbred bull generated by TALENs technology. This hornless dairy cattle from genome-edited cell lines was developed by the company Acceligen in partnership with University of California-Davis. This consultation was later retrieved by the company, as the U.S. Federal Drug Administration detected the presence of plasmid backbone in the bull`s genome. The second case was in 2021 for a double muscle (muscle hypertrophy) bull generated by TALENs technology from a Nelore breed bull semen. The third

case was also in 2021, for an Angus breed bull and cow generated by CRISPR/Cas9 technology. The trait for these two cattle was thermotolerance (slick hair). These three cattle cases were evaluated by CTNBio and were not considered a “genetically modified organism”.

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 58 GE vaccines released by CTNBio for commercial use, 5 microorganisms, and four GE animals.

c) EXPORTS

None for commercial use.

d) IMPORTS

None for commercial use.

e) TRADE BARRIERS

FAS Brasilia 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 are subject to the approval of CTNBio. See Regulatory Framework, under Chapter 1, Part B (Policy) in this report. 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.

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.

A Draft Bill (PLS 73, dated March 7, 2007), which passed the Senate on February 20, 2013, and was sent to the Chamber of Deputies with a new identification (PL 5010/13), hasn’t yet been fully approved by the Brazilian Congress. Bill 5010/13 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. The approval on December 7, 2022, of a version of the bill at the Commission of Agriculture, Livestock, Food Supply, and Rural Development is the last movement of the analysis process.

For a table of legal terms relevant to animal biotechnology in Brazil, see see Chapter 1, Part B, Sub-paragraph A.

b) APPROVALS/AUTHORIZATIONS

GENETICALLY ENGINEERED ANIMALS APPROVED COMMERCIALLY IN BRAZIL

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

Source: CTNBio, updated on May 16, 2023.

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

Product	**Characteristics**	**Company**	***Document/Year***
PUREVAX RCPCh FeLv	Multiple vaccine against feline viral rhinotracheitis, calicivirus, chlamydiosis, panleukopenia and feline leukemia	Boehringer Animal Health do Brasil Ltda.	8431/2023
Yescarta	It is a gene therapy of genetically modified autologous T cells directed to the recognition of the glycoprotein antigen CD19 - marker for neoplastic cells.	Treatment of oncological disease - Relapsed or refractory Large B-Cell Lymphoma and Relapsed or refractory Follicular	8242/2022

		Lymphoma.	
Roctavian	It is a gene therapy vector, incompetent for replication, being an inactive version of a non-pathogenic wild type of adenoassociated virus/serotype 5 (AAV5) that has been modified to contain the factor VIII gene.	Indication: Treatment of severe hemophilia A (congenital factor VII deficiency).	8241/2022
Oncept	Canine melanoma DNA vaccine	Boehringer Animal Health do Brasil Ltda.	8182/22
Vaxxitek HVT + IBD + ILT	Recombinant, frozen live virus vaccine against Marek and Gumboro diseases	Boehringer Ingelheim Animal Health do Brasil Ltda.	7912/22
Ciltacabtagene autoleucel	Commercial Release of ciltacabtagene autoleucel (cilta-cel, JNJ-68284528), indicated for treatment of multiple myeloma	Janssen-Cilag Farmacêutica Ltda	7779/2021
Poulvac Procerta	Poulvac Procerta HVT-IBD – Frozen live vector vaccine against Gumboro and Marek Diseases	Novartis Biociências S.A.	7666/2021
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
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
Covid-19 Vaccine	Commercialization of the Covid-19 vaccine (Ad26.COV2.S1 – recombinant and incompetent replicant), indicated for the active immunization in prevention	Janssen-Cilag Farmacêutica Ltda	7400/2021

	of the disease caused by severe acute respiratory syndrome Ccoronavirus type 2 (SARSCoV-2)		
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
FVAX-20SA01 Vaccine	Specific Vaccine against Strepstococcus for captive-bred tilapia	Tevah Consultoria Empresarial, Regulatória, Governamental e Engenharia Ltda.	7480/2021
CIRCOGARD Recombinant Vaccine	Vaccine against Swine Circovirus Type 2 (PCV2)	Eco Animal Health do Brasil, Comércio de Produtos Veterinários Ltda	7449/2021
G608 Vaccine	Vaccine against Edema Disease in piglets, inactivated	Ceva Saúde Animal	7340/2021
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
CIRCO/MYCOGARD	Recombinant Vaccine against Swine Circovirus and Mycoplasma hyopneumoniae	Eco Animal Health do Brasil, Comércio de Produtos Veterinários Ltda	7239/2020
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
Avian Recombinant Vaccine Code 1A89.R0	Avian Vaccine for the Prevention against Marek Disease, Newcastle Disease	Ceva Saúde Animal LTDA	7055/2020

