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Report Highlights:

Brazil is the second-largest producer of biotech crops in the world, with 131 events approved for plants. For the 2024/2025 crop season, FAS Brasilia forecasts 68.5 million hectares planted with GE traits. Adoption rates for soybeans and cotton reached 99 percent and for corn, 95 percent. The biotechnology sector has experienced no significant change to date. Continued use of biotechnology seeds has been a major contributor to yield growth in Brazil since its adoption. 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, 260 applications related to GE organisms approved since the creation of CTNBio in 1998 between plants, animals, and microbial events, only behind the United States. A total of 131 events have been approved since then for plants. This report is separated in three major sections: plant biotechnology, animal biotechnology, and microbial biotechnology. Currently, almost the entirety of the Brazilian soybeans, cotton, and corn productions are genetically engineered, which are major commodities exported by Brazil. Biotechnology in Brazil has been expanding significantly and the perspective is to increase the pipeline of biotech products through investments, research and development, besides the constant support through policies and new companies entering the market.

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 August 2024, the Government of Brazil published a Decree that establishes an Advisory Committee of the Latin American Biotechnology Center (CABBIO in Portuguese), idealized through the Memorandum of Understanding signed in 2023 between the Ministry of Science, Technology and Innovation of the Argentinian Republic, the Ministry of Science, Technology and Innovation of the Federative Republic of Brazil and the Ministry of Education and Culture of the Oriental Republic of Uruguay.

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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), since 2003, benefits from biotech crops in Brazil were US\$26.6 billion, bringing economic advantages to thousands of biotech farmers. Currently in Brazil, foods that contain genetically engineered organisms in their composition are cooking oil; corn flour; cornmeal, ready-made “farofa” (a Brazilian meal made from toasted cassava flour); textured protein; soy sauce; breakfast cereals; ready-made polenta; margarine; mayonnaise; tomato sauce; canned goods; tofu; cake mix; chocolate; chocolate powder; candy; pasta; cookies; cheese; yogurt; and frozen foods.

In November 2023, FuturaGene, Suzano's Biotechnology Division, which is a Brazilian leader company in the renewable farm sector, received CTNBio approval for the world's first combined genetically modified eucalyptus. Herbicide tolerance, it is a new variety of its kind, and the first combined genetically modified eucalyptus approved in the world. The evaluation and approval of this new eucalyptus validates its safety for human and animal health, as well as the environment. The combined genetically engineered eucalyptus will enable increased productivity and more effective use of the herbicides used to control weeds, which will reduce operating costs and increase safety for workers. To obtain the new variety, two genetically modified eucalyptus trees were crossed using classical breeding techniques. The herbicide tolerance trait has a history of more than 25 years of safe use in agricultural crops in different regions of the world.

According to FuturaGene, global wood demand is projected to annually increase from three to ten billion m³ by 2050 to face growing population, diminishing resources and climate change. Moreover, 250 million hectares of new forests would need to be added to the current 264 million hectares without degrading natural forests in an irreparable way. Thus, biotechnology is key to sustainably intensifying wood production. Technologies of FuturaGene are applicable not only to the forestry, but also to biofuels, biochemical and biomaterial sectors. The key crop of the company is the sub-tropical eucalyptus. However, within the renewable wood-based goods, production includes pulp, paper, wood panel, and furniture. Within biofuels, cellulose is used to produce ethanol and products from biochemicals and biomaterials include fibers and fabric fossil fuel replacement for plastics. After large-scale tests, partners will have free access to the technology without the need to pay royalties, as is traditionally done.

A case that is currently in the testing phase is a GE variety of wheat that is drought tolerant and expresses the HB4 sunflower gene. CTNBio's approval occurred 2021, which allowed for the world's first occurrence of commercial trade and production of a GE wheat variety. Such phase includes Embrapa's evaluation of the benefits and limitations of such wheat variety production in Brazil. Further commercial approval of transgenic wheat (HB4) by farmers in the Brazilian national territory by CTNBio occurred in 2023 and the initial results of the research are likely to be available in two years. 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. According to Post contacts, HB4 is of very good quality and is largely used for animal fodder and

commercial bakery. It brings a peculiar interest in the Brazilian Central-West, since there is a lot of irrigated wheat due of long periods of drought.

b) COMMERCIAL PRODUCTION

CTNBio data from 2024 shows there are 131 GE events approved for plants commercial cultivation in Brazil, of which 64 events are for corn, 25 for cotton, 22 for soybeans, 7 for sugarcane, 10 for eucalyptus, 1 for a virus-resistant variety dry edible bean, and 2 for wheat HB4. According to post contacts, the logic of soybean and corn production is different. Soybeans has closed pollination, maintaining the seed characteristics, whereas corn is more complex as the seeds are not kept. Good genetics, which brings high productivity, are considered hybrid corn, with more than one variety. Once planted, the seed is highly pollinated. When this is the case, the genome is diluted, and the hybrid vigor is lost, since it mixes with other plants, losing its premium characteristic. Thus, the normal practice is to buy seed every season. It's also important to highlight that the seed goes through drying and storage process, with lower germination rate, whereas the grain is the product harvested, not favorable for germination and with stricter rules for commercialization.

Latin America comprises 45 percent of the world's sown area with transgenic crops, according to Biotec-Latam. Out of the 19 Latin American countries, ten have adopted GM crops being Brazil the largest in Latin America and the second largest worldwide. Brazil accounts for above 30 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. For 2023/2024 season, Post forecasts 68.5 million hectares planted with GE traits. 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](https://biotec-latam.com/en/)¹ reports the following adoption rates in Brazil according to latest data available:

- Soybeans: The adoption rate of GE soybean seeds is 99 percent.
- Corn: The adoption rate of GE corn seeds is 97 percent.
- Cotton: The adoption rate of GE cotton is 99 percent.
- Sugarcane: The adoption rate of GE sugarcane is 0.45 percent.
- Dry Edible Beans: the adoption rate of GE dry edible beans is 0.17 percent.
- Eucalyptus: Although recently approved, GE eucalyptus is not yet commercially cultivated.

According to Post contacts, despite forty years of biotechnology study worldwide in cotton plants, there has been no solution for cotton boll weevil, a cotton pest.

c) EXPORTS

According to CEPEA, Brazilian agribusiness GDP fell by 2.2 percent in the first quarter of 2024. Based on this performance, the GDP of Brazilian agribusiness was BRL2.45 trillion (USD435 billion) in 2024, of which BRL1.65 trillion (USD 293 billion) in the agricultural sector and BRL801 billion (USD 142

¹ <https://biotec-latam.com/en/>

billion) in the livestock sector. Therefore, it is estimated that the sector's share of the economy will be close to 21.5 percent in 2024, down from the 24 percent recorded in 2023.

