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Report Highlights:

Brazil is the second-largest producer of biotech crops in the world, with 134 events approved for plants. For the 2024/2025 crop season, FAS Brasilia forecasts 69.6 million hectares planted with GE traits. Adoption rates for soybeans and cotton reached 99 percent and for corn, 96 percent. Biotechnology has played a transformative role in Brazilian agriculture, driving significant gains in productivity and innovation. Continued use of biotechnology seeds is 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 technologies.

EXECUTIVE SUMMARY

Brazil ranks as the world's second-largest producer of biotech crops, following the United States. Since the establishment of CTNBio in 1998, Brazil has approved 260 applications for genetically engineered (GE) plants, animals, and microbial events. Of these, 134 approvals have been for GE plant events, underscoring Brazil's significant role in advancing agricultural biotechnology. This report is separated into three major sections: plant biotechnology, animal biotechnology, and microbial biotechnology. Nearly all major Brazilian commodity exports, including soybeans, cotton, and corn, are currently genetically engineered. Biotechnology utilization in Brazil continues to expand significantly, increasing the pipeline of biotech products through investments, research and development, new companies entering the market, and enabling regulatory policies.

The National Technical Biosafety Commission (CTNBio) is a multidisciplinary collegiate body composed of scientists who perform 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.

This report was prepared by the Office of Agricultural Affairs Brasilia, for U.S. exporters of domestic food and agricultural products. While every possible care was taken in the preparation of this report, information provided may not be completely accurate either as policies have changed since its preparation, or due to clear and consistent information about these policies was not available. The OAA is available to answer questions and receive any comments, corrections or suggestions about this report and to provide assistance to export U.S. agricultural products to Brazil:

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PART A: PRODUCTION AND TRADE

a) RESEARCH AND PRODUCT DEVELOPMENT

Over the past 25 years, the adoption of agricultural biotechnology, particularly in crops like soybeans, corn, and cotton, has tripled Brazil's agricultural productivity. Biotechnology advancements injected an estimated BRL 295.7 billion (USD 56 billion) into Brazil's agricultural sector and boosted exports by 39.6 million tons, valued at USD 20.6 billion.

Genetically engineered (GE) foods in Brazil include cooking oil, corn products, soy-based items, and various processed foods. In November 2023, FuturaGene, received CTNBio approval for the world's first combined genetically modified eucalyptus with herbicide tolerance. This innovation enhances productivity, reduces costs, and improves worker safety. Researchers developed the eucalyptus by crossing two GE varieties using classical breeding techniques, and the herbicide-tolerance trait has a 25-year record of safe use globally.

FuturaGene highlights the growing global demand for wood, projected to rise to 10 billion m^3 annually by 2050, requiring innovative intensification of production. Its technologies support forestry, biofuels, biochemicals, and biomaterials, with eucalyptus as the key crop. Products include pulp, paper, wood panels, furniture, ethanol, and fossil-fuel alternatives. After large-scale testing, partners will access the technology royalty-free.

Brazil is testing a genetically engineered (GE) wheat variety with drought tolerance, expressing the HB4 sunflower gene. Approved by CTNBio in 2021, it marked the first global commercial trade and production of GE wheat. Embrapa (Brazilian Agricultural Research Corporation) is evaluating its benefits and limitations, with initial research results expected by 2025. CTNBio granted further commercial approval in 2023, but full-scale production will require additional authorization and a royalty payment system. HB4 wheat, valued for animal fodder and commercial baking, is particularly promising for Brazil's drought-prone Central-West region, where irrigated wheat is common.

Industry sources shared that the introduction of HB4 transgenic wheat could be a pivotal factor in expanding wheat cultivation in Brazil. Such a shift could present Brazil with a significant opportunity to achieve greater self-sufficiency in wheat production.

The Brazilian biotechnology industry, represented by the National Association of Biotechnology and Life Sciences Companies (ANBIOTEC Brasil), is actively engaging with governmental ministries to address key challenges, such as reducing the high costs and long wait times for international certifications and improving the competitiveness of domestic production.

ANBIOTEC Brasil successfully proposed several measures for inclusion in the 2024-2027 Participatory Multi-Year Plan (PPA), including increasing the qualification and capacity of regulatory agencies, expediting product registration processes, and fostering clinical research to accelerate the delivery of innovative health solutions. ANBIOTEC underscored the importance of biotechnology as a driver of economic growth, job creation, and improved public health.

b) COMMERCIAL PRODUCTION

CTNBio data from 2024 shows there are 134 GE events approved for plants commercial cultivation in Brazil, of which 65 events are for corn, 25 for cotton, 24 for soybeans, 7 for sugarcane, 10 for eucalyptus, 1 for a virus-resistant variety dry edible bean, and 2 for wheat HB4.

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 GE 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 People's Republic of China (PRC). For 2024/2025 season, Post forecasts 69.6 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[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 96 percent.
- Cotton: The adoption rate of GE cotton is 100 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.

c) EXPORTS

There is no specific export data for biotechnology products. Brazil's agricultural sector grew by 6.49 percent in the first quarter of 2025, according to Cepea (Center for Advanced Studies in Applied Economics) at Esalq/USP (Luiz de Queiroz College of Agriculture within the University of São Paulo), in partnership with CNA (Confederation of Agriculture and Livestock of Brazil). Researchers from Cepea/CNA noted that this performance continues the recovery trend observed in the fourth quarter of 2024, which reversed the declines recorded up to the third quarter of that year.

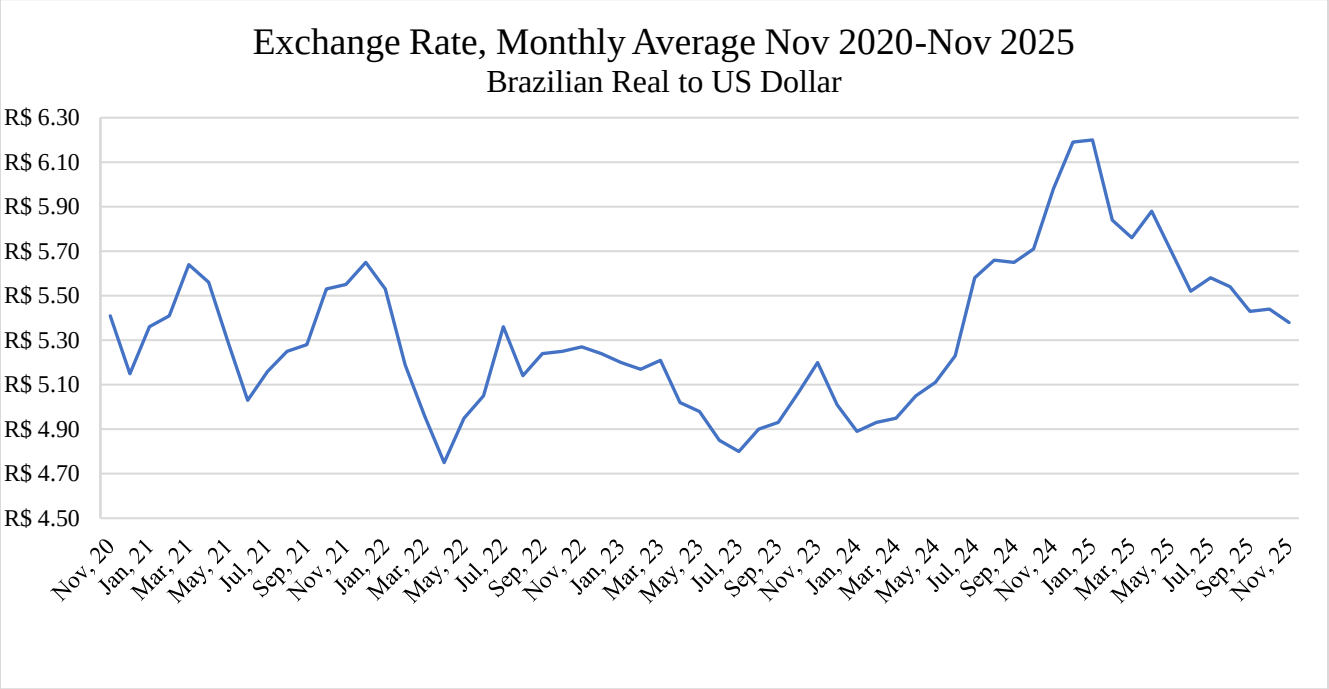
Agribusiness GDP is projected to account for 29.4 percent of Brazil's total GDP in 2025, a significant increase compared to 23.5 percent in 2024. Rising prices primarily spurred growth, particularly in on-farm activities such as agriculture and livestock. Additionally, increased production across various agricultural and livestock activities contributed to the growth, although the input segment experienced a contraction.

d) IMPORTS

The Brazilian currency remains devalued, as shown on the exchange rate graphic.

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

Figure 1
Exchange Rate, Monthly Average Nov 2020-Nov 2025; Brazilian Real to US Dollar



Data Source: Brazilian Central Bank

Brazil's commodity imports remained minimal, with virtually no imports of sugar or cotton (1,100 metric tons in MY 2024/25); 900,000 metric tons of soybeans imported in MY 2023/24; and 46.4 MMT of corn in TY 2024/25.