	and Gumboro Diseas		
Zolgensna	Commercialization of Live Recombinant Vaccine for pediatric patients with Spinal Muscular Atrophy (SMA)	Novartis Biociência S.A.	6495/2020
(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
MHYOSPHERE PCV ID	Commercialization of an innactivated vaccine. The active substance MHYOSPHERE PCV ID is a inactivated recombinant strain of Mycoplasma hyopneumoniae	Hipra Saúde	6910/2020
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
Fostera Gold PCV MH	Innactivated Vaccne Against Pork and Mycoplasma hyopneumoniae	Zoetis Industria de Produtos Veterinários	6221/2018
Avipro Megan VAC 1	Live Vaccine against Salmonella in Broiler chicken	Elanco Saúde Animal	6220/2018
PREVEXXION RN	Vaccine for Marek Diseas in Birds	Merial Saúde Animal Ltda	6162/2018
Avian Recombinant Vaccine Code 1062.R0	Against Marek Disease and Avian Influenza	Ceva	5997/2018
Recombinant Vaccine Against Pork Circovirus type 2	Marek Disease and Avian Influenza	Ourofino Saúde Animal Ltda	*6056/2018*
TROVAC-NDV	Live Recombinant Virus Vaccine for Newcastle Disease and Avian Yaws	Merial Saúde Animal LTDA	*6055/2018*

Ingelvac Provenza	Swine Influenza Live Modified Virus Vaccine	Boehringer	*6062/2018*
Newxxitek HVT+ND	Live Vaccine for Marek Disease, Newscastle Disease – Marek Diases as vector, Serotype 3	Merial	*5861/2018*
INNOVAX ND-IBD	Live Recombinant Vaccine for Marek Disease, Newscastle Disease and Gumboro Disease	Merial	*5836/18*
Purevax Felv	Feline Leukemia Live Vaccine	Merial	*5935/2018*
PROTEQFLU	Equine Influenza Vaccine	Merial	*5486/2017*
PUREVAX RAIVA Vaccine	Feline Raibes Vaccine	Merial	*5407/2017*
Biotech Vac Salmonella Vaccine	Avian Salmonellosis Vaccine	Vetanco do Brasil Importação e Exportação Ltda	*5331/2017*
OncoVEXGM-CSF	Melanomas Treatment	Lab. Bergamo	*5099/2016*
HIPRABOVIS IBR MARKER LIVE	Bovine Herpes Vaccine	Hipra	*5005/2016*
Bay98	Immunostimulant	Bayer	*4915/2016*
Dengvaxia	Dengue Vaccine	Sanofi Aventis	*4759/2015*
Dengue Vaccine 1,2,3,4	Dengue Vaccine	Inst. Butantan	*4673/2015*
Bovela	Bovine Diarrhea	Boehringer	*4594/2015*
B058	Swine Circovirus	Ourofino	*4202/2014*
PRO-VAC Circomaster	Swine Circovirus	Vencofarma	*4090/2014*
Vectormune HVT-LT	Avian Laryngotracheitis Marek Disease, Serotype 3	Ceva	*4304/2014*
ProteqFlu	Equine Influenza	Merial	*3637/2013*
ProteqFlu TE	Equine Influenza and tetanus	Merial	*3636/2013*
InnovaxND	Birds/Marek and Newcastle	Intervet	*3265/2012*
INNOVAX ILT	Birds/Marek and Laryngotracheitis	Intervet	*2872/2011*
Vectormune FP-LT-AE	Avian yaws, avian laryngotracheitis and Avian encephalomyelitis	Ceva	*2958/2011*
Vectormune FP-LT	Avian yaws and avian laryngotracheitis	Ceva	*2957/2011*
PouvacSt	Birds/Salmonellosis	Fort Dodge	*2741/2010*
Vectormune HVT-NDV	Birds/Marek-Newcastle	Ceva	*2279/2010*