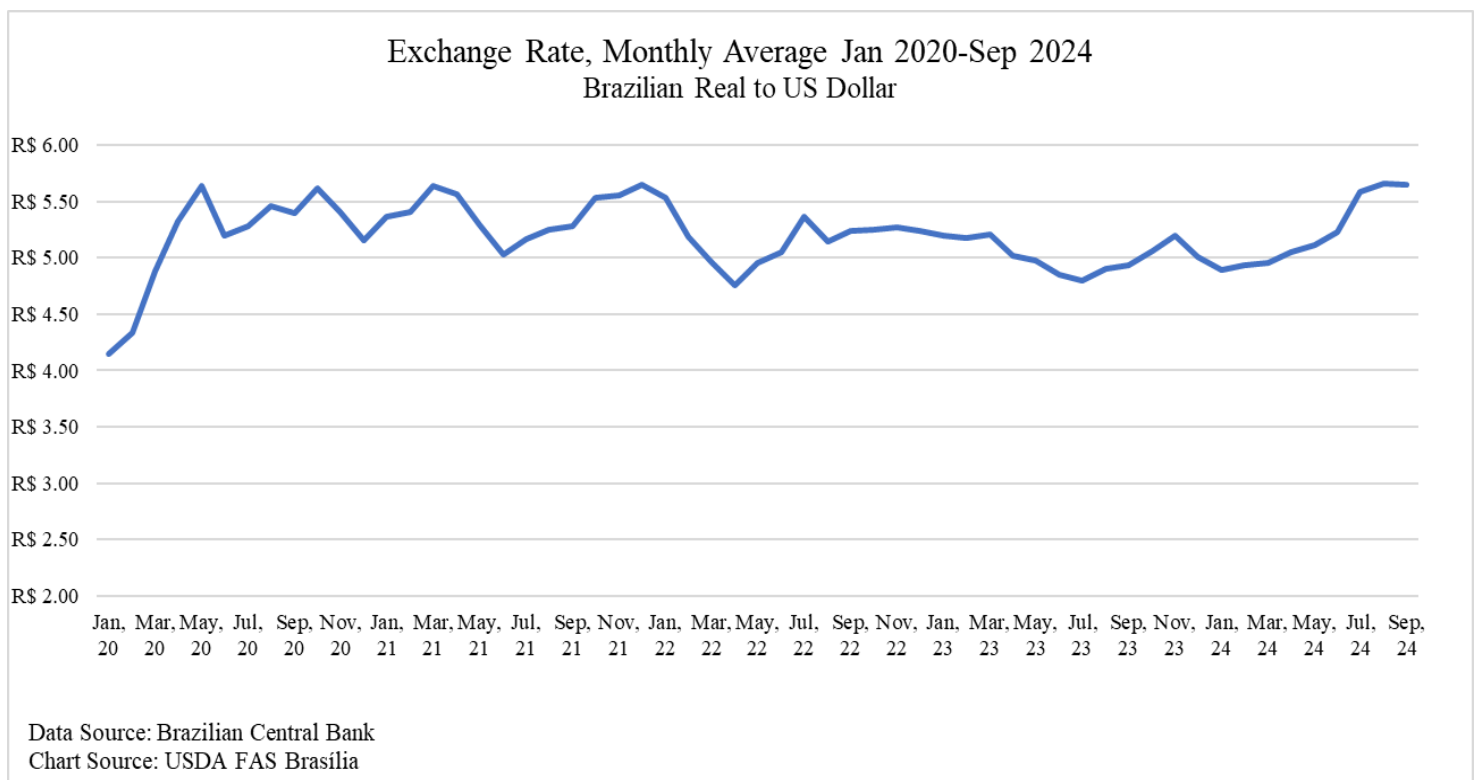
Lower prices and a drop in production impacted the performance of agribusiness to several products. CEPEA also informs that under the sector's segments, the GDP of inputs and the primary sector shrank. This impacted productivity due to prices devaluation of crucial commodities: cotton, coffee, corn, soybeans, wheat, beef and dairy cattle, pig, and by the projection of a retraction in annual production. According to Post contacts, seed business in Brazil is segmented and producers license technologies from the industry to incorporate them for commercialization.

Brazilian main export products comprise soybean and its byproducts, such as, but not limited to petroleum, iron ores, cellulose, maize, beef, chicken, sugar, orange juice, cotton, tobacco, and coffee. 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 to other Asian countries. Corn exports are mainly bound for China, followed by Egypt, Iran, Algeria, and Vietnam. Brazil is also an exporter of conventional soybeans, mainly to China, European Union and Asian countries.

d) IMPORTS

The value of the Brazilian domestic currency keeps devalued as shown on the graphic below.

Figure 1:
Exchange Rate



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.

Normative Instruction 32 has effectively guaranteed since 2021 that imported corn from the United States can be quickly approved for food and feed uses in Brazil.

e) FOOD AID

As already informed in the previous report, in Brazil, food aid for humanitarian purposes is governed by Law 12429 of 2011, amended by Law 13001 of 2014. Per the law, there's a list of specific countries from Central and South America, Europe, Africa, and Asia that can receive Brazilian humanitarian food. It's a joint work between the Brazilian National Supply Company (CONAB), which administers the program, and the Brazilian Ministry of External Affairs, which in turn works with the United Nations World Food Program and determines how much and where to donate. 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.

Nevertheless, donation of food to other countries occurs if it does not jeopardize assistance to populations victimized by adverse socio-natural events in Brazilian territory, and occurs in cases of socio-environmental disasters, catastrophes, public calamities and food and nutritional insecurity. In April to May 2024, Brazil faced a disaster in the state of Rio Grande do Sul. Storms and torrential rain battered the state, causing deadly, destructive flooding. In April 2024, CONAB and cooperatives donated more than thirty tons of food in Porto Alegre, capital of Rio Grande do Sul. In a May-2024 joint action with CONAB, the Ministry of Development and Social Assistance mobilized millions of reais (Brazilian currency) to purchase 97,000 units of food baskets for distribution to municipalities in Rio Grande do Sul in an emergency situation recognized by the Federal Government.

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. In 2023, PAA project applications from family farming associations and cooperatives totaled around BRL1.1 billion (USD 195 million), with more than 3,700 proposals submitted. To carry out these projects, CONAB received the largest amount of funds in the history of the Program from the Federal Government, around BRL712 million (USD126 million).

f) TRADE BARRIERS

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

PART B: POLICY

a) REGULATORY FRAMEWORK

The governmental ministries and regulatory agencies that regulate biotechnology in Brazil are 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 one with different roles in the regulation. Under the MCTI falls the National Technical Biosafety Commission (CTNBio), the multidisciplinary collegiate body that performs safety assessments of biotechnologies in Brazil. 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.

Law [11105/2005](#)² is the overarching regulatory framework on biotechnologies, further regulated by [Decree 5591 of November 22, 2005](#)³. Minor amendments to the second biosafety law are present in Law 11460 of 2007, but the most up-to-date version of Law 11105/2005 is available in Portuguese in [this link](#)⁴, compiling all changes made to it after its publication.

All legislation related to biotechnology, including several other pieces that compose the entire regulatory framework is compiled by CTNBio at the [Norms and Laws](#)⁵ link on their website and is available in Portuguese and some in English. Prior to its use, the product needs to abide by all applicable regulations by the different governmental bodies.

The two main governing bodies regulating agricultural biotechnology in Brazil are the National Biosafety Council (CNBS, in Portuguese), which falls under the Office of the President and is responsible for the formulation and implementation of the national biosafety policy in Brazil; and the National Technical Biosafety Commission (CTNBio), initially established in 1995 under the first Brazilian biosafety law (Law 8974/1995). CNBS considers all approvals of biotech events by CTNBio as conclusive. Currently, there are 27 board members working on a case-by-case basis approval.

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. The same applies to GE plant products considered living versus non-living. Article 3 of the Biosafety Law of 2005 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 the abovementioned article establishes that results from direct introduction techniques into an organism, such as in vitro fecundation conjugation, transduction, transformation, polyploid induction and any other natural process are not considered GMO; neither is a GMO by-product a chemically defined pure substance obtained from biological processes that do not contain GMOs, heterologous protein or recombinant DNA.