Normative Instruction 32 establishes the regulations for the commercial release and monitoring of genetically engineered organisms and their derivatives of plant and animal origin. It has since 2021 effectively guaranteed that imported corn from the United States can be quickly approved for food and feed uses in Brazil.

e) FOOD AID

Brazil is not a food aid recipient from the United States. In Brazil, food aid for humanitarian purposes is governed by Law 12429 of 2011, updated by Law 13001 of 2014. The 2011 law stipulates which countries can receive Brazilian food aid and which products can be sent, and limits of tonnage, per year. Per the law, the only countries that can receive Brazilian humanitarian food aid are: Bolivia, El Salvador, Guatemala, Haiti, Nicaragua, Zimbabwe, Cuba, country-members of the Community of Portuguese Language Countries, Palestine National Authority, Sudan, Ethiopia, Central African Republic, Democratic Republic of Congo, Somali, Niger, and North Korea. The products and annual limits as established by the laws are: rice (up to one million tons), dry edible beans and corn (up to one hundred thousand tons, each), powdered milk (up to ten thousand tons), and vegetable seeds (up to one ton). The Brazilian National Supply Company (CONAB) administers the program with the Brazilian Ministry of External Affairs. The Ministry works with the United Nations World Food Program and

determines the amounts and destination of the donations. Brazil can also donate food aid as emergency assistance to people in vulnerabilities caused by migration fluxes caused by humanitarian crises, as established on Law 13684 of 2018.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 a few 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 reviewing applications on a case-by-case basis.

Genetically Engineered (GE) organisms are defined under Law 11,105 as those whose genetic material—DNA or RNA—altered using genetic engineering techniques. Genetic engineering refers to the manipulation of recombinant DNA or RNA molecules. GEs are organisms whose DNA is modified in a laboratory by introducing specific genetic segments into the recipient organism to express a targeted, desired trait. The same applies to GE plant products considered living versus non-living.

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[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

Article 3 of the Biosafety Law of 2005 defines "GMO" as "an organism the genetic material of which – DNA/RNA was 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. The Law also 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.

CTNBio defines what applications are eligible for submission to get approval, authorization, and risk analysis evaluation. Applicants must provide supporting data demonstrating the safety of the product. Commercial plant approvals do not have an expiration date, but approvals can be reassessed when new scientific data becomes available. Further information on biotechnological legislation in Brazil can be found at the previous biotechnology report in this link.

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, is increasing.

Since 2021, CTNBio has approved seven new governmental 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.

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 a proposed regulation PL 6432/2013 to prohibit 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. In May 2025, a proposal was submitted at the Lower House to postpone the discussion of the bill. According to Post contacts, the law would be a major impediment for the agricultural sector.

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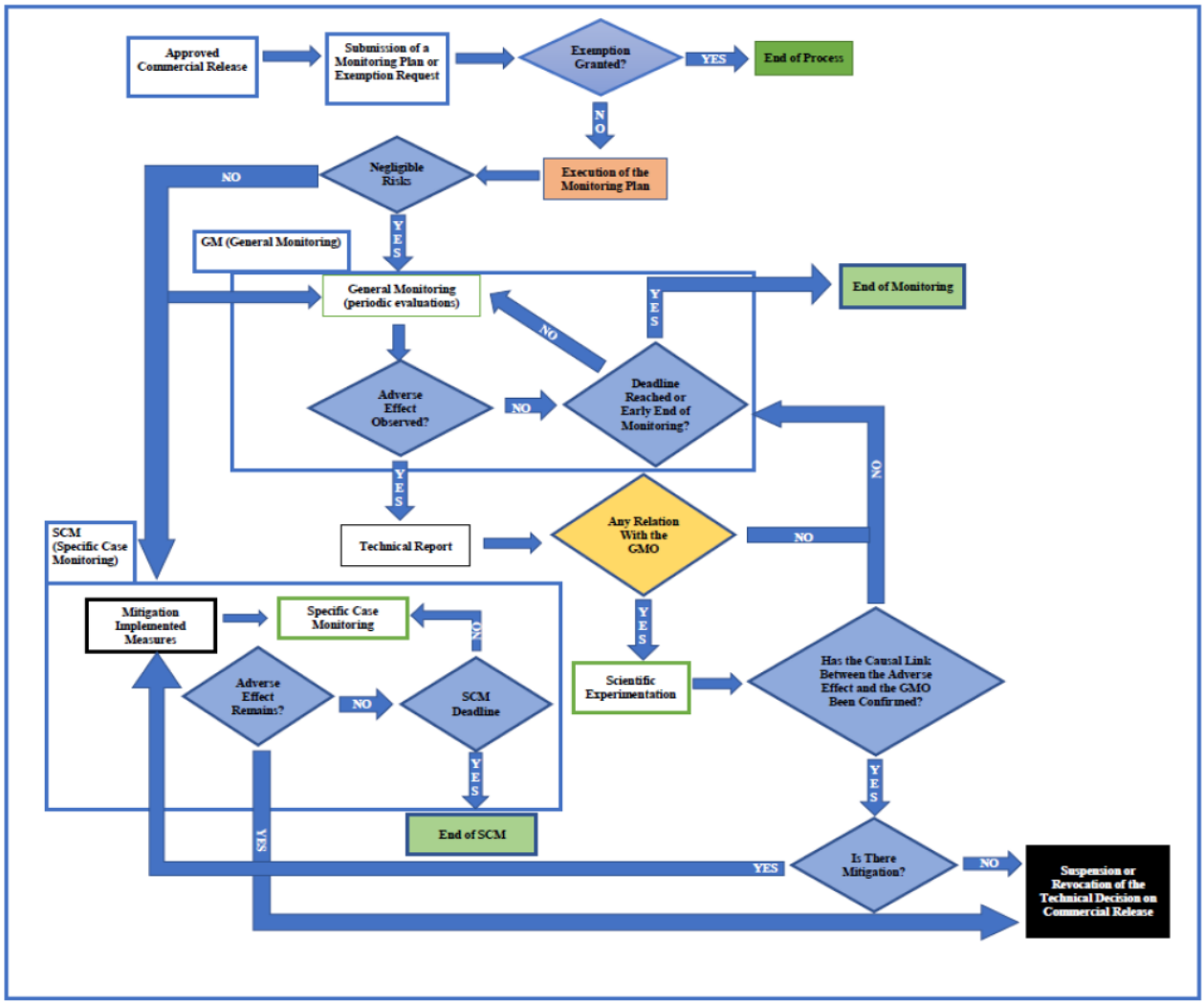
[6] Available in Portuguese at https://antigo.mctic.gov.br/mctic/opencms/legislacao/outros_atos/resolucoes/Resolucao_Normativa_CTNBio_38_de_27092023.html#:~:text=Art.%201%C2%BA%20Esta%20Resolu%C3%A7%C3%A3o%20Normativa%20estabelece%20os%20procedimentos%20para%20o

[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=Altera%20a%20Resolu%C3%A7%C3%A3o%20Normativa%20CTNBio%20n%C2%BA

Brazil's Review Process for GE Products



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

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 (LPMA in Portuguese) 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 Agrobacterium sp. or gene constructs containing the gene of interest to obtain a temporary expression at high levels located in the infiltrated area or with viral vector for systemic expression without the modification being transmitted to subsequent generations.
Requerente	Applicant	CTNBio Normative Resolution 32/2021	Any legal entity, holder of a Quality Certificate in Biosafety – CQB, which intends to conduct a commercial release, according to this Normative Resolution.
Embriões congelados disponíveis	Available frozen embryo	Decree 5591/2005	An embryo frozen on or before March 28, 2005, after three years from the date of its freezing have elapsed genitor.
Clonagem	Cloning	Law 11105/2005; Decree 5591/2005	An asexual reproduction process, artificially produced, based on a sole genetic patrimony, by using or not genetic engineering techniques.
Clonagem para fins reprodutivos	Cloning for reproductive means	Law 11105/2005	Cloning the end purpose of which is to make an individual.
Liberação Planejada no Meio Ambiente	Commercial release in the environment	CTNBio Normative Resolution 35/2021	Commercial release in the environment of a GMO and its derivatives, for experimental evaluations under monitoring, in accordance with the dispositions of this Normative Resolution.
Dano	Damage	CTNBio Normative Resolution 32/2021	Harm to the environment and/or human, animal, and plant health.

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

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

Construção genética idêntica	Identical genetic construct	CTNBio Normative Resolution 35/2021	Genetic construct which contains the same genes and promotors that result in the same expression product inside the same species.
Fertilização in vitro	In vitro fertilization	Decree 5591/2005	The fusion of gametes conducted by any technique of extracorporeal fertilization.
Tecnologias genéticas de restrição do uso	Limited use genetic technologies	Decree 5591/2005	Any process of human intervention to generate or multiply plants "genetically modified" to produce sterile reproductive structures, as well as any form of genetic manipulation with the purpose of activating or deactivating genes related to plant fertility by external chemical inductors.
Microrganismo	Microorganism	CTNBio Normative Resolution 21/2018	All microscopic biological entity, uni or pluricellular capable of reproducing or transferring genetic material, including virus and other classes that come to be known.
Plano de monitoramento pós-liberação comercial	Monitoring plan after commercial release	CTNBio Normative Resolution 32/2021	Pool of procedures to monitor the effects derived from the commercial release of the GMO and its derivatives on the environment and to the human and animal health.
Risco negligenciável	Negligible risk	CTNBio Normative Resolution 32/2021	Risk associated to a reduced damage with negligible likelihood to take place over the probable term of the GMO commercial use.
Embriões inviáveis	Non-viable embryo	Decree 5591/2005	An embryo with genetic alterations evidenced by preimplant diagnosis, according to the Ministry of Health specific rules, whose development was interrupted by spontaneous absence of cleavage for a period exceeding twenty-four hours from the in vitro fertilization, or an embryo with morphologic alteration that adversely affects its full development.

