

REGULATORY SYSTEM FOR GMOs in BRAZIL: the *CTNBio*

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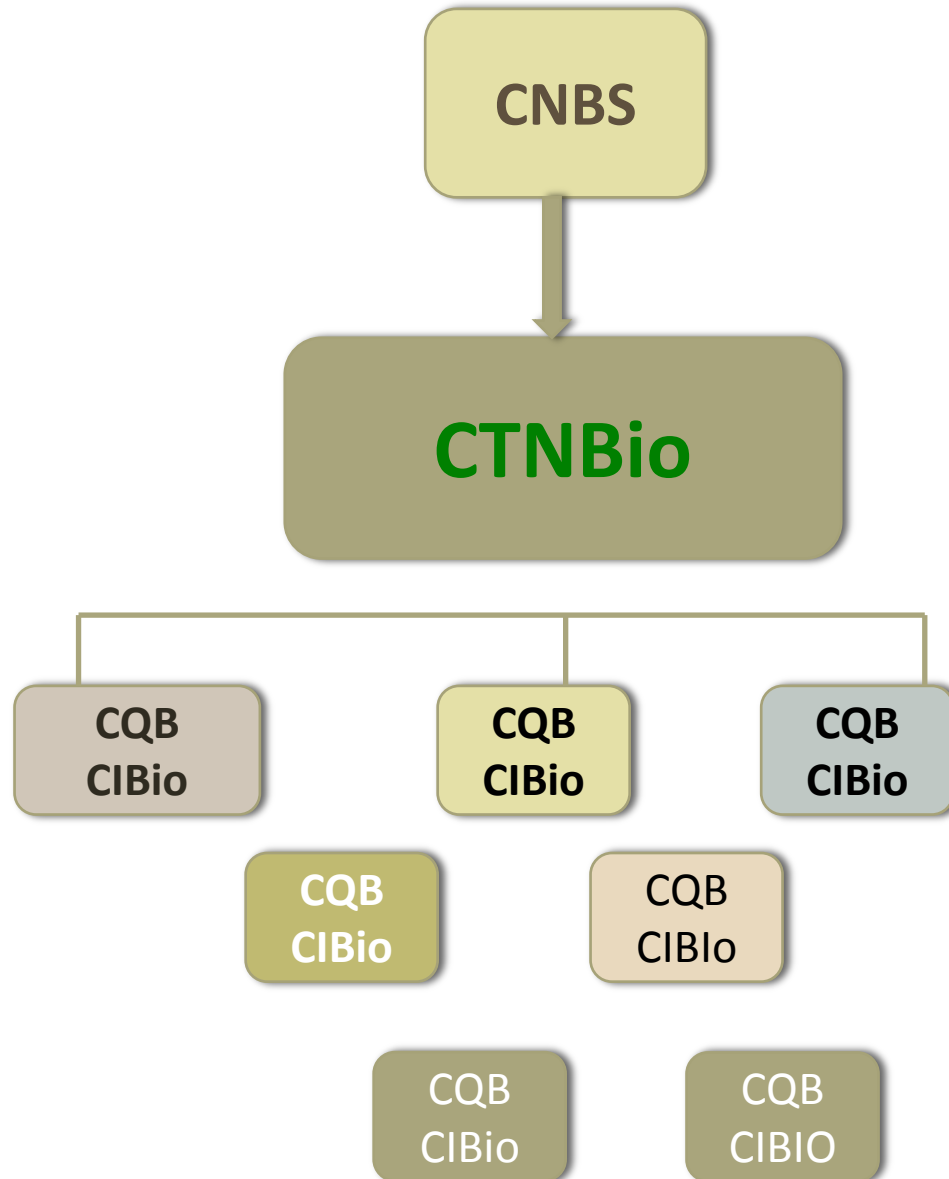
- CTNBio is a multidisciplinary collegiate body, created by Law No. 11.105, of March 24, 2005, whose purpose is to provide **technical advisory support** and advice to the Federal Government in the formulation, updating and implementation of the National Biosafety Policy on GMOs and as the establishment of technical safety standards and technical reports **relating to the protection of human health, living organisms and the environment**, for activities involving the construction, experimentation, cultivation, handling, transporting, marketing, consumption, storage, release and disposal GMOs and derivatives.