² Available in Portuguese at https://www.planalto.gov.br/ccivil_03/_Ato2004-2006/2005/Lei/L11105.htm

³ 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

⁴ http://www.planalto.gov.br/ccivil_03/_Ato2004-2006/2005/Lei/L11105.htm#art42

⁵ <http://ctnbio.mctic.gov.br/normas-e-leis>

The scope of CTNBio defines what applications are eligible for submission to get approval, authorization, and risk analysis evaluation. It is required from the applicants supporting data to the safety of the product. Commercial plant approvals do not have an expiration date, but it is important to note that approvals can be reviewed upon new scientific data reported by the applicant or by scientific literature. Further information on biotechnological legislation in Brazil can be found at the previous biotechnology report [in this link](#).

Since 2021, CTNBio has approved 7 new resolutions, and focused on resolutions 32, 35, and 38. [Resolution 38](#)⁶, published on September 27, 2023, facilitates cooperation between CTNBio and its counterparts in foreign countries, including coordination on approvals with Argentina.

A recent regulation from CTNBio was published on April 29, 2024. [CTNBio Normative Resolution 40](#)⁷ amends CTNBio Normative Resolution 2, of November 27, 2006, which provides for the classification of risks of Genetically Modified Organisms (GMOs) and the biosafety levels to be applied in activities and projects with GMOs and their derivatives in containment. The Resolution is now in force with the following amendment: “windows or side and roof structures can be opened for ventilation and must have mechanisms to prevent pollinators from entering when the plants are in the reproductive stage. In the case of allogamous, anemophilous or zoophilous plants in the reproductive stage, pollen dispersal must be prevented by protecting the reproductive structures or by physical barriers. When producing seedlings only in the vegetative stage and without the possibility of flowering, pollen barriers or anti-aphid screens are not required”.

There is proposed regulation [PL 6432/2013](#) to prohibit in Brazil the sale, cultivation and importation of seeds of transgenic food plants with tolerance to herbicides. In addition, the proposal includes a ban on the import of food products, both fresh and processed, derived from those plants. The last movements on this were in 2015, but the approval of the law would be a bottleneck for the biotechnology sector, according to Post contacts.

Considering the approved materials by CTNBio, almost 50 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.

Brazil’s Review Process for GE Products

When CTNBio received the proposal, the Executive Secretariat has 30 days to check required documentation. After that period, the various applications have different deadlines for analysis determined in CTNBio's normative resolutions. However, other variables, such as a confidentiality analysis, technical diligence, public consultation and CTNBio deliberations, can extend the initial deadline.

⁶ Available in Portuguese at

https://antigo.mctic.gov.br/mctic/opencms/legislacao/outros_atos/resolucoes/Resolucao_Normativa_CTNBio_38_de_27092023.html#:~:text=Art.%201%C2%BA%20Esta%20Resolu%C3%A7%C3%A3o%20Normativa%20estabelece%20os%20procedimentos%20para%20o

⁷ Available in Portuguese at <https://ctnbio.mctic.gov.br/comunicados1/->

[/asset_publisher/Uht2qGSWGC8b/content/resolucao-normativa-n%C2%BA-40-de-29-de-abril-de-2024#:~:text=Alterar%20a%20Resolu%C3%A7%C3%A3o%20Normativa%20CTNBio%20n%C2%BA](https://ctnbio.mctic.gov.br/comunicados1/-/asset_publisher/Uht2qGSWGC8b/content/resolucao-normativa-n%C2%BA-40-de-29-de-abril-de-2024#:~:text=Alterar%20a%20Resolu%C3%A7%C3%A3o%20Normativa%20CTNBio%20n%C2%BA)

For commercial releases, CTNBio's Internal Regulations and Normative Resolution No. 5, related to Commercial Release, set a deadline of 90 days for approval or rejection. For Biosafety Quality Certificate grants, Normative Resolution No. 1 sets a deadline of 120 days to either review, extend, suspend or cancel the certificate. In the case of planned releases, the Normative Resolutions are No. 6, which sets out the rules for the planned release into the environment of GMOs, and No. 8, which sets out simplified rules for such release, as well as a time limit of 90 days for analyzing applications.

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 <i>Agrobacterium</i> 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 desoxirribonucleico - ADN, ácido ribonucleico - 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 synthesized 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 promoters 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	Herbicide	Dow	DAS-21023-5 x	Herbicide	6657/2019

2019	Tolerant/Insect Resistant		DAS – 24236-5 x SYN-IR102-7 x DAS-81910-7	Tolerant Insect resistant	Textile Fibers Food and Feed
Cotton 2018	Herbicide Tolerant Insect Resistant	Monsanto	COT102 x MON15985 x MON88913 x MON88701 (BGIIIRRFlexDGT)	Herbicide Tolerant, Insect Resistant	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 (BGIIIFlex)	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 2011	Herbicide Tolerant Insect Resistant	Bayer	T 304-40 x GHB 119 (TwinLink)	Gossypium hirsutum L.	2795/11 Textile Fibers Food and Feed
Cotton 2010	Herbicide Tolerant	Bayer	GHB 614 (GlyTol)	Gossypium hirsutum L.	2754/10 Textile Fibers Food and Feed
Cotton 2009	Herbicide Tolerant Insect Resistant	Monsanto	MON 531 x MON 1445 (Round Ready BGR)	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 July 17, 2024

Corn

Crop - Year	Trait Category	Applicant	Event (Commercial Name)	Trait Description	Document Number/ Uses within Brazil
Corn 2024	Herbicide Tolerant	Corteva Agriscience	DAS1131	Tolerant to herbicide glyphosate	8949/2024
Corn 2023	Herbicide and insect tolerant	Monsanto	MON 94804	Insect resistant and herbicide tolerant	8779/2023
Corn 2023	Herbicide Tolerant	Corteva Agriscience	DP-91Ø521-2; DP-91Ø521	Protection against certain susceptible lepidopteran pests and tolerance to herbicide	8778/2023

				glufosinate	
Corn 2023	Herbicide Tolerant	Corteva Agriscience	DP-2Ø2216-6	Herbicide Tolerant glufosinate ammonium	8693/2023
Corn 2023	Insect Resistant	Monsanto	MON 95275	Insect Resistant	8544/2023 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 2020	Herbicide Tolerant	DuPont	NK603 x T25 x DAS-40278	Herbicide Tolerant	6797/2020 Food and Feed
Corn 2019	Herbicide Tolerant	Monsanto	MON 87427 x MON89034 x MIR162 x NK603 (and undercombinations)	Herbicide Tolerant	6519/2019 Food, Feed, Imports
Corn 2019	Herbicide Tolerant Insect Resistant	Monsanto	MON 87427 x MON87419 x 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	Drought Stress	Monsanto	MON87460	Approved only	5224/16

2016				for human and animal food	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 Restoration	Du Pont	SPT 32138 (32138 Mantenedor SPT)	Fertility Restoration	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 MIR162	Herbicide Tolerant Insect	4465/15 Food, Feed, Imports

			Undercombinations approved and already referred previously	Resistant	
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 Tole rant 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	Herbicide Tolerant	Monsanto	NK 603	Glyphosate	1596/08

2008			(Roundup Ready 2)	Tolerant	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 July 17, 2024

Soybeans

Crop - Year	Trait Category	Applicant	Event (Commercial Name)	Trait Description	Document Number/Uses within Brazil
Soybeans 2024	Herbicide Tolerant	BASF	GMB151 and DAS-444Ø6-6	Resistant to plant-parasitic nematodes and tolerant to HPPD-inhibiting herbicides; tolerant to glyphosate herbicides and tolerant to 2,4-D herbicide	8870/2024
Soybeans 2023	Herbicide Tolerant	Tevah Consultoria	DBN-09004-6	Tolerance to glyphosate and glufosinate ammonium herbicides	8777/2023
Soybeans 2023	Insect Resistant	Monsanto	MON 94637	Insect Resistant	8762/2023
Soybeans 2023	Glyphosate herbicide resistance	GDM	GTS 40- 3-2 x A5547-127 (Roundup Ready)	Glyosphate 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	Herbicide Tolerant Insect	5832/18 Food and Feed