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

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

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

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

b) APPROVALS/AUTHORIZATIONS

Cotton

Crop - Year	Trait Category	Applicant	Event (Commercial Name)	Trait Description	Document Number/Uses within Brazil
Cotton 2023	Herbicide Tolerant	BASF	LLCotton25 x GBH811 (GLI)	Herbicide tolerance to glyphosate base and inhibitory herbicides	8540/2023 Release into the environment of the cotton variety; commercial use
Cotton 2022	Insects and pests resistant	Monsanto	MON 15985	Resistant to certain Insects and pests	8038/2022 Commercial Release of MON 15947 cotton, obtained through the segregation and selection of MON 15985 cotton
Cotton 2021	Insect Resistant	Syngenta Seeds Ltda.	COT102	Insect Resistant	RN32 Not available
Cotton 2019	Herbicide Tolerant, Insect Resistant	BASF	GHB811 x T-304-40 x GHB119 x COT102 x COT102	Herbicide Tolerant, Insect Resistant	6405/2019 Textile Fibers Food and Feed
Cotton 2019	Herbicide Tolerant/Insect Resistant	Dow	DAS-21023-5 x DAS – 24236-5 x SYN-IR102-7 x DAS-81910-7	Herbicide Tolerant Insect resistant	6657/2019 Textile Fibers Food and Feed
Cotton 2018	Herbicide Tolerant Insect Resistant	Monsanto	COT102 x MON15985 x MON88913 x MON88701 (BGIIIRRFlexDGT	Herbicide Tolerant, Insect Resistant	6139/2018 Textile Fibers Food and Feed

			)		
Cotton 2018	Herbicide Tolerant Insect Resistant	Monsanto	MON88913 x MON88701 (RRFlexDGT)	Herbicide Tolerant, Insect Resistant	6139/18 Textile Fibers Food and Feed
Cotton 2018	Herbicide Tolerant Insect Resistant	BASF	T304-40 x GHB119 x COT102	Herbicide Tolerant, Insect Resistant	6130/18 Textile Fibers Food and Feed
Cotton 2018	Herbicide Tolerant	Dow	DAS 81910 (Enlist)	Herbicide Tolerant	6107/18 Textile Fibers Food and Feed
Cotton 2018	Insect Resistant	Dow	DAS-21023-5 x DAS24236-5 x SYN-IR102-7 (Widestrike 3)	Insect Resistant	5955/18 Textile Fibers Food and Feed
Cotton 2017	Herbicide Tolerant Insect Resistant	Bayer	GHB614 x T304-40 x GHB119 x COT 102	Herbicide Tolerant Insect Resistant	5400/17 Textile Fibers Food and Feed
Cotton 2017	Herbicide Tolerant	Monsanto	MON88701 (DGT)	Herbicide Tolerant	5429/17 Textile Fibers Food and Feed
Cotton 2016	Herbicide Tolerant Insect Resistant	Monsanto	COT102 x MON15985 x MON88913 (BGIIIRRFlex)	Herbicide Tolerant Insect Resistant	5155/16 Textile Fibers Food and Feed
Cotton 2012	Herbicide Tolerant Insect Resistant	Bayer	GHB614 x T304-40x GHB119 (GlytoIxTwinLink)	Gossypium hirsutum L.	3286/12 Textile Fibers Food and Feed
Cotton 2012	Herbicide Tolerant Insect Resistant	Monsanto	MON 15985 x MON 88913 (BGIIFlex)	Herbicide Tolerant Insect Resistant	3365/12 Textile Fibers Food and Feed
Cotton 2012	Herbicide Tolerant	Bayer	GHB614 x LL Cotton 25 (GTxLL)	Gossypium hirsutum L.	3290/12 Textile Fibers Food and Feed
Cotton 2011	Herbicide Tolerant	Monsanto	MON 88913	Gossypium hirsutum L.	2956/11 Textile Fibers Food and Feed
Cotton 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 hirsutumm L.	2754/10 Textile Fibers Food and Feed
Cotton	Herbicide Tolerant	Monsanto	MON 531 x	Gossypium	2051/09

2009	Insect Resistant		MON 1445 (Round Ready BGRR)	hirsutum L. Glyphosate Herbicide	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, as of February 2nd, 2025

Corn

Crop - Year	Trait Category	Applicant	Event (Commercial Name)	Trait Description	Document Number/ Uses within Brazil
Corn 2024	Herbicide Tolerant	Corteva Agriscience	DP202216	Enhanced grain yield and tolerant to the herbicide glufosinate ammonium	9356/2024
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 glufosinate	8778/2023
Corn 2023	Herbicide Tolerant	Corteva Agriscience	DP-2Ø2216-6	Herbicide Tolerant glufosinate	8693/2023

				ammonium	
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 MON 89034 x MIR162 x NK603 (and undercombinations)	Herbicide Tolerant	6519/2019 Food, Feed, Imports
Corn	Herbicide Tolerant	Monsanto	MON 87427 × MON	Herbicide Tolerant	6448/2019

2019	Insect Resistant		87419 × NK603	Insect Resistant	Not available
Corn 2019	Herbicide Tolerant Insect Resistant	Dow	MON87427-7 x MON89034-3 x DAS01507-1 x MON87411-9 x DAS59122-7 x DAS40278-9	Herbicide Tolerant and Insect Resistant	6363/2019 Food, Feed, Imports
Corn 2018	Insect Resistant	Syngenta	MZIR 098	Approved only for human and animal food	6115/18 Food, Feed Imports
Corn 2018	Insect Resistant Herbicide Tolerant	Dow	MON 89034 x TC1507 x MIR162 x NK603 x DAS40278-9 (PowerCore Ultra Enlist)	Insect Resistant Herbicide Tolerant	6035/18 Food, Feed, Imports
Corn 2017	Herbicide Tolerant Insect Resistant	Dow	MON89034 x TC1507 x NK603 x MIR162 (PowerCore Ultra)	Herbicide Tolerant Insect Resistant	5425/17 Food, Feed, Imports
Corn 2017	Insect Resistant	Syngenta	MIR162 x MON89034	Insect Resistant	5412/17 e 6310/2019 Food, Feed, Imports
Corn 2017	Herbicide Tolerant Insect Resistant	Syngenta	Bt11 x MIR162 x MON89034 (VIP4)	Herbicide Tolerant Insect Resistant	5412/17 Food, Feed, Imports
Corn 2017	Herbicide Tolerant Insect Resistant	Syngenta	Bt11 x MIR162 x MON89034 x GA21 (VIP4TG)	Herbicide Tolerant Insect Resistant	5412/17 Food, Feed, Imports
Corn 2016	Drought Stress	Monsanto	MON87460	Approved only for human and animal food	5224/16 Food, Feed, Imports
Corn 2016	Amylase Thermostability Increase	Syngenta	3272 (Enogen)	Approved only for human and animal food	5226/2016 e 7891/2022 Food, Feed, Imports
Corn 2016	Herbicide Tolerant	Monsanto	MON87427	Herbicide Tolerant	5221/16 Food, Feed, Imports
Corn	Herbicide Tolerant	Monsanto	MON97411	Herbicide	5162/2016

2016	Insect Resistant			Tolerant Insect Resistant	Food, Feed, Imports
Corn 2016	Herbicide Tolerant Insect Resistant	Dow AgroSciences	MON89034 x MON88017 x TC1507 x DAS59122-7 (SmartStax)	Herbicide Tolerant Insect Resistant	5128/16 Food, Feed, Imports
Corn 2016	Herbicide Tolerant Insect Resistant	Dow AgroSciences	MON89034 x TC1507 x NK603 x DAS40278-9 (PowerCore Enlist)	Herbicide Tolerant Insect Resistant	4949/16 Food, Feed, Imports
Corn 2015	Fertility Restauration	Du Pont	SPT 32138 (32138 Mantenedor SPT)	Fertility Restauration	4865/15 Food, Feed, Imports
Corn 2015	Herbicide Tolerant Insect Resistant	Syngenta	BT11 x MIR162 (VIP2)	Herbicide Tolerant Insect Resistant	4764/15 Food, Feed, Imports
Corn 2015	Insect Resistant	Syngenta	5307 (Agrisure Duracade)	Insect Resistant	4764/15 Food, Feed, Imports
Corn 2015	Herbicide Tolerant Insect Resistant	Syngenta	BT11 x MIR162 x MIR604 x TC1507 x 5307 x GA21 (Agrisure Duracade 5222)	Herbicide Tolerant Insect Resistant	4764/15 Food, Feed, Imports
Corn 2015	Herbicide Tolerant	Dow AgroSciences	DAS40278-9 x NK603 (Enlist RR)	Herbicide Tolerant	4763/15 Food, Feed, Imports
Corn 2015	Herbicide Tolerant Insect Resistant	Du Pont	TC1507 x MON810 x MIR162 Undercombinations approved and already referred previously	Herbicide Tolerant Insect Resistant	4465/15 Food, Feed, Imports
Corn 2015	Insect Resistant	Du Pont (RN15)	MON 810 x MIR162	Insect Resistant	4409/15 Food, Feed, Imports
Corn 2015	Herbicide Tolerant Insect Resistant	Du Pont (RN15)	MIR162 x NK603	Herbicide Tolerant Insect Resistant	4409/15 Food, Feed, Imports