Vectormune HVT-IBD	Birds/Marek-Gumboro	Ceva	*2280/2010*
Vectormune **FP-MG+AE**	Birds/Roup-Encephalomyelitis	Ceva	*2226/2009*
Vectormune FP-MG	Birds/Roup-Mycoplasma	Ceva	*2214/2009*
Poulvac	Birds/*E. coli*	Fort Dodge	*2146/2009*
P. Circumvent	Swine/Circovirus	Intervet	*1591/2008*
Ingelvac	Swine/Circovirus	Boehringer	*1427/2008*
Suvaxyn PCV2	Swine/Circovirus	Fort Dodge	*1300/2008*
Vaxxitek MD/IBD	Birds/Marek-Gumboro	Merial	*Com 99/04*
Recombivax	Haemophilus type B and Hepatitis B conjugate vaccine (COMVAX)	Merck Sharp Dhome Farmacêutica Ltda.	*Com 99/00*
Recombitek	Dogs/Viruses	Merial	*Com 38/98*

Source: CTNBio, updated on May 16, 2023

c) INNOVATIVE BIOTECHNOLOGIES

Animal biotechnology has been vigorously evolving 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$9 billion a year, according to EMBRAPA. But there are other problems, such as 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.

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. After the U.S. Food and Drug Administration found a fragment of bacterial DNA used to deliver the hornless trait to the bull in the cow in the States, the company withdrew its application in Brazil. In 2021, other two cattle cases were "non-GMO" by CTNBio, there were myostatin knockout of a Nelore bull, for the double muscle (muscle hypertrophy) trait, and the slick allele Angus cattle to improve heat-tolerance developed via CRISPR/Cas 9.

Another case analyzed by CTNBio was the Nile tilapia generated by CRISPR/Cas9 technology. This tilapia has increased growth rate (to augment fillet yield) and feed conversion and was not considered a "genetically modified organism" in 2019.

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. 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

FAS Brasilia 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.

g) INTERNATIONAL TREATIES AND FORUMS

Brazil is a member of both the Codex Alimentarius (CODEX) and the World Organization for Animal Health (OIE). FAS Brasilia 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

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 (FDA) 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 July 2022, Anvisa has decided that "genetically modified" mosquitos used as control vectors for public health are subject to sanitary regulation, so as to assure the sanitary safety of the use and its efficacy. Anvisa will need to analyze and grant registration of such products after it performs its evaluation of safety and efficacy. The agency is now working a new set of rules under their regulatory agenda on macroorganisms for biological control of vectors and pathogens in the urban environment. On the specific case for the Oxitec mosquito, as it is an innovative and distinct technology from all other products regulated at this point, Anvisa will establish an instrument similar to the RET to regulate the use of this mosquito in research throughout Brazil to produce the scientific evidence needed on its safety and efficacy.

Oxitec also has another *Aedes aegypti* mosquito, a second generation one (OX5034) approved in 2020 by CNTBio, and a *Spodoptera frugiperda* moth (OX5382G) approved in 2021 by CTNBio. Based on this July 2022 decision by Anvisa, FAS Brasilia assumes that the second-generation mosquito and the moth will likely be impacted by the decision, just as the OX513A mosquito. Oxitec has other projects targeted at Brazil in different stages at this point.

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS

FAS Brasilia is not aware of any public studies about producer or consumer acceptance of these new technologies, although genetic engineering has been increasingly used to enhance animal genetics in Brazil.

b) MARKET ACCEPTANCE/STUDIES

FAS Brasilia 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 over 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. FAS Brasilia does not have a list of specific products, quantities, or values exported. FAS Brasilia 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

FAS Brasilia 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.