			MON89788	Resistant	
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 Insect Resistant	Dow	DAS 44406-6 x DAS 81419-2 (Conkesta Enlist E3)	Herbicide Tolerant Insect Resistant	5500/2017 Food and Feed
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 July 17, 2024

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 July 17, 2024

Eucalyptus

Crop - Year	Trait Category/Description	Applicant	Event (Commercial Name)	Document number
Eucalyptus 2024	Increased productivity, herbicide tolerant to glyphosate and insect resistant	Suzano	H421 x 955S024 x 1521K059	9117/2024
Eucalyptus 2024	Increased productivity, herbicide tolerant to glyphosate and insect resistant	Suzano	H421 x 955P082 x 1521K059	8960/2024
Eucalyptus 2023	Tolerant to herbicide glyphosate; resistant to antibiotics	Suzano	H421 x 751K032	8780/2023
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 July 17, 2024

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
Sugarcane 2017	Insect Resistant	CTC	CTB141175/01-A	5483/17 and 6974/2020

Source: CTNBio, updated on July 17, 2024

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 July 17, 2024

c) STACKED OR PYRAMIDED EVENT APPROVALS/AUTHORIZATIONS

As previously informed, CTNBio published in 2021 [Normative Resolution 32](#)⁸ establishing that for food and feed, CTNBio no longer will need to evaluate combined events obtained from conventional breeding of single events.

⁸ 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

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 (CQB) 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. [Normative Resolution \(NR\) 16](#)⁹ establishes the requirements to evaluate Precision Breeding Innovation (TIMP, in Portuguese) and encompasses genome edited products. CTNBio exempts genome edited products from regulation when there is no insertion of transgenes. Specialists consider this a hybrid system, focusing mainly on the characteristics and safety of the final product. NR 16 contains an annex with a list of genetic engineering procedures that may create a product not considered a "GMO". An informal translation of NR 16 in the appendix of this report.

The Brazilian agricultural research service (EMBRAPA) is developing projects using clustered regularly interspaced short palindromic repeats (CRISPR) technology. It is a technology that scientists use to selectively modify the DNA of living organisms. In Brazil, such technology has been in use since 2018, in four crops: soybeans, corn, edible beans, and sugarcane. It was adapted for use in the laboratory from naturally occurring genome editing systems found in bacteria.

On September 1st, 2022, CTNBio considered 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.

CRISPR-Cas9 genome editing has been used to modify a variety of crops in Brazil, such as sugarcane, soybean, corn, and yeast. Such editing is a type of immune system discovered in bacteria. According to Post contacts, CRISPR-Cas9 can be used to precisely target nearly any gene. Scientists have adapted its components into a biotechnology tool for editing DNA. It's made up of a DNA-cutting enzyme (Cas9) and a programmable RNA molecule.

⁹ 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

A world leader in sugarcane science, the Sugarcane Technology Center (CTC in Portuguese) announced in June 2024 a partnership with Ginkgo Bioworks (NYSE-DNA), a US genetic engineering company, to discover and optimize new molecules for the control of relevant sugarcane pests. The CTC will take advantage of Ginkgo's extensive bioinformatics experience, which allows it to rapidly design and build thousands of new molecules. The aim is to discover molecules capable of effectively controlling the pests of interest. The CTC will then apply its knowledge of sugarcane biotechnology to design and develop innovative products with optimum protection against those pests, providing producers with a long-lasting management solution.

CTC also announced in September 2024 a partnership with Israeli company PlantArcBio (PAB in Portuguese) to develop pest-resistant sugarcane in a collaboration of research and development. The company is specialized in the discovery of genes and biological components to improve the characteristics of agricultural crops. The aim is to discover new molecules and harness technologies to biologically control sugarcane pests.

f) COEXISTENCE

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](#), 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 2366 of November 5, 1997](#)¹⁰, established the National Plant Varieties Protection Service under MAPA and regulates the registration of GE and non-GE seeds. [Normative Resolution 04/07](#)¹¹, issued by CTNBio, established rules specifically for GE corn, regarding the coexistence of GE and non-GE crops in Brazil.

g) LABELING AND TRACEABILITY

[Decree 4680/2003](#)¹² established only products that have more than one percent GE material in their final composition must be labeled, including food and food ingredients destined for human or animal consumption containing or being produced with biotech events. Another important item is the decision to withdraw the requirement for a GE label of a “T” symbol in black in a yellow triangle, established in

¹⁰ Available in Portuguese at: http://www.planalto.gov.br/ccivil_03/decreto/1997/d2366.htm

¹¹ 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

¹² Available in Portuguese at: http://www.planalto.gov.br/ccivil_03/decreto/2003/d4680.htm

2003 by [Ordinance 2658/03](#)¹³. The withdraw requirement [PLC 34/2015](#)¹⁴ is still under consideration in the Brazilian Senate and the last movements on it were in December 2023 to be resumed, but no further steps were taken until. Thus, the referred Decree remains in force, and it applies to bulk shipments, raw material, packaged food, feed, or other products derived from and/or containing ingredients from GE plants. The content above one percent does not differentiate between products containing DNA and those that do not. The requirement became effective on February 27, 2004.

Figure 2:
Brazilian supermarket showing the GE label “T”



Source: FAS Brasilia

h) MONITORING AND TESTING

CTNBio’s obligations include case-by-case risk assessments of activities and projects concerning GE crop events and their by-products, to authorize GE crop research activities. It also identifies 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 on environmental permits, as well as cases that may cause environmental degradation.

According to the legislation MAPA oversees inspection of these events intended for agriculture, animal use, and related fields in the agricultural industry. The National Surveillance Agency (ANVISA) inspects the events for toxicology, while the Ministry of the Environment - through the Brazilian Institute of Environment and Renewable Natural Resources (IBAMA) - monitors and inspects the events and their impact on the environment.

¹³ Available in Portuguese at: <https://www.gov.br/agricultura/pt-br/assuntos/insumos-agropecuarios/insumos-pequenos-alimentacao-animal/arquivos-alimentacao-animal/legislacao/portaria-no-2-658-de-22-de-dezembro-de-2003.pdf/view>

¹⁴ Available in Portuguese at <https://www25.senado.leg.br/web/atividade/materias/-/materia/120996>

i) LOW LEVEL PRESENCE (LLP) POLICY

Low Level Presence is incidental presence of GE material not yet approved in food, feed or grain at reduced levels. According to Post contacts, the percentage level is not defined and even the concept is not recognized worldwide. If it was, it could benefit industry, growers and sustainable agriculture, since it would speed up the offer of new technologies. Mercosur is the only region that has approved this non-implemented system that should be recognized and replicated in other regions.

CTNBio has not recognized low level presence, despite the note on the subject published by Mercosur, allowing it on food and crops in the provisions of the EU-Mercosur agreement. CTNBio claims that there is no legal provision for low level presence

j) ADDITIONAL REGULATORY REQUIREMENTS

An event approved by CTNBio requires no further review.

k) INTELLECTUAL PROPERTY RIGHTS (IPR)

In Brazil, intellectual property rights for biotechnology are covered under the Industrial Property Law, [Law 9279](#)¹⁵, 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.