Corn 2015	Herbicide Tolerant Insect Resistant	Du Pont (RN15)	TC1507 x MIR162	Herbicide Tolerant Insect Resistant	4409/15 Food, Feed, Imports
Corn 2015	Herbicide Tolerant Insect Resistant	DuPont (RN15)	TC1507 x MON 810 x MIR 162 x NK603	Herbicide Tolerant	4409/15 Food, Feed, Imports
Corn 2015	Herbicide Tolerant Insect Resistant	DuPont (RN15)	TC1507 x MIR162 x NK603	Herbicide Tolerant Insect Resistant	4409/15 Food, Feed, Imports
Corn 2015	Herbicide Tolerant	Monsanto	NK603 x T25	Glyphosate and Glufosinate Herbicides	4407/15 Food, Feed, Imports
Corn 2015	Herbicide Tolerant	Dow Agro Science	DAS 40278-9 (Enlist)	Herbicide Tolerant	4406/15 Food, Feed, Imports
Corn 2014	Insect Resistant	Syngenta	MIR 604	Insect Resistant	4207/14 Food, Feed, Imports
Corn 2014	Herbicide Tolerant Insect Resistant	Syngenta	Bt11 x MIR162 x MIR604 x GA21 (Viptera4)	Glyphosate Tolerant Glufosinate Ammonium	4207/14 Food, Feed, Imports
Corn 2013	Herbicide Tolerant Insect Resistant	DuPont and Dow AgroSciences	MON89034 x MON88017 x DAS-01507-1 (Herculex XTRA maize)	Glyphosate Herbicide Ammonium	3674/13 and 7467/2021 Food, Feed, Imports
Corn 2011	Herbicide Tolerant Insect Resistant	Monsanto	MON 89034 x MON 88017	Glyphosate Herbicide	3045/11 Food, Feed, Imports
Corn 2011	Herbicide Tolerant Insect Resistant	DuPont	TC1507 x MON 810	Glyphosate Herbicide Ammonium	3021/11 Food, Feed, Imports
Corn 2011	Herbicide Tolerant Insect Resistant	DuPont	MON 810 x TC 1507 x NK 603 (Optimum Intrasect)	Glyphosate Herbicide Lepidoptera R.	2955/11 Food, Feed, Imports
Corn 2010	Herbicide Tolerant Insect Resistant	Monsanto and Dow Agrosciences	MON 89034 x TC 1507 x NK 603 (Power Core PW/Dow)	Glyphosate Herbicide Ammonium	2753/10 Food, Feed, Imports

Corn 2010	Herbicide Tolerant Insect Resistant	Monsanto	MON 88017 (Yield Guard VT)	Glyphosate Herbicide Ammonium	2761/10 Food, Feed, Imports
Corn 2010	Herbicide Tolerant Insect Resistant	Monsanto	MON 89034 x NK 603 (PRO2)	Glyphosate Herbicide Ammonium	2725/10 Food, Feed, Imports
Corn 2010	Herbicide Tolerant Insect Resistant	Syngenta	BT 11 x MIR 162 x GA 21 (TL TG Viptera)	Glyphosate Herbicide Ammonium	2722/10 Food, Feed, Imports
Corn 2009	Insect Resistant	Monsanto	MON 89034 (Pro)	Lepidoptera Resistant	2052/09 Food, Feed, Imports
Corn 2009	Herbicide Tolerant Insect Resistant	DuPont	TC1507 x NK603 (HR Herculex/RR2)	Glyphosate Tolerant Insect Resistant	2053/09 Food, Feed, Imports
Corn 2009	Insect Resistant	Syngenta	MIR162 (Viptera-MIR162)	Lepidoptera Resistant	2042/09 Food, feed, Imports
Corn 2009	Herbicide Tolerant Insect Resistant	Syngenta	BT 11 x GA 21 (TL/TG)	Glyphosate Tolerant Lepidoptera R.	2040/09 Food, Feed, Imports
Corn 2009	Herbicide Tolerant Insect Resistant	Monsanto	NK603 x MON810 (YGRR2)	Glyphosate Tolerant Lepidoptera R.	2041/09 Food, Feed, Imports
Corn 2008	Herbicide Tolerant Insect Resistant	Dupont and Dow AgroScience	TC1507 (Herculex)	Glyphosate ammonium Herbicide Tolerant	1679/08 Food and Feed
Corn 2008	Herbicide Tolerant	Syngenta	GA 21 (TG)	Glyphosate Tolerant	1597/08 Food and Feed
Corn 2008	Herbicide Tolerant	Monsanto	NK 603 (Roundup Ready 2)	Glyphosate Tolerant	1596/08 Food and Feed
Corn 2008	Insect Resistant Herbicide Tolerant	Syngenta	Bt 11 (TL)	Lepidoptera resistant	1255/08 Food and Feed
Corn 2007	Herbicide Tolerant	Bayer	T 25 (Liberty Link)	Ammonium Glyphosate tolerant	987/07 Food and Feed
Corn 2007	Insect Resistant	Monsanto	MON 810 (Yield Guard)	Lepidoptera resistant	1100/07 Food and Feed

Source: CTNBio, as of February 2nd, 2025

Soybeans

Crop - Year	Trait Category	Applicant	Event (Commercial Name)	Trait Description	Document Number/Uses within Brazil
Soybeans 2025	Herbicide Tolerant Insect Resistant	Monsanto	MON 94637 × MON-87751-7 × MON 87701 × MON 94313 × MON 89788	Resistant to lepidopteran insect pests and tolerant to the herbicides glyphosate, glufosinate, dicamba, 2,4-dichlorophenoxyacetic acid (2,4-D) and mesotrione.	9471/2025
Soybeans 2024	Herbicide Tolerant	BASF	GMB151 x DAS-81419-2 x DAS-444Ø6-6	Tolerant to HPPD-inhibiting herbicides, 2,4-D and glufosinate ammonium	9317/2024
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)	Glysophate and ammonium glusophinate herbicide tolerant	8565/2023 Release for free registration, use, testing, sowing, transportation, storage, marketing, consumption, importation, and disposal
Soybeans 2021	Herbicide Tolerant	BASF	GMB151	Nematode resistance and selectivity to HPPD-inhibiting herbicides	7306/2021 Commercial use
Soybeans 2019	Herbicide Tolerant	TMG	HB4 and HB4 x RR	Herbicide and Drought Tolerant	6540/2019 Food and Feed
Soybeans 2018	Herbicide Tolerant Insect Resistant	Monsanto	MON87751 x MON87708 x MON87701 x MON89788	Herbicide Tolerant Insect Resistant	5832/18 Food and Feed
Soybeans	GM-HRA; GM-	Du Pont	DP-305423-1 x	GM-HRA; GM-	5821/18

2018	FAS2-1 (partial sequence); cp4 epsps (aroA:CP4)		MON 04032-6 (Plenish x Plenish; Plenish RR1)	FAS2-1 (partial sequence); cp4 epsps (aroA:CP4)	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, as of February 2nd, 2025

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, as of February 2nd, 2025

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, as of February 2nd, 2025

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, as of February 2nd, 2025

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, as of February 2nd, 2025

c) STACKED OR PYRAMIDED EVENT APPROVALS/AUTHORIZATIONS

In 2021, CTNBio published 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. The Food Safety Risk Assessment Protocol, established by FAO/WHO Codex Alimentarius, provides an internationally recognized framework. Data generated in other environments or biomes were not widely accepted domestically. Achieving acceptance of such data represents a crucial milestone. CTNBio is debating the validity of environmental risk assessments based on data from different biomes and countries, aiming to establish a more comprehensive and accepted approach.

d) FIELD TESTING

[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

In accordance with article 14 of the Law 11105/2005, CTNBio is responsible for granting prior approval for all field trials in Brazil. The technology provider must obtain a Certificate of Quality in Bio Safety (CQBs) from CTNBio to perform field-testing. All providers must create an Internal Biosafety Commission (CIBio) and indicate for each specific project a principal researcher, defined in CTNBio's regulations as the "Principal Technical Officer". The provider's CIBio is an essential component for monitoring and testing the work of genetic engineering, manipulation, production, and transportation of GE crops, as well as enforcing biosafety regulations.

e) INNOVATIVE BIOTECHNOLOGIES

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, which scientists use to selectively modify the DNA of living organisms. Brazil approved its first agricultural product resulting from CRISPR technology in 2018: an edible corn that contains a higher concentration of amylopectin. On September 1st, 2022, CTNBio considered editing of the soybean genome, conducted by Embrapa with the CRISPR technique to deactivate specific anti-nutritional factors, resulting in conventional (non-transgenic or not-"genetically modified") soybeans and allowing it to be exempt from biotechnology regulations. CRISPR-Cas9 genome editing is 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.