For a table of legal terms related to microbial biotechnology in Brazil, see Chapter 1, Part B, Sub-paragraph A.

b) APPROVALS/AUTHORIZATIONS

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

Product	**Characteristics**	**Company**	**Document/Year**
Saccharomyces cerevisiae, Linhagens	"Commercial Release of “GMO” Derivative *Yeast Saccharomyces cerevisiae* Strains M32465, M32679 and	Lallemand Soluções Biológicas ltda.	8344/2022

M32465, *M32679* and *M32680*	M32680 to be used in the production of ethanol"		
Saccharomyces cerevisiae GICC03587 (GPY10138)	"Commercial Release of "GMO" Derivative *Yeast Saccharomyces cerevisiae* GICC03587 (GPY10138) developed for ethanol production"	Danisco Brasil Ltda.	8343/2022
Saccharomyces cerevisiae lineage *M12156*	Commercial release of "GMO" *Saccharomyces cerevisae* strain M12156 and derivatives for ethanol production from corn	Lallemand Soluções Biológicas Ltda.	8271/2022
TRP-Prosin	Commercial release of "GMO" derivative TRP-Prosin or dryed *Corynebacterium glutamicum* strain KCCM 80346 for animal feed manufacturing	CJ do Brasil Indústria e Comércio de Produtos Alimentícios Ltda.	8264/2022
Saccharomyces cerevisae lineages M32292, M32376 e M32379	Commercial release "GMO" *Saccharomyces cerevisae* (M32292, M32376 and M32379) for ethanol production from sugarcane	Lallemand Soluções Biológicas Ltda.	8263/2022
Saccharomyces cerevisae lineage *PRCH20080 - FS0436*	Commercial release "GMO" *Saccharomyces cerevisae* strain PRCH20080-FS0436 for ethanol production	Danisco Brasil Ltda.	8243/2022
Saccharomyces cerevisae lineage *Y62840*	Commercial release "GMO" *Saccharomyces cerevisae* strain 62840 for vanillin production	Amyris Biotecnologia do Brasil Ltda.	7978/2022
Saccharomyces cerevisae (SCY014)	*Saccharomyces cerevisae* SCY017 to be used in ethanol production	Novozymes Latin America LTDA	7780/2021
Saccharomyces cerevisae (SCY018)	*Saccharomyces cerevisae* SCY017 to be used in ethanol production	Novozymes Latin America LTDA	7752/2021
Saccharomyces cerevisae (strain Y67383)	*Saccharomyces cerevisae* (Strain Y67383) genetically engineered for steviol glycoside Reb-M production	Amyris Biotecnologia do Brasil LTDA	7663/2021
Saccharomyces cerevisae (SCY017)	*Saccharomyces cerevisae* SCY017 to be used in ethanol production	Novozymes Latin America LTDA	7662/2021
Saccharomyces cerevisae	*Saccharomyces cerevisae* M23541 to be used in corn-based ethanol production	Lallemand Brasil LTDA	7661/2021

M23541			
S.cerevisae (GICC03578 and GICC03588)	Yeast for ethanol production	Danisco Brasil LTDA	7643/2021
Saccharomyces cerevisae M24296	Yeast for corn-based ethanol production	Lallemand Brasil Ltda	7561/2021
Saccharomyces cerevisae – CelluXTM 4	Yeast for ethanol production	BioSpringer do Brasil Indústria de Alimentos S.A.	7481/2021
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
Alpha Amylase enzyme (GICC03561)	Alpha Amylase enzyme (GICC03561)	Danisco Brasil Ltda	7250/2020
Prototheca moriformis Strain S9120	Strain S9120 of the microorganism *Prototheca moriformis*	Corbion Produtos Renováveis Ltda	7205/2020
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
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
Saccharomyces serevisae M15419	Industrial Production of Corn-based Ethanol fuel	Lallemand Brasil Ltda	7059/2020
Derivative of alpha amylase enzyme microorganism	Product derivative from the genetically engineered organism alpha amylase enzyme (GICC03556) destined for the formulation of washing machine and dish washer soaps to assist in the removal of	Danisco Brasil Ltda	7002/2020

(GICC03556)	starch origin stains		
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
Saccharomyces cerevisae (Y63348)	*Saccharomyces cerevisae* genetically engineered (Strain Y63348) and its derivatives	Amyris do Brasil Ltda	6.822/2020
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	6.821/2020
S. cerevisiae (GICC03506)	Yeast for the production of ethanol fuel for the ethanolic fermentation from carbohydrates and grains processing	Danisco Brasil Ltda	6729/2019
Threonym	Derivative ofgenetically engineered microorganism – Granulated Threonym THR Pro (L-Treonina 75%)	CJ do Brasil Industria e Comercio de Produtos Alimentícios Ltda	6623/2019
Substilisin	Derivative of genetically engineered microorganism Substilisin (GICC03528)	Danisco do Brasill Ltda.	6592/2019
Saccharomyces cerevisiae lineage Y47220	Commercial release "GMO" *Saccharomyces cerevisiae* strain Y47220 for the production of steviol and derivatives	Amyris Biotecnologia do Brasil Ltda.	6.551/2019
S. cerevisiae (SCY011)	*Saccaromyces cerevisae* microorganism to be used in the commercial production of ethanol – Lineage SCY011	Novozymes Latin America Ltda	6507/2019
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
Alpha amylase (GICC03469)	"GMO" derivative of alpha amylase (GICC03469)	Danisco	6063/2018
Alpha amylase GICC03515	Commercial release "GMO" derivative alpha-amylase (*Bacillus licheniformis* strain GICC03515) for application in the	Danisco Brasil Ltda.	6.237/2018