The project “*Cultive Biotec*” (Cultivate Biotech), created by BASF, Bayer, Corteva, and Syngenta in 2021, an initiative to promote a collective management model for the recognition of intellectual property is active and open to any companies that provide biotechnology products protected by intellectual property rights intended to commercialize their products in the Brazilian market. It develops a collective industry solution, creating a structured environment for the recognition of intellectual property rights and allowing new soybean biotechnologies to enter the Brazilian market. More information on this project, can be found at their [website](#)¹⁶, available in Portuguese.

Regarding Bayer court case in Brazil highlighted in the previous report, in August 2022, a Mato Grosso judge had issued an injunction that Bayer would need to deposit in escrow a third of the total amount it has received in royalties since 2018 for the technology “Intacta RR2 PRO”. According to Aprosoja, the Association of Soybean and Corn Producers of Mato Grosso, BRL 1.3 billion (USD 230 million) was 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 BRL 1.2 billion (USD 213 million). In total, there are three patents that include the Intacta technology. On March 12, 2024, the Brazilian Federal

¹⁵ Available in Portuguese at: https://www.planalto.gov.br/ccivil_03/leis/l9279.htm

¹⁶ <https://www.cultivebiotec.com.br/>

Supreme Court rejected the appeal against the decision of the Court of Justice of Mato Grosso, a decision that benefits soybean producers. The lawsuit that questioned the payment of royalties was filed in the state court by Aprosoja. The Intacta RR2 PRO technology is applied for soybeans developed for the Brazilian market that are resistant to caterpillars and tolerant to glyphosate, one of the most widely used pesticides in the country. Bayer's patent expired in 2018 was charged as an extension request had not yet been analyzed by the Brazilian National Institute of Industrial Property (INPI).

l) CARTAGENA PROTOCOL RATIFICATION

[Legislative Decree 136](#)¹⁷ 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. Brazil ratified the United Nations' Cartagena Protocol on Biosafety in 2003, 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).

m) INTERNATIONAL TREATIES AND FORUMS

During a meeting of the U.S.-Brazil High Level Working Group in April 2024, both sides noted their strong partnership and biotechnology's important role in confronting challenges related to food security and climate change. Highlights include Brazilian work with Argentina regarding biotech approvals; coexistence of measures in Brazil; and further biotech discussions under the OECD works.

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, represented by the Ministry of External Relations (MRE) at the body. Locally, the Government of Brazil (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.

Historical initiatives that Brazil has in bilateral cooperation include the Latin American Biotechnology Center (CABBIO) which emerged as the Argentine-Brazilian Center thirty years ago, and the Brazilian-Argentine Nanotechnology Center, CBAN. 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.

¹⁷ Available in Portuguese at: <https://www2.camara.leg.br/legin/fed/decleg/2020/decretolegislativo-136-11-agosto-2020-790527-norma-pl.html>

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 MCTI, the network has the participation of Argentina's Ministry of Economy and the Ministries of Agriculture and Livestock of Paraguay and Uruguay. The CABBIO Advisory Committee was finally created through the publication of [MCTI Ordinance 8425](#)¹⁸ on August 12, 2024. The Committee has a consultative nature and is headquartered at the Ministry of Science, Technology and Innovation. The Committee is responsible for taking a stand on the technical-scientific feasibility and cost-benefit ratio of research, development and innovation (RD&I) projects and short courses to be submitted to the CABBIO Board of Directors.

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 is a driving force behind enhanced collaboration. Asynchronous approvals are a relevant issue for biotech companies in Brazil. According to Post contacts, this is a subject that has already been discussed with five countries in the Americas: United States, Canada, Brazil, Argentina, and Mexico. The issuing of Biosafety certificates from China for grain import, such as soybeans and corn for food and feed in China has no predictability, which creates a non-tariff barrier by the importing country, postponing the launch of new technologies.

Other concerns of the biotech sector include revision of the Plant Variety Protection Legislation in Brazil; Maximum residue level (MRL); and simplification of the international movement of seeds.

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS

The worldwide perception shows divided opinions on genetically engineered food. A study published in the American Journal of Polymer Science and Technology, entitled as “Review on: Public Perception of Biotechnology on Genetically Modified Crops, Bio Policy and Intellectual Property Rights” provides a general view in the five continents:

1. America: in North America, GE food is considered important for national food security and in Latin America a context-dependent acceptance of GE
2. In Europe, people’s reluctant attitude towards GE has reduced
3. In Africa, awareness and perception of GE crops is at low level
4. In Asia, there are varying degrees of public acceptance and perception of GE
5. In Oceania, more specifically Australia and New Zealand, there’s willingness to purchase GE food if it is cheap or environmental friendly

¹⁸ Available in Portuguese at

https://antigo.mctic.gov.br/mctic/opencms/legislacao/portarias/Portaria_MCTI_n_8425_de_12082024.html#:~:text=Portaria%20MCTI%20n%C2%BA%208.425,%20de%2012.08.2024.

Despite the large acceptance regarding GE plants, Brazilian public perception varies by audience. Considering the large adoption of biotechnology in the country, Brazilian farmers' and ranchers' acceptance of these techniques is very well established throughout the entire country.

There was a larger movement against “transgenic” plants by the consumers in 1998 but as time passed acceptance increased, although some concern remains on the consumer side. A poll conducted in 2016 regarding public perceptions of GE products concluded that 80 percent of Brazilians were concerned with the word “*transgenic*,” and that 33 percent of Brazilians think that consuming these products can do harm. 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 to a new variety of wheat amongst consumers. The research showed that 72 percent claimed no major concerns.

In 2024, two different public perceptions assured the current wide acceptance. Thousands of people from almost all Brazilian states answered a questionnaire including several issues regarding lettuce consumption, according to the study “Public perception of folate-biofortified genetically modified lettuce varieties in Brazil”. When informed that the folic acid biofortified lettuce is a transgenic plant, 46.1 percent stated that they would eat it and 30.5 percent stated that they possibly would. As long as people are well informed, biotechnology is wide accepted. Once the respondents learned on the advantage of the enrichment with folic acid, the number of positive responses increased.

The same study referred to in the first paragraph of this subchapter informs that in Brazil genetic modification for drug and vaccine production is more widely accepted (87%) than for crops (81%) or food (66%).

b) MARKET ACCEPTANCE/STUDIES

Acceptance of GE crops in Brazil is widespread among producers in support of new agricultural techniques, such as increased yields, reduced use of crop protection products, and reduced losses due to diseases. According to CropLife Brazil, in the last 40 years, Brazil has increased agricultural production by 503 percent, productivity has grown by 216 percent and planted area by only 93 percent.

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 \(ABIA\)](https://www.abia.org.br/)¹⁹

[Brazilian Agricultural Research Corporation \(EMBRAPA\)](https://www.embrapa.br/en/international)²⁰ **Error! Hyperlink reference not valid.**

[CropLife Brasil \(CLB\)](https://croplifebrasil.org/)²¹

[Biotec-LATAM](https://biotec-latam.com/en/)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

The Brazilian body responsible for animal biotechnology is Embrapa. Successful cases include two calves born in 2013; GE technology to improve the health of beef cattle and increase cattle weight; two GE goats, along with the University of California at Davis, produced in the state of Ceará with effective protein in treating diarrhea in young pigs.

Embrapa Genetic Resources and Biotechnology unit is responsible for animal reproduction, with several techniques developed for the productive sector, such as in vitro fertilization (IVF), transfer, and embryo sexing, amongst others. Cloning research started in the late 1990s in Brazil, mostly focused on cattle. Successful clones include a Simmental heifer named "*Vitória*" in 2001; a Holstein cow named "*Lenda da Embrapa*" in 2003; Clone "Porã" from cow breed "*Junqueira*" in 2005; "Piatã" in 2010, an offspring of "Porã" and from the *Junqueira* cow breed.