In 2025, researchers at Embrapa used CRISPR-Cas9 gene editing technology to make the fungus *Beauveria bassiana* more lethal against agricultural pests. This innovation enhances the fungus' ability to eliminate insects more quickly and efficiently, reducing the need for chemical pesticides. *Beauveria bassiana naturally* infects and kills insects, but its effectiveness is limited by the time required for it to act and the high doses needed.

Brazil already employs biocontrol methods, especially in soybean and coffee cultivation, but faces challenges related to efficiency and costs. Brazil's biodiversity offers potential for developing even more tailored fungal strains suited to local climate conditions, further strengthening innovative agriculture and environmental health.

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[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

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. However, discussions are ongoing in the Brazilian Congress regarding the potential withdrawal of the requirement for genetically engineered (GE) products to display a "T" symbol in black within a yellow triangle, as established by Ordinance 2658/03 in 2003. The proposed withdrawal, outlined in PLC 34/2015, remains under consideration in the Brazilian Senate. Thus, the referred decree remains in force, and 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.

[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

Figure 2:
Two products commonly consumed in Brazil - cornstarch and oil - displaying 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.

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 innovative agriculture, since it would speed up the offer of new technologies.

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[13], 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 Roundup Ready soybean technology.

The project "*Cultive Biotec*" (Cultivate Biotech), created by BASF, Bayer, Corteva, and Syngenta in 2021, is 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 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 soybeans biotechnologies to enter the Brazilian market. More information on this project, can be found at their website[14], available in Portuguese.

In June 2025, the Mato Grosso State Court (TJMT) granted Bayer an injunction suspending a December 2024 ruling that allowed Brazilian soybean producers to claim reimbursement for royalties paid on expired patents for genetically modified soybean seeds. Bayer appealed the lower court's decision, seeking to correct terms related to the Intacta RR2 PRO soybean technology, originally developed by Monsanto, which Bayer acquired in 2016. The injunction halts royalty repayments until the TJMT reviews the case's merits.

l) CARTAGENA PROTOCOL RATIFICATION

Legislative Decree 136[15] 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

[13] Available in Portuguese at: https://www.planalto.gov.br/ccivil_03/leis/l9279.htm
[14] https://www.cultivebiotec.com.br/
[15] Available in Portuguese at: https://www2.camara.leg.br/legin/fed/decleg/2020/decretolegislativo-136-11-agosto-2020-790527-norma-pl.html

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.

The Memorandum of Understanding between Brazil, Argentina, Paraguay, and Uruguay established the International Network for the Biosafety of Products Derived from Modern Biotechnology (ABRE-Bio) to streamline procedures, reduce costs and time, and assess the regulatory status of products from New Breeding Technologies (NBTs) and modern biotechnology. On August 12, 2024, Brazil's Ministry of Science, Technology, and Innovation (MCTI) created the CABBIO Advisory Committee through MCTI Ordinance 8425[16]. The consultative committee, headquartered at MCTI, evaluates the technical feasibility and cost-benefit of research, development, and innovation (RD&I) projects and short courses for submission to the CABBIO Board of Directors.

Brazil and PRC have agreed to establish a standardized cooperation mechanism in biotechnology by jointly implementing scientific and technological projects in the field of life sciences. On April 14, 2023, the two countries signed the "Joint Declaration on the Deepening the Comprehensive Strategic Partnership between the Federative Republic of Brazil and the People's Republic of China", which identified health medicine, bioagriculture, bioenergy and the conservation and innovative use of biodiversity as fundamental directions for cooperation.

In the biotechnology area, both nations intend to cooperate to foster a collaborative, inclusive, and mutually beneficial innovation by encouraging standardized cooperation between research institutes, universities, and medical institutions in biology. Both countries plan to jointly implement life sciences projects and collaborate on basic research and technological development in biomedicine, bioagriculture, bioenergy, and biodiversity.

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.

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.

[16] 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.

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 environmentally friendly

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.

In 1998, there was significant consumer resistance to "transgenic" plants, driven by concerns about their safety and environmental impact. Over time, however, acceptance has grown as awareness of their benefits, such as increased agricultural productivity and reduced pesticide use, has improved. Despite this progress, a few consumer concerns persist.

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)[17]
Brazilian Agricultural Research Corporation (EMBRAPA)[18]**Error! Hyperlink reference not valid.**
CropLife Brasil (CLB)[19]
Biotec-LATAM [20]**Error! Hyperlink reference not valid.**

[17] https://www.abia.org.br/
[18] https://www.embrapa.br/en/international
[19] https://croplifebrasil.org/
[20] 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, which has successfully bred GE dairy cattle and has research on recombinant proteins. Two calves born in 2013 are part of this research. Other project focused on the use of GE technology to improve the health of beef cattle and increase cattle weight. Additionally, two GE goats produced in the state of Ceará have high levels of a human antimicrobial proteins proven effective in treating diarrhea in young pigs. The research demonstrated the potential for food products from GE animals to benefit human health. This project was carried out in cooperation with the University of California at Davis.

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 *"Junque*ira" in 2005; "Piatã" in 2010, an offspring of "Porã" and from the *Junqueira* cow breed.

In 2016, the Embrapa biotechnology animal reproduction team developed 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 worked 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 were 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

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.

The Draft Bill (PLS 73/2007), later renamed Bill 5010/13, aimed to regulate the cloning of animals, including wild species and their offspring. It was enacted as Law 15,021, published on November 12, 2024. This law governs the control of animal genetic material, the production and supply of clones of domestic animals intended for breeding purposes in zootechnical applications, and includes additional provisions.

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 COMMERCIALLY IN BRAZIL

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

Source: CTNBio, as of March 18th, 2025.

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

Product	**Characteristics**	**Company**	***Document/Year***
Vaccine P728	*P728 is an inactivated vaccine indicated for the active immunization of pigs from 3 weeks of age against Porcine Circovirus Type 2 (PCV2) and Mycoplasma hyopneumoniae infection*	Ceva Saúde Animal Ltda.	9506/2025
Vaccine NOBIVAC PUPPY DP Plus	*Live attenuated vaccine against canine distemper and parvovirosis for import and commercialization activities*	Merck Sharp & Dohme Saúde Animal Ltda.	9504/2025
Vaccine Volvac® B.E.S.T AI + ND KV	*Vaccine indicated for the active immunization of healthy chickens, from ten days of age, against the highly pathogenic Avian Influenza virus (H5N1) and against velogenic Newcastle Disease*	Boeringer Ingelheim Animal Health do Brasil Ltda.	9503/2025
Respiratory Virus Panel Molecular Kit	*Respiratory Virus Panel Molecular Kit (VR1/VR2) for diagnosis derived from molecular GEs of risk class 1*	Instituto de Tecnologia em Imunobiológicos - Bio-Manguinhos/ Fiocruz	9451/2025
Elevidys	*This is an Elevidys drug, with the active ingredient delandistrogene moxeparvoveque for gene therapy, indicated for Duchenne Muscular Dystrophy (DMD)*	Produtos Roche Químicos e Farmacêuticos S.A.	9184/2024
(VR1/VR2) for molecular diagnostics	*Molecular Diagnostic Kits involving derivatives of Genetically Engineered Organisms - GEs of risk class 1*	Instituto de Tecnologia em Imunobiológicos Bio-Manguinhos/ Fiocruz	9071/2024
Biotech vaccine Vac COX	*A vaccine for veterinary use, derived from a genetically engineered microorganism of risk class 1, for use in*	Vetanco do Brasil Importação e Exportação Ltda.	8962/2024

	poultry and pigs		
POULVAC PROCERTA HVT-IBD-ND	*Commercial Release for the product containing Genetically engineered (GE) called POULVAC PROCERTA HVT-IBD-ND, Frozen live vectored vaccine against Gumboro, Marek and Newcastle Diseases*	Zoetis Indústria de Produtos Veterinários Ltda.	8911/2024
Upstaza	*Gene therapy product Upstaza (eladogeno exuparvoveque) for the treatment of the ultra-rare disease, aromatic L-amino acid decarboxylase deficiency (AADC)*	PTC Farmacêutica do Brasil Ltda.	8721/2023
Vaccine INNOVAX ILT-IBD	*INNOVAX ILT-IBD vaccine, live recombinant vaccine in associated cell form against Marek's disease, infectious bursal disease and infectious laryngotracheitis*	Merck Sharp & Dohme Saúde Animal Ltda.	8621/2023
Brexucabtageno autoleucel	*This gene therapy product, Tecartus® (brexucabtagene autoleucel), is a genetically engineered autologous T-cell immunotherapy targeting CD19 - a marker for neoplastic cells*	Gilead Sciences Farmacêutica do Brasil Ltda.	8552/2023
PUREVAX RCPCh FeLv	*Multiple vaccine against feline viral rhinotracheitis, calicivirus, chlamydiosis, panleukopenia and feline leukemia*	Boehringer Animal Health do Brasil Ltda.	8431/2023
Takeda's tetravalent dengue vaccine (TDV)	*Takeda's tetravalent dengue vaccine (TDV) is indicated for the prevention of dengue disease caused by any dengue virus serotype*	Takeda Pharma Ltda.	8401/2023
Yescarta	*It is a gene therapy of genetically modified autologous T cells directed to the recognition of the glycoprotein antigen CD19 - marker for neoplastic cells.*	Gilead Sciences Farmacêutica do Brasil Ltda.	8242/2022