	area of cleaning products		
Saccharomyces cerevisiae lineage Y27011	Commercial release of "GMO" Saccharomyces cerevisae strain Y27011 and its derivatives for the production of farnesene	Amyris Biotecnologia do Brasil Ltda.	6.165/2018
B. licheniformis	Alpha amylase of *Cytophaga sp* expressed in *Bacillus lichenifromis*	Du Pont do Brasil	6152/2018
Saccharomyces cerevisiae lineage Y22021	*Saccharomyces cerevisae* Yeast genetically engineered (strain Y22021) and its derivatives	Amyris do Brasil	5827/2018
Saccharomyces cerevisiae lineage SCY010	Commercial release "GMO" *Saccharomyces cerevisiae* strain SCY010 for use in ethanol production	Novozymes Latin America Ltda.	5.941/2018
Hemicellulase	"GMO" derivative of Hemicellulase	Du Pont do Brasil	5798/2018
A-glucosidase	"GMO" derivative of alpha glucosidase	Du Pont do Brasil	5797/2018
GICC03299	"GMO" derivative of a-amylase	Du Pont do Brasil	5496/2017
S1260	*Saccharomyces cerevisae* (S1260) for the comercial production of ethanol.	Novozymes Latin America Ltda	5333/2017
S8885	*Prototheca moriformis* microorganism	Solazyme Brasil Óleos Renováveis e Bioprodutos Ltda	5286/2016
M10682	*Saccharomyces cerevisae* Yeast	Lallemand Brasil Ltda	5285/2016
S8695	*Prototheca moriformis* microorganism	Solazyme Brasil Óleos Renováveis e Bioprodutos Ltda	5238/2016
Derivative	Import of alcaline protease	Du Pont do Brasil	5153/2016
S6697	*Prototheca moriformis* microorganisms for the production of triglycerides e bioproducts.	Solazyme Brasil Óleos Renováveis e Bioprodutos Ltda	4768/2015
S5223	*Prototheca moriformis* lineage S5223 for the production of triglycerides and bioproducts	Solazyme Brasil Óleos Renováveis e Bioprodutos Ltda	4675/2015
Celere-2L	Genetically engineered microorganisms and its derivatives of the biological risk class I	Bio Celere Agroindustrial Ltda	4526/2015
Bioproduct S5223	*Prototheca moriformis* microorganism derivative	Solazyme Brasil Óleos Renováveis e Bioprodutos Ltda	4203/2014
RN1016	Yeast (*Saccharomyces cerevisiae*) lineage genetically engineered for the production of ethanol	Bio Celere Agroindustrial Ltda	3877/2013
S2014	*Prototheca moriformis* for the production	Solazyme Brasil	3775/2013

	of triglycerides and bioproducts	Óleos Renováveis e Bioprodutos Ltda	
Y5056	Yeast (*Saccharomyces cerevisiae*) genetically engineered for the production of Farnesene	Amyris do Brasil	3287/2012
Y1979	Yeast (*Saccharomyces cerevisiae*) genetically engineered for the production of Farnesene	Amyris do Brasil	2281/2010

Source: CTNBio, updated on May 16, 2023.

c) LABELING AND TRACEABILITY

FAS Brasilia 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 Decree 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

FAS Brasilia 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. FAS Brasilia is not aware of any IPR laws or regulations specific to microbial biotechnology products.

g) RELATED ISSUES

FAS Brasilia is not aware of any related issues.

PART I: MARKETING

a) PUBLIC/PRIVATE OPINIONS

FAS Brasilia 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.

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