The biotechnology animal reproduction team of the Embrapa developed in 2016 a technology called Intrafollicular Transfer of Immature Oocytes (TIFOI, in its Portuguese acronym), a biotechnique that does not need to be performed at a laboratory. Since 1983, Embrapa has been working on genetic resources conservation of domestic animals such as cattle, swine, goats, horses, donkeys, and sheep to avoid the extinction of species.

b) COMMERCIAL PRODUCTION

CTNBio has evaluated three cases of genome edited cattle for commercial production: polled bull in 2018, later retrieved by the company TALENs; double muscle bull generated by TALENs technology in 2021; Angus breed bull and cow generated by CRISPR/Cas9 technology in 2021. None of these three cattle cases was considered a "genetically modified organism" by CTNBio.

In June 2021, CTNBio approved the commercial release of AquaBounty's GE Atlantic salmon in Brazil, concluding 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.

c) EXPORTS

None for commercial use.

d) IMPORTS

None for commercial use.

e) TRADE BARRIERS

Brazil is a significant importer of U.S. animal genetics including cattle semen, embryos and live animals for reproduction. The country imports live animals, reproductive material and livestock products from Unites States. To provide a general overview, within the poultry sector, Brazil imports day-old chicks and hatching eggs; in the swine sector, Brazil imports live animals; in the goat and sheep sector, Brazil imports semen and embryos.

Regarding livestock products, US does not export poultry and pork meat to Brazil as there is no export certificate

PART E: POLICY

a) REGULATORY FRAMEWORK

Since there is no regulation in place for cloned animals and their products, MAPA cannot authorize imports to Brazil of cloned animals or their derived products, such as meat or dairy. See Regulatory Framework, under Chapter 1, Part B (Policy) in this report. Animal cloning and their products, although approved and permitted by CTNBio, do not have a specific regulatory framework approved in Brazil either at federal or state levels.

A Draft Bill (PLS 73, dated March 7, 2007), which passed the Senate on February 20, 2013, and was sent to the Chamber of Deputies with a new identification (Bill 5010/13), hasn't yet been fully approved by the Brazilian Congress. The Bill proposes to regulate the cloning of animals, including wild animals and their offspring. 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 Chapter 1, Part B, Sub-paragraph A.

b) APPROVALS/AUTHORIZATIONS

GENETICALLY ENGINEERED ANIMALS APPROVED COMMERCIALY IN BRAZIL

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

<i>Aedes aegypti</i> , lineage OX513A	Mosquito	Oxitec	3964/2014
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Source: CTNBio, updated on May 16, 2023.

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

Product	Characteristics	Company	Document/Year
<i>PUREVAX RCPCh FeLv</i>	<i>Multiple vaccine against feline viral rhinotracheitis, calicivirus, chlamydiosis, panleukopenia and feline leukemia</i>	<i>Boehringer Animal Health do Brasil Ltda.</i>	<i>8431/2023</i>
<i>Yescarta</i>	<i>It is a gene therapy of genetically modified autologous T cells directed to the recognition of the glycoprotein antigen CD19 - marker for neoplastic cells.</i>	<i>Treatment of oncological disease - Relapsed or refractory Large B-Cell Lymphoma and Relapsed or refractory Follicular Lymphoma.</i>	<i>8242/2022</i>
<i>Roctavian</i>	<i>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.</i>	<i>Indication: Treatment of severe hemophilia A (congenital factor VII deficiency).</i>	<i>8241/2022</i>
<i>Oncept</i>	<i>Canine melanoma DNA vaccine</i>	<i>Boehringer Animal Health do Brasil Ltda.</i>	<i>8182/22</i>
<i>Vaxxitek HVT + IBD + ILT</i>	<i>Recombinant, frozen live virus vaccine against Marek and Gumboro diseases</i>	<i>Boehringer Ingelheim Animal Health do Brasil Ltda.</i>	<i>7912/22</i>
<i>Ciltacabtagene autoleucel</i>	<i>Commercial Release of ciltacabtagene autoleucel (cilta-cel, JNJ-68284528), indicated for treatment of multiple myeloma</i>	<i>Janssen-Cilag Farmacêutica Ltda</i>	<i>7779/2021</i>
<i>Poulvac Procerta</i>	<i>Poulvac Procerta HVT-IBD</i>	<i>Novartis</i>	<i>7666/2021</i>

	<i>– Frozen live vector vaccine against Gumboro and Marek Diseases</i>	<i>Biociências S.A.</i>	
<i>Kymriah</i>	<i>KYMRIAH, tisagenlecleucel (CTL019) treatment for Refractory acute B-cell lymphoblastic leukemia and in post-transplant relapse, in second relapse or in later relapse</i>	<i>Novartis Biociências S.A.</i>	<i>7502/2021</i>
<i>Covid-19 Vaccine</i>	<i>Commercialization of the GAM-COV-VAC (SPUTNIK V) Vaccine, against SARS-CoV-2, developed by the Gamaleya Institute (Russia)</i>	<i>União Química Farmacêutica Nacional S.A</i>	<i>7440/2021</i>
<i>Covid-19 Vaccine</i>	<i>Commercialization of the Covid-19 vaccine (Ad26.COV2.S1 – recombinant and incompetent replicant), indicated for the active immunization in prevention of the disease caused by severe acute respiratory syndrome Ccoronavirus type 2 (SARSCoV-2)</i>	<i>Janssen-Cilag Farmacêutica Ltda</i>	<i>7400/2021</i>
<i>Covid-19 Vaccine</i>	<i>Commercialization of the recombinant Covid-19 vaccine based on microorganism of Risk Class I (ChAdOx1+nCoV19)</i>	<i>Instituto de Tecnologia em Imunobiológicos-Bio Manguinhos (FIOCRUZ)</i>	<i>7292/2021</i>
<i>FVAX-20SA01 Vaccine</i>	<i>Specific Vaccine against Streptococcus for captive-bred tilapia</i>	<i>Tevah Consultoria Empresarial, Regulatória, Governamental e Engenharia Ltda.</i>	<i>7480/2021</i>
<i>CIRCOGARD Recombinant Vaccine</i>	<i>Vaccine against Swine Circovirus Type 2 (PCV2)</i>	<i>Eco Animal Health do Brasil, Comércio de Produtos Veterinários Ltda</i>	<i>7449/2021</i>
<i>G608 Vaccine</i>	<i>Vaccine against Edema Disease in piglets, inactivated</i>	<i>Ceva Saúde Animal</i>	<i>7340/2021</i>
<i>Poulvac Procerta HV-</i>	<i>Poulvac Procerta HV-ND</i>	<i>Zoetis Indústria de</i>	<i>7249/2020</i>

ND	Vaccine – Vectorized live frozen vaccine against Marek and Newcastle diseases	Produtos Veterinários Ltda	
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-mannosidase enzyme deficiency	Chiesi Farmacêutica Ltda	7201/2020
Avian Recombinant Vaccine Code 1A89.R0	Avian Vaccine for the Prevention against Marek Disease, Newcastle Disease and Gumboro Diseases	Ceva Saúde Animal LTDA	7055/2020
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, Infectious Laryngotracheitis, derived from a GMO (INNOVAX ND-ILT)	Merck Sharp & Dohme Saúde Animal Ltda	6923/2020
MHYOSPHERE PCV ID	Commercialization of an inactivated 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	Novartis Biociências S.A.	6849/2020