Roctavian	*It is a gene therapy vector, incompetent for replication, being an inactive version of a non-pathogenic wild type of adenoassociated virus/serotype 5 (AAV5) that is modified to contain the factor VIII gene*	Biomarin Farmacêutica Ltda.	8241/2022
Oncept	*Canine melanoma DNA vaccine*	Boehringer Animal Health do Brasil Ltda.	8182/22
Covid-19 Vaccine	*Commercialization of the Covid-19 vaccine (Ad26.COV2.S1 – recombinant and incompetent replicant), indicated for the active immunization in prevention of the disease caused by severe acute respiratory syndrome Ccoronavirus type 2 (SARSCoV-2)*	Janssen-Cilag Farmacêutica Ltda.	8123/2022
Vaxxitek HVT + IBD + ILT	*Recombinant, frozen live virus vaccine against Marek and Gumboro diseases*	Boehringer Ingelheim Animal Health do Brasil Ltda.	7912/22
Ciltacabtagene autoleucel	*Commercial Release of* ciltacabtagene autoleucel (cilta-cel, JNJ-68284528), indicated for treatment of multiple myeloma	Janssen-Cilag Farmacêutica Ltda.	7779/2021
Poulvac Procerta	*Poulvac Procerta HVT-IBD – Frozen live vector vaccine against Gumboro and Marek Diseases*	Novartis Biociências S.A.	7666/2021
Kymriah	*KYMRIAH, tisagenlecleucel (CTL019) treatment for Refractory acute B-cell lymphoblastic leukemia and in post-transplant relapse, in second relapse or in later relapse*	Novartis Biociências S.A.	7502/2021
Covid-19 Vaccine	*Commercialization of the GAM-COV-VAC (SPUTNIK V) Vaccine, against SARS-CoV-2, developed by the*	União Química Farmacêutica Nacional S.A	7440/2021

	Gamaleya Institute (Russia)		
Covid-19 Vaccine	*Commercialization of the recombinant Covid-19 vaccine based on microorganism of Risk Class 1 (ChAdOx1+nCoV19)*	Instituto de Tecnologia em Imunobiológicos-Bio Manguinhos (FIOCRUZ)	7292/2021
FVAX-20SA01 Vaccine	*Specific Vaccine against Strepstococcus for captive-bred tilapia*	Tevah Consultoria Empresarial, Regulatória, Governamental e Engenharia Ltda.	7480/2021
CIRCOGARD Recombinant Vaccine	*Vaccine against Swine Circovirus Type 2 (PCV2)*	Eco Animal Health do Brasil, Comércio de Produtos Veterinários Ltda.	7449/2021
G608 Vaccine	*Vaccine against Edema Disease in piglets, inactivated*	Ceva Saúde Animal	7340/2021
Poulvac Procerta HV-ND	*Poulvac Procerta HV-ND Vaccine – Vectorized live frozen vaccine against Marek and Newcastle diseases*	Zoetis Indústria de Produtos Veterinários Ltda.	7249/2020
CIRCO/MYCOGARD	*Recombinant Vaccine against Swine Circovirus and Mycoplasma hyopneumoniae*	Eco Animal Health do Brasil, Comércio de Produtos Veterinários Ltda.	7239/2020
Lamzede	*LAMZEDE, commercial name of active component alfavelmannase, which is a human recombinant alpha-mannosidase, indicated for treatment of adult and pediatric patients who suffer from lysosomal alpha-mannosidade enzyme deficiency*	Chiesi Farmacêutica Ltda.	7201/2020
Avian Recombinant Vaccine Code 1A89.R0	*Avian Vaccine for the Prevention against Marek Disease, Newcastle Disease and Gumboro Diseas*	Ceva Saúde Animal Ltda.	7055/2020
Zolgensna	*Commercialization of Live Recombinant Vaccine for*	Novartis Biociência S.A.	6495/2020

	pediatric patients with Spinal Muscular Atrophy (SMA)		
(INNOVAX ND – ILT)	*Commercialization of a Recombinant Live Vaccine against Marek Disease, Newcastle Disease, Infectiou Laryngotracheitis, derived from a GMO (INNOVAX ND-ILT)*	Merck Sharp & Dohme Saúde Animal Ltda.	6923/2020
MHYOSPHERE PCV ID	*Commercialization of an innactivated vaccine. The active substance MHYOSPHERE PCV ID is a inactivated recombinant strain of Mycoplasma hyopneumoniae*	Hipra Saúde	6910/2020
LUXTURNA (voretigene neparvovec)	*Genetic Therapy LUXTURNA (voretigene neparvovec) which is indicated for the treatment of adult and pediatric patients with eyesight loss due to hereditary retinal dystrophy caused by bialletic RPE65 gene mutations*	Novartis Biociências S.A.	6849/2020
Fostera Gold PCV MH	*Innactivated Vaccne Against Pork and Mycoplasma hyopneumoniae*	Zoetis Industria de Produtos Veterinários	6221/2018
Avipro Megan VAC 1	*Live Vaccine against Salmonella in Broiler chicken*	Elanco Saúde Animal	6220/2018
PREVEXXION RN	*Vaccine for Marek Diseas in Birds*	Merial Saúde Animal Ltda.	6162/2018
Avian Recombinant Vaccine Code 1062.R0	*Against Marek Disease and Avian Influenza*	Ceva	5997/2018
Recombinant Vaccine Against Pork Circovirus type 2	*Marek Disease and Avian Influenza*	Ourofino Saúde Animal Ltda.	6056/2018
TROVAC-NDV	*Live Recombinant Virus Vaccine for Newcastle Disease and Avian Yaws*	Merial Saúde Animal Ltda.	6055/2018
Ingelvac Provenza	*Swine Influenza Live Modified Virus Vaccine*	Boehringer	6062/2018

Newxxitek HVT+ND	*Live Vaccine for Marek Disease, Newscastle Disease – Marek Diases as vector, Serotype 3*	Merial	5861/2018
INNOVAX ND-IBD	*Live Recombinant Vaccine for Marek Disease, Newscastle Disease and Gumboro Disease*	Merial	5836/18
Purevax Felv	*Feline Leukemia Live Vaccine*	Merial	5935/2018
PROTEQFLU	*Equine Influenza Vaccine*	Merial	5486/2017
PUREVAX RAIVA Vaccine	*Feline Raibes Vaccine*	Merial	5407/2017
Biotech Vac Salmonella Vaccine	*Avian Salmonellosis Vaccine*	Vetanco do Brasil Importação e Exportação Ltda.	5331/2017
OncoVEXGM-CSF	*Melanomas Treatment*	Lab. Bergamo	5099/2016
HIPRABOVIS IBR MARKER LIVE	*Bovine Herpes Vaccine*	Hipra	5005/2016
Bay98	*Immunostimulant*	Bayer	4915/2016
Dengvaxia	*Dengue Vaccine*	Sanofi Aventis	4759/2015
Dengue Vaccine 1,2,3,4	*Dengue Vaccine*	Inst. Butantan	4673/2015
Bovela	*Bovine Diarrhea*	Boehringer	4594/2015
B058	*Swine Circovirus*	Ourofino	4202/2014
PRO-VAC Circomaster	*Swine Circovirus*	Vencofarma	4090/2014
Vectormune HVT-LT	*Avian Laryngotracheitis Marek Disease, Serotype 3*	Ceva	4304/2014
ProteqFlu	*Equine Influenza*	Merial	3637/2013
ProteqFlu TE	*Equine Influenza and tetanus*	Merial	3636/2013
InnovaxND	*Birds/Marek and Newcastle*	Intervet	3265/2012
INNOVAX ILT	*Birds/Marek and Laryngotracheitis*	Intervet	2872/2011
Vectormune FP-LT-AE	*Avian yaws, avian laryngotracheitis and Avian encephalomyelitis*	Ceva	2958/2011
Vectormune FP-LT	*Avian yaws and avian laryngotracheitis*	Ceva	2957/2011
PouvacSt	*Birds/Salmonellosis*	Fort Dodge	2741/2010
Vectormune HVT-NDV	*Birds/Marek-Newcastle*	Ceva	2279/2010
Vectormune HVT-IBD	*Birds/Marek-Gumboro*	Ceva	2280/2010
Vectormune FP-	*Birds/Roup-*	Ceva	2226/2009

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

Source: CTNBio, as of March 18th, 2025.

c) INNOVATIVE BIOTECHNOLOGIES

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

Brazilian research prioritizes preventing and curing animal diseases, a key challenge for producers. CRISPR technology offers potential solutions, such as producing medicines in animal milk or curing herd diseases. On September 3, 2024, Embrapa's Genetic Resources and Biotechnology Center launched a groundbreaking update to Intergen, Brazil's widely used genetic evaluation software for beef cattle breeding. Originally developed in 2008 and expanded in 2016, the latest version introduces two new modules - IntergenIOD and IntergenACC - marking significant advancements in genetic improvement programs.

In February 2025, the leading tilapia producer announced its successful development of gene-edited tilapia in partnership with the U.S.-based Center for Aquaculture Technologies (CAT), revolutionizing breeding efficiency by reducing the timeline from 20 years to just one. Through reproductive induction and in vitro fertilization, CAT scientists and Brazilian Fish's R&D team created precise genetic variations to enhance growth, yield, and feed efficiency. After two years of research, the first gene-edited tilapia is ready for performance and genomic evaluations. This breakthrough positions tilapia as an innovative and competitive protein source globally, with the company advancing its myostatin gene-editing project under CTNBio regulations to ensure biosafety compliance.

d) LABELING AND TRACEABILITY

The same regulations and laws as described under Chapter 1, Part B (Policy), Section (g) apply to GE animals, although specific requirements such as labeling and traceability have not yet been developed

for GE animals. Brazilian consumer laws apply to all products of GE plants, GE animals, or animal cloning in terms of basic and general information about the product for the consumer.

e) ADDITIONAL REGULATORY REQUIREMENTS

FAS Brasilia is not aware of any additional regulatory requirements.

f) INTELLECTUAL PROPERTY RIGHTS (IPR)

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

g) INTERNATIONAL TREATIES AND FORUMS

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

h) RELATED ISSUES

FAS Brasilia is not aware of any related issues.

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS

In 2025, a MAPA representative stated that biotechnologies have enabled Brazil to increase food production while preserving land and biodiversity, supported by a robust regulatory framework, including the Biosafety Law of 1995 and the regulation of New Breeding Techniques (NBTs) like genome editing in 2018.

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.

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

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

Product	**Characteristics**	**Company**	**Document/ Year**
Saccharomyces cerevisae strain	Genetically Engineered Microorganism *Saccharomyces cerevisiae* - strain	PHIBRO Saúde Animal International	9507/2025

PHI093/PHI094	PHI093/PHI094 and derivatives, used for ethanol production	Ltda.	
Saccharomyces cerevisiae lineages M41756 and M41758	Commercial release of *Saccharomyces cerevisiae* lineages M41756 and M41758 and their derivatives, used to produce ethanol from sugar cane	Lallemand Soluções Biológicas Ltda.	9505/2025
Prosin	GMO, ARG - Prosin, produced from C. glutamicum KCCM 80182	CJ do Brasil Indústria e Comércio de Produtos Alimentícios Ltda.	9450/2025
Paenibacillus polymyxa strains BEC253, BEC259, BEC260, BEC261, BEC262 and BEC264	*Paenibacillus polymyxa* with related modifications aimed at improving the efficiency of biological nitrogen fixation for agricultural use named BEC253, BEC259, BEC260, BEC261, BEC262 and BEC264	Prophyto Comércio e Serviços Ltda.	9414/2025
Bacillus thuringiensis strain *BEC184*	BEC184 strain was developed from BEC168 strain, a rhizosphere isolate with the ability to colonize and promote plant growth, through two successive genetic modifications carried out by homologous recombination	Prophyto Comércio e Serviços Ltda.	9355/2024
4 enzymes derived from *Trichoderma reesei GMM* (Cellic RZ Crude)	A mixture of four enzymes derived from GE *Trichoderma reesei* microorganisms (Cellic RZ Crude) that will be used in the commercial production of ethanol	Novozymes Latin America Ltda.	9186/2024
Soybean leghemoglobin produced by *Picchia pastoris* MxY1100	Soy leghemoglobin produced by the GE microorganism *Picchia pastoris*, MxY1100, indicated/used for addition to vegetable products similar to ground meat such as hamburgers, sausages, nuggets and congeners	Jomakol Representações e Serviços Ltda.	9185/2024
Saccharomyces cerevisiae lineages M30262 and M32172	*Saccharomyces cerevisiae* lineage M30262 and M32172 for ethanol production from corn	Lallemand Soluções Biológicas Ltda.	9120/2024
Saccharomyces cerevisiae strain *Evolve Evergreen*	*Saccharomyces cerevisiae* strain Evolve Evergreen, used to produce fuel ethanol from corn	BioSpringer do Brasil	9119/2024
Bacillus subtilis (GICC03667)	Commercial release of GE microorganism derivative, subtilisin enzyme (GG145)	Danisco Brasil Ltda	9072/2024
Bacillus thuringiensiscepas BEC183 and BEC185	Commercial Release of GE Microorganism Bacillus thuringiensis strains BEC183 and BEC185	Prophyto Comércio e Serviço Ltda.	8904/2024

Saccharomyces cerevisiae (Sourvisiae) M16141	Commercial release of the microorganism *Saccharomyces cerevisiae* (Sourvisiae), which will be used in the beer fermentation process	Lallemand Soluções Biológicas Ltda.	8820/2023
Alpha-amylase (GICC03665)	Commercial release of the *alpha-amylase* enzyme (GICC03665), derived from a GE microorganism, which will be used in cleaning applications	Danisco Brasil LTDA	8776/2023
Saccharomyces cerevisiae GICC03661 (GPY010272)	Commercial Release NB-1 Commercial release derived from GE Microorganisms Yeast *Saccharomyces cerevisiae* GICC03661 (GPY010272), to be used by the fuel ethanol industry	Danisco Brasil Ltda.	8720/2023
Saccharomyces cerevisiae strain Y78585	Commercial release of genetically engineered *Saccharomyces cerevisiae* yeast (strain Y78585) for the production of a sweetening molecule, and any progenies derived from this GE	Amyris Biotecnologia do Brasil Ltda.	8679/2023
Corynebacterium glutamicum KCCM 80367 *THR Prosin*	Commercial release of the product derived from a GE microorganism (*C. glutamicum* KCCM 80367), *THR Prosin*, and its formulations	CJ do Brasil Indústria e Comércio de Produtos Alimentícios Ltda.	8637/2023
Corynebacterium glutamicum Bacterium, strain DM34.00	Bacteria	Evonik Brasil Ltda.	8636/2023
Subtilisin (GG145) from *Alkalihalobacillus clausii* expressed in *Bacillus subtilis* MD703 (GICC03655)	Commercial release of the product derived from GE *Microorganism Subtilisin* (GG145) from *Alkalihalobacillus clausii* expressed in *Bacillus subtilis* MD703 (GICC03655)	Danisco Brasil Ltda.	8635/2023
Saccharomyces cerevisiae (strain Y69682)	Commercial release of GE *Saccharomyces cerevisiae* yeast (strain Y69682) and its derivatives	Amyris Biotecnologia do Brasil Ltda.	8622/2023
THR-Pro	Commercial release of a GE microorganism derivative (*C. glutamicum* KCCM 80367), *THR Pro*, and its formulations for use in the manufacture of animal feed (poultry and pigs).	CJ do Brasil Indústria e Comércio de Produtos Alimentícios Ltda.	8553/2023
Saccharomyces cerevisiae, Lineages M32465, M32679 and	Commercial Release of GE Derivative *Yeast Saccharomyces Cerevisiae* lineages M32465, M32679 and M32680 to be used in the production of ethanol	Lallemand Soluções Biológicas Ltda.	8344/2022

M32680			
Saccharomyces cerevisiae GICC03587 (GPY10138)	Commercial Release of GE Derivative Yeast *Saccharomyces cerevisiae* GICC03587 (GPY10138) developed for ethanol production	Danisco Brasil Ltda.	8343/2022
Saccharomyces cerevisiae lineage *M12156*	Commercial release of GE *Saccharomyces cerevisiae* lineage M12156 and derivatives for ethanol production from corn	Lallemand Soluções Biológicas Ltda.	8271/2022
TRP-Prosin	Commercial release of GE derivative *TRP-Prosin* or dryed *Corynebacterium glutamicum* lineage KCCM 80346 for animal feed manufacturing	CJ do Brasil Indústria e Comércio de Produtos Alimentícios Ltda.	8264/2022
Saccharomyces cerevisiae lineages M32292, M32376 e M32379	Commercial release of GE *Saccharomyces cerevisiae* (M32292, M32376 and M32379) for ethanol production from sugarcane	Lallemand Soluções Biológicas Ltda.	8263/2022
Saccharomyces cerevisiae lineage *PRCH20080 - FS0436*	Commercial release of GE *Saccharomyces cerevisiae* lineage PRCH20080-FS0436 for ethanol production	Danisco Brasil Ltda.	8243/2022
Saccharomyces cerevisiae lineage *Y62840*	Commercial release GE *Saccharomyces cerevisiae* lineage 62840 for vanillin production	Amyris Biotecnologia do Brasil Ltda.	7978/2022
Saccharomyces cerevisiae (SCY014)	Commercial release of GE *Saccharomyces cerevisiae* lineage SCY014 for ethanol production	Novozymes Latin America Ltda.	7780/2021
Saccharomyces cerevisiae (SCY018)	Commercial release of GE *Saccharomyces cerevisiae* lineage SCY018 for ethanol production	Novozymes Latin America Ltda.	7752/2021
Saccharomyces cerevisiae (lineage Y67383)	Commercial release of GE *Saccharomyces cerevisiae* lineage Y67383 for production of steviol and derivatives	Amyris Biotecnologia do Brasil Ltda.	7663/2021
Saccharomyces cerevisiae (SCY017)	Commercial release of the GE *Saccharomyces cerevisiae* lineage SCY017 for ethanol production	Novozymes Latin America Ltda.	7662/2021
Saccharomyces cerevisiae M23541	Commercial release of GE *Saccharomyces cerevisiae* M23541 for ethanol production from corn	Lallemand Brasil Ltda.	7661/2021
Saccharomyces cerevisiae (GICC03578 and GICC03588)	Commercial release of GE *Saccharomyces cerevisiae* lineages GICC03578 and GICC03588 for ethanol production	Danisco Brasil Ltda.	7643/2021
Saccharomyces cerevisiae M24296	Commercial release of GE *Saccharomyces cerevisiae* lineage	Lallemand Brasil Ltda.	7561/2021