	<i>adult and pediatric patients with eyesight loss due to hereditary retinal dystrophy caused by biallelic RPE65 gene mutations</i>		
<i>Fostera Gold PCV MH</i>	<i>Inactivated Vaccine Against Pork and Mycoplasma hyopneumoniae</i>	<i>Zoetis Industria de Produtos Veterinários</i>	<i>6221/2018</i>
<i>Avipro Megan VAC 1</i>	<i>Live Vaccine against Salmonella in Broiler chicken</i>	<i>Elanco Saúde Animal</i>	<i>6220/2018</i>
<i>PREVEXXION RN</i>	<i>Vaccine for Marek Disease in Birds</i>	<i>Merial Saúde Animal Ltda</i>	<i>6162/2018</i>
<i>Avian Recombinant Vaccine Code 1062.R0</i>	<i>Against Marek Disease and Avian Influenza</i>	<i>Ceva</i>	<i>5997/2018</i>
<i>Recombinant Vaccine Against Pork Circovirus type 2</i>	<i>Marek Disease and Avian Influenza</i>	<i>Ourofino Saúde Animal Ltda</i>	<i>6056/2018</i>
<i>TROVAC-NDV</i>	<i>Live Recombinant Virus Vaccine for Newcastle Disease and Avian Yaws</i>	<i>Merial Saúde Animal LTDA</i>	<i>6055/2018</i>
<i>Ingelvac Provenza</i>	<i>Swine Influenza Live Modified Virus Vaccine</i>	<i>Boehringer</i>	<i>6062/2018</i>
<i>Newxxitek HVT+ND</i>	<i>Live Vaccine for Marek Disease, Newcastle Disease – Marek Disease as vector, Serotype 3</i>	<i>Merial</i>	<i>5861/2018</i>
<i>INNOVAX ND-IBD</i>	<i>Live Recombinant Vaccine for Marek Disease, Newcastle Disease and Gumboro Disease</i>	<i>Merial</i>	<i>5836/18</i>
<i>Purevax Felv</i>	<i>Feline Leukemia Live Vaccine</i>	<i>Merial</i>	<i>5935/2018</i>
<i>PROTEQFLU</i>	<i>Equine Influenza Vaccine</i>	<i>Merial</i>	<i>5486/2017</i>
<i>PUREVAX RAIVA Vaccine</i>	<i>Feline Raibes Vaccine</i>	<i>Merial</i>	<i>5407/2017</i>
<i>Biotech Vac Salmonella Vaccine</i>	<i>Avian Salmonellosis Vaccine</i>	<i>Vetanco do Brasil Importação e Exportação Ltda</i>	<i>5331/2017</i>
<i>OncoVEXGM-CSF</i>	<i>Melanomas Treatment</i>	<i>Lab. Bergamo</i>	<i>5099/2016</i>
<i>HIPRABOVIS IBR MARKER LIVE</i>	<i>Bovine Herpes Vaccine</i>	<i>Hipra</i>	<i>5005/2016</i>
<i>Bay98</i>	<i>Immunostimulant</i>	<i>Bayer</i>	<i>4915/2016</i>
<i>Dengvaxia</i>	<i>Dengue Vaccine</i>	<i>Sanofi Aventis</i>	<i>4759/2015</i>

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/ <i>E. coli</i>	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

Pro-nuclear microinjections of embryos in the 1980's to produce transgenic animals; nuclear transfer cloning and the birth of Dolly the sheep in Scotland and the produced cow Vitória in Brazil, both in the 1990's; further techniques incorporated into the scientific toolkit in the 2000's marked the passing of the centuries. Since 2010, the CRISPR technology has been dominating the area of animal reproduction biotechnology in Brazil.

The focus of Brazilian research remains the prevention and curing of animal diseases, the major problem of producers. The CRISPR technology can be a tool in the search for solutions either through the production of medicines in animal milk or to cure diseases that afflict the herds. Embrapa's Genetic Resources and Biotechnology Center launched on September 3, 2024, a revolutionary update to Intergen, the genetic evaluation software widely used in beef cattle breeding in Brazil. This new version brings significant advances that promise to transform the way genetic improvement programs operate in the country. Initially developed in 2008 and expanded in 2016, Intergen now has two new modules: IntergenIOD and IntergenACC.

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)

- g) 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.
- #### 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. The genetically engineered insects manufactured by the company are all male and have a gene that causes their offspring to die before reaching adulthood. Thus, by copulating with wild females, they make the offspring unviable. The technique works by introducing a self-limiting gene (tTAV) that interrupts the proper cycle of *Aedes* cells by overproducing a protein responsible for producing other essential proteins necessary for the animal's development, which hinders the ability of females to survive to adulthood.

Despite commercial approval by CTNBio, ANVISA did not approve the commercial use of OX513A in Brazil, but instead provided a Temporary Special Registry (RET, in Portuguese) for research use.

In July 2022, Anvisa decided that “genetically modified” mosquitos used as control vectors for public health are subject to sanitary regulation, to assure the sanitary safety of the use and its efficacy. The agency has been working on a new set of rules under their regulatory agenda on macroorganisms for biological control of vectors and pathogens in the urban environment.

Oxitec also has another *Aedes aegypti* mosquito, OX5034, a second generation approved in 2020 by CNTBio, and a *Spodoptera frugiperda* moth OX5382G approved in 2021. Oxitec's product is not marketed directly to governments or companies. Since 2022, however, the company has only been operating through authorized distributors.

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS

On April 27, 2024, the Brazilian daily newspaper Folha de São Paulo revealed that experts dispute the home effectiveness of a device with transgenic mosquitoes against dengue. Interviewed experts believe the efficiency of the genetically engineered mosquito is debatable, since they compete with the not-engineered males and the result can only be seen in the next generation, if it works. Others believe that it would take a very large number of mosquitoes for the experiment to be effective. Another concern highlighted by the article is the contact of the insect with a substance called tetracycline. The GE mosquito is developed and raised in an environment rich in the compost, which means that, when in contact with the substance, the female would not die in the larval stage.

b) MARKET ACCEPTANCE/STUDIES

FAS Brasilia is not aware of any market studies or surveys related to consumer acceptance of innovative 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.

There's a recent project in Brazil announced by São Paulo State University (UNESP) in March 2024 called MicroBioBank, which aims at promoting innovation for scientific research and technological development. The project will map fungi and bacteria with potential to generate new biotechnology products. The initiative will use innovative methodology to analyze material housed in different collections in the state of São Paulo, with a focus on applications in the areas of health and agro-industry. The criteria for selecting the microorganisms will be their potential to produce innovative molecules, with possible applications in the fields of health and agribusiness.