	M24296 to produce ethanol from corn		
Saccharomyces cerevisiae - CelluXTM 4	Commercial release of GE *Saccharomyces cerevisiae* lineage CelluXTM 4 for ethanol production	BioSpringer do Brasil Indústria de Alimentos S.A.	7481/2021
Saccharomyces cerevisiae lineages SCY015 and SCY016	Commercial release of GE *Saccharomyces cerevisiae* lineages SCY015 and SCY016 for industrial ethanol production	Novozymes Latin American Ltda.	7398/2020
Alpha-Amylase	Commercial release of GE derivative *Alpha-amylase* enzyme (*Bacillus licheniformis* GICC03561) for use in cleaning products	Danisco Brasil Ltda.	7250/2020
Prototheca moriformis lineage S9120	Commercial release of GE *Prototheca moriformis* lineage S9120 to produce triglyceride oils and their derivatives	Corbion Brasil	7205/2020
Soy Leghemoglobin	Commercial release of the GE derivative Leghemoglobin from Soy (*Picchia pastoris* lineage MXY0541) for use in ground meat analogs for human consumption	Jomakol Representações e Serviços Ltda.	7060/2020
Saccharomyces cerevisiae M15419	Commercial release of GE *Saccharomyces cerevisiae* lineage M15419 for use in the production of corn-based ethanol	Lallemand Brasil Ltda.	7059/2020
L-Lysine (*BestAmino™)*	Commercial release of GE derivative L-Lysine (BestAmino™) (*Corynebacterium glutamicum* lineage KCCM80183) for use as an additive in the manufacture of animal feed	CJ do Brasil Indústria e Comércio de Produtos Alimentícios Ltda.	7056/2020
Saccharomyces cerevisiae SCY010Y	Exemption from the Post Commercial Release monitoring plan for GE *Saccharomyces cerevisiae* strain SCY010Y, approved by technical opinion	Novozymes Latin America Ltda.	7010/2020
Derivative of *alpha-amylase* enzyme microorganism (GICC03556)	Product derivative from the genetically engineered organism *alpha-amylase* enzyme (GICC03556) for the formulation of washing machine and dish washer soaps to assist in the removal of starch origin stains	Danisco Brasil Ltda.	7002/2020
Granulated Valine VAL PRO	Commercial release of GE derivative - VAL PRO granulated valine (L-Valine 70%) for use in animal feed production	CJ do Brasil Ind. E Com. De Produtos Alimentícios Ltda.	6925/2020
Saccharomyces cerevisiae lineage *Y63348*	Commercial release of the yeast *Saccharomyces cerevisiae* lineage Y63348 for the production of steviol	Amyris do Brasil Ltda.	6822/2020

	and derivatives		
Granulated Tryptophan TRP Pro	Derivative of genetically engineered microorganism, Granulated Tryptophan TRP Pro (LTriptofano 60%) for use in animal feed production	CJ do Brasil Industria e Comercio de Produtos Alimentícios Ltda.	6821/2020
Saccharomyces cerevisiae lineage GICC03506	Commercial release of the GE *Saccharomyces cerevisiae* lineage GICC03506 for use in the industrial production of ethanol	Danisco Brasil Ltda.	6729/2019
Granulated Thr Pro (L-Threonine 75%)	Derivative of genetically engineered microorganism - Granulated Threonine THR Pro (L- Threonine 75%)	CJ do Brasil Industria e Comercio de Produtos Alimentícios Ltda.	6623/2019
Substilisin	Commercial release of GE derivative Substilisin (*Bacilus subtilis* lineage GICC03528) for use in cleaning products	Danisco do Brasil Ltda.	6592/2019
Saccharomyces cerevisiae lineage Y47220	Commercial release "GMO" *Saccharomyces cerevisiae* lineage Y47220 for the production of steviol and derivatives	Amyris Biotecnologia do Brasil Ltda.	6.551/2019
Saccharomyces cerevisiae lineage SCY011	Commercial release of GE *Saccharomyces cerevisiae* lineage SY011 for use in ethanol production	Novozymes Latin America Ltda.	6507/2019
Corynebacterium glutamicum lineage DM24.60	Commercial release of GE *Corynebacterium glutamicum* lineage DM24.60 and its derivative for use in industrial fermentation and its derivative as a feed additive	Evonik Brasil Ltda.	6476/2019
Alpha-amylase GICC03515	Commercial release GE derivative alpha-amylase (*Bacillus licheniformis* lineage GICC03515) for use in cleaning products	Danisco Brasil Ltda.	6237/2018
Saccharomyces cerevisiae lineage Y27011	Commercial release of GE *Saccharomyces cerevisae* lineage Y27011 and its derivatives to produce farnesene	Amyris Biotecnologia do Brasil Ltda.	6165/2018
Alpha-amylase	Commercial release of GE derivative alpha-amylase (Bacillus licheniformis lineage Bra7) for use in the production of ethanol and the lysine amino acid	Danisco Brasil Ltda.	6152/2018
Alpha amylase (GICC03469)	"GMO" derivative of alpha amylase (GICC03469)	Danisco	6063/2018
Saccharomyces cerevisiae lineage Y22021	Commercial release *of GE Saccharomyces cerevisae* lineage Y22021 and its derivatives to produce	Amyris Biotecnologia do Brasil Ltda.	5827/2018

	farnesene		
Saccharomyces cerevisiae lineage SCY010	Commercial release of GE *Saccharomyces cerevisiae* lineage SCY010 for use in ethanol production	Novozymes Latin America Ltda.	5.941/2018
Hemicellulase	Commercial release of GE hemicellulase derivative (Trichoderma reesei strain GICC20007658) for use in ethanol production	Danisco Brasil Ltda.	5798/2018
Alpha-glucosity	Commercial release of GE derivative alpha-glucosidase (Trichoderma reesei strain GICC03289) for use in the production of ethanol, organic acids and amino acids	Danisco Brasil Ltda.	5797/2018
Alpha-amylase	Commercial release of GE derivative alpha-amylase (Bacillus licheniformis strain GICC03299) for use in cleaning products	Danisco Brasil Ltda.	5496/2017
Saccharomyces cerevisae lineage S1260	Commercial release of GE *Saccharomyces cerevisae* lineage S1260 for commercial ethanol production	Novozymes Latin America Ltda.	5333/2017
Prototheca moriformis lineage S8885	Commercial release of GE *Prototheca moriformis* lineage S8885 for the production of triglyceride oils and derived bioproducts	Solazyme Brasil Óleos Renováveis e Bioprodutos Ltda.	5286/2016
Saccharomyces cerevisae lineage M10682	Commercial release of the *Saccharomyces GE cerevisae* lineage M10682 for ethanol production	Lallemand Brasil Ltda.	5285/2016
Prototheca moriformis lineage S8695	Commercial release of GE *Prototheca moriformis* lineage S8695 for the production of triglyceride oils and derived bioproducts	Solazyme Brasil Óleos Renováveis e Bioprodutos Ltda.	5238/2016
Alkaline Protease (Subtilisin)	Commercial release of the GE alkaline protease derivative *(Bacilus subtilis lineage* GICC03436) (subtilisin) for use in cleaning products	Danisco Brasil Ltda.	4768/2015
Prototheca moriformis lineage S6697	*Prototheca moriformis* microorganisms to produce triglycerides e bioproducts.	Solazyme Brasil Óleos Renováveis e Bioprodutos Ltda.	4768/2015
Prototheca moriformis lineage S5223	*Prototheca moriformis* lineage S5223 to produce triglycerides and bioproducts	Solazyme Brasil Óleos Renováveis e Bioprodutos Ltda.	4675/2015
Celere-2L	Genetically engineered microorganisms and their derivatives of the biological risk class I	Bio Celere Agroindustrial Ltda.	4526/2015
Bioproduct S5223	*Prototheca moriformis* microorganism derivative	Solazyme Brasil Óleos Renováveis e	4203/2014

		Bioprodutos Ltda.	
Saccharomyces cerevisiae lineage RN1016	Yeast (*Saccharomyces cerevisiae*) lineage genetically engineered to produce ethanol	Bio Celere Agroindustrial Ltda.	3877/2013
Prototheca moriformis lineage S2014	*Prototheca moriformis* to produce triglycerides and bioproducts	Solazyme Brasil Óleos Renováveis e Bioprodutos Ltda.	3775/2013
Saccharomyces cerevisiae lineage Y5056	Yeast (*Saccharomyces cerevisiae*) genetically engineered to produce Farnesene	Amyris do Brasil	3287/2012
Y1979	Yeast (*Saccharomyces cerevisiae*) genetically engineered to produce Farnesene	Amyris do Brasil	2281/2010

Source: CTNBio, as of May 16th, 2023.

c) LABELING AND TRACEABILITY

FAS Brasilia is not aware of any specific regulation for labeling 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.

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 was 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 is assessed.

Attachments:

No Attachments