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, nor is it 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

**GENETICALLY ENGINEERED MICROORGANISMS AND DERIVED PRODUCTS
APPROVED COMMERCIALY IN BRAZIL FOR INDUSTRIAL USE**

Product	Characteristics	Company	Document/Year
<i>Saccharomyces cerevisiae</i> , <i>Linhagens M32465, M32679 and M32680</i>	"Commercial Release of "GMO" Derivative <i>Yeast Saccharomyces cerevisiae</i> Strains M32465, M32679 and M32680 to be used in the production of ethanol"	Lallemand Soluções Biológicas Ltda.	8344/2022
<i>Saccharomyces cerevisiae</i> GICC03587 (GPY10138)	"Commercial Release of "GMO" Derivative <i>Yeast Saccharomyces cerevisiae</i> GICC03587 (GPY10138) developed for ethanol production"	Danisco Brasil Ltda.	8343/2022
<i>Saccharomyces cerevisiae</i> lineage <i>M12156</i>	Commercial release of "GMO" <i>Saccharomyces cerevisiae</i> 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 dried <i>Corynebacterium glutamicum</i> strain KCCM 80346 for animal feed manufacturing	CJ do Brasil Indústria e Comércio de Produtos Alimentícios Ltda.	8264/2022
<i>Saccharomyces cerevisiae</i> lineages M32292, M32376 e M32379	Commercial release "GMO" <i>Saccharomyces cerevisiae</i> (M32292, M32376 and M32379) for ethanol production from sugarcane	Lallemand Soluções Biológicas Ltda.	8263/2022
<i>Saccharomyces cerevisiae</i> lineage <i>PRCH20080 - FS0436</i>	Commercial release "GMO" <i>Saccharomyces cerevisiae</i> strain <i>PRCH20080-FS0436</i> for ethanol production	Danisco Brasil Ltda.	8243/2022
<i>Saccharomyces cerevisiae</i> lineage <i>Y62840</i>	Commercial release "GMO" <i>Saccharomyces cerevisiae</i> strain 62840 for vanillin production	Amyris Biotecnologia do Brasil Ltda.	7978/2022
<i>Saccharomyces cerevisiae</i> (SCY014)	<i>Saccharomyces cerevisiae</i> SCY017 to be used in ethanol production	Novozymes Latin America LTDA	7780/2021
<i>Saccharomyces cerevisiae</i> (SCY018)	<i>Saccharomyces cerevisiae</i> SCY017 to be used in ethanol production	Novozymes Latin America LTDA	7752/2021
<i>Saccharomyces cerevisiae</i>	<i>Saccharomyces cerevisiae</i> (Strain Y67383) genetically engineered for	Amyris Biotecnologia do	7663/2021

(strain Y67383)	steviol glycoside Reb-M production	Brasil LTDA	
<i>Saccharomyces cerevisiae</i> (SCY017)	<i>Saccharomyces cerevisiae</i> SCY017 to be used in ethanol production	Novozymes Latin America LTDA	7662/2021
<i>Saccharomyces cerevisiae</i> M23541	<i>Saccharomyces cerevisiae</i> M23541 to be used in corn-based ethanol production	Lallemand Brasil LTDA	7661/2021
<i>S. cerevisiae</i> (GICC03578 and GICC03588)	Yeast for ethanol production	Danisco Brasil LTDA	7643/2021
<i>Saccharomyces cerevisiae</i> M24296	Yeast for corn-based ethanol production	Lallemand Brasil Ltda	7561/2021
<i>Saccharomyces cerevisiae</i> – CelluXTM 4	Yeast for ethanol production	BioSpringer do Brasil Indústria de Alimentos S.A.	7481/2021
<i>Saccharomyces cerevisiae</i> 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
<i>Prototheca moriformis</i> Strain S9120	Strain S9120 of the microorganism <i>Prototheca moriformis</i>	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 <i>Pichia pastoris</i>	The derivate is destined for adding in analogous products of ground beef for human consumption	Jomakol Representações e Serviços Ltda	7060/2020
<i>Saccharomyces</i>	Industrial Production of Corn-based	Lallemand Brasil	7059/2020

es cerevisiae M15419	Ethanol fuel	Ltda	
Derivative of alpha amylase enzyme microorganism (GICC03556)	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 starch origin stains	Danisco Brasil Ltda	7002/2020
Derivative of genetically engineered microorganism <i>Corynebacterium glutamicum</i>	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 cerevisiae (Y63348)	<i>Saccharomyces cerevisiae</i> 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 (L-Triptofano 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 of genetically engineered microorganism – Granulated Threonym THR Pro (L-Treonina 75%)	CJ do Brasil Industria e Comercio de Produtos Alimentícios Ltda	6623/2019
Subtilisin	Derivative of genetically engineered microorganism Subtilisin (GICC03528)	Danisco do Brasil Ltda.	6592/2019
<i>Saccharomyces cerevisiae</i> lineage Y47220	Commercial release “GMO” <i>Saccharomyces cerevisiae</i> strain Y47220 for the production of steviol and derivatives	Amyris Biotecnologia do Brasil Ltda.	6.551/2019
S. cerevisiae (SCY011)	<i>Saccharomyces cerevisiae</i> microorganism to be used in the commercial production of ethanol – Lineage SCY011	Novozymes Latin America Ltda	6507/2019
<i>Corynebacterium glutamicum</i> strain DM24.60	Genetically engineered microorganism of the bacteria <i>Corynebacterium glutamicum</i> strain DM24.60 and its derivative for the use in industrial yeast and its derivative for animal feed as feed	Evonik Degussa do Brasil	6476/2019

	aditive		
Alpha amylase (GICC03469)	“GMO” derivative of alpha amylase (GICC03469)	Danisco	6063/2018
Alpha amylase GICC03515	Commercial release “GMO” derivative alpha-amylase (<i>Bacillus licheniformis</i> strain GICC03515) for application in the area of cleaning products	Danisco Brasil Ltda.	6.237/2018
<i>Saccharomyces cerevisiae</i> lineage Y27011	Commercial release of “GMO” <i>Saccharomyces cerevisiae</i> strain Y27011 and its derivatives for the production of farnesene	Amyris Biotecnologia do Brasil Ltda.	6.165/2018
B. licheniformis	Alpha amylase of <i>Cytophaga sp</i> expressed in <i>Bacillus licheniformis</i>	Du Pont do Brasil	6152/2018
<i>Saccharomyces cerevisiae</i> lineage Y22021	<i>Saccharomyces cerevisiae</i> Yeast genetically engineered (strain Y22021) and its derivatives	Amyris do Brasil	5827/2018
<i>Saccharomyces cerevisiae</i> lineage SCY010	Commercial release “GMO” <i>Saccharomyces cerevisiae</i> 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	<i>Saccharomyces cerevisiae</i> (S1260) for the comercial production of ethanol.	Novozymes Latin America Ltda	5333/2017
S8885	<i>Prototheca moriformis</i> microorganism	Solazyme Brasil Óleos Renováveis e Bioprodutos Ltda	5286/2016
M10682	<i>Saccharomyces cerevisiae</i> Yeast	Lallemand Brasil Ltda	5285/2016
S8695	<i>Prototheca moriformis</i> microorganism	Solazyme Brasil Óleos Renováveis e Bioprodutos Ltda	5238/2016
Derivative	Import of alkaline protease	Du Pont do Brasil	5153/2016
S6697	<i>Prototheca moriformis</i> microorganisms for the production of triglycerides e bioproducts.	Solazyme Brasil Óleos Renováveis e Bioprodutos Ltda	4768/2015
S5223	<i>Prototheca moriformis</i> 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	<i>Prototheca moriformis</i> microorganism derivative	Solazyme Brasil Óleos Renováveis e Bioprodutos Ltda	4203/2014
RN1016	Yeast (<i>Saccharomyces cerevisiae</i>) lineage genetically engineered for the production of ethanol	Bio Celere Agroindustrial Ltda	3877/2013
S2014	<i>Prototheca moriformis</i> for the production of triglycerides and bioproducts	Solazyme Brasil Óleos Renováveis e Bioprodutos Ltda	3775/2013
Y5056	Yeast (<i>Saccharomyces cerevisiae</i>) genetically engineered for the production of Farnesene	Amyris do Brasil	3287/2012
Y1979	Yeast (<i>Saccharomyces cerevisiae</i>) 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, as previously informed, 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

Among CTNBio's obligations are 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 Brazilian biosafety laws provide a clear regulatory framework for the research and marketing of biotechnology crops and related products, as well as for innovative technologies. The federal government embraces and protects such 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