Biosafety Law 11.105

March 24, 2005

- Article 1. This Law provides **for safety norms and inspection mechanisms for the construction, culture, production, manipulation, transportation, transfer, import, export, storage, research, marketing, environmental release and disposal of genetically modified organisms** – GMOs and their by-products, guided by the drive for attaining scientific development in the biosafety and biotechnology area, the protection of life and human beings, of animal and plant health, and the compliance with the principle of environmental precaution.

- Article 3. Under this Law, it shall be considered:
- I – an organism: each and every biological entity that is capable of reproducing or transferring genetic material, including virus and other classes that may be made known;
- II – deoxyribonucleic acid - DNA, ribonucleic acid - RNA: genetic material which contains determining information about transmissible hereditary characters to progeny;
- **III – recombinant DNA/RNA molecules: 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;**
- IV – genetic engineering: the activity of manipulating DNA/RNA recombinant molecules;
- V – genetically modified organism - GMOs: an organism the genetic material of which – DNA/RNA has been modified by any genetic engineering technique;
- VI –GMO by-product: a product obtained from a GMO and that is not capable of autonomously replicating, or that does not contain a feasible GMO form;
- VII – human germinal cell: 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;
- VIII – cloning: an asexual reproduction process, artificially produced, based on a sole genetic patrimony, by using or not genetic engineering techniques;
- IX – cloning for reproductive means: cloning the end purpose of which is to make an individual;
- X – therapeutic cloning: cloning the end purpose of which is to produce embryonic stem cells for therapeutic purposes;
- XI – embryonic stem cells: embryonic cells that are capable of modifying the cells of any organism tissue.



Regulatory/Inspection Organs

- MAPA – Ministry of Science, Livestock and Food Supply
- ANVISA – National Agency for Sanitary Surveillance (linked to the Ministry of Health)
- IBAMA – Brazilian Institute of Environment and Natural Resources (linked to the Ministry of Environment)
- MPA – Ministry of Fishing and Aquiculture (*)
- (The Company/institution will be assessed for not complying with the requirements of the law)

CTNBio

(27 members and 27 alternate members)

- 3 specialists of human health
- 3 specialists of animal health
- 3 specialists of vegetal area
- 3 specialists of environmental area
- 1 representative of Ministry of Science and Technology
- 1 representative of the Ministry of Agriculture, Livestock and Supplies (MAPA)
- 1 representative of the Ministry of Health
- 1 representative of the Ministry of Environment
- 1 representative of the Ministry of Agriculture Development
- 1 representative of the Ministry of Development, Industry and Foreign Commerce
- 1 representative of the Ministry of Defense
- 1 representative of the Ministry of External Relationship
- 1 representative of the Ministry of Fishing and Waterculture
- 1 specialist in Familiar Agriculture
- 1 specialist in Biotechnology
- 1 specialist in Consumer Defense
- 1 Specialist in environment
- 1 specialist in worker 's health
- 1 specialist in the health area.

CTNBio

- 2 sectors
 - Human/animal
 - Plants/environmental
- 1 plenary session
- 2 day meetings, 10 times a year, in Brasilia

CTNBio

- Evaluates not only the product, but performs a broader evaluation of the laboratory that produces that GMO, the people working there, the biosafety level, and the biosafety conditions.
- CASE BY CASE ANALYSIS
 - PROJETS
 - PLANNED RELEASES
 - COMMERCIAL RELEASES (evaluated by 4 sectors: human, animal, plants and environmental)

CTNBio Ruling Instructions

SPECIFY SOME ASPECTS OF THE LAW 11.105.

Ruling Instructions numbers 1-16.

<http://ctnbio.mcti.gov.br/en/resolucoes-normativas>

CTNBio

- **Ruling Instruction No. 05, of March 12, 2008**
- Provides information on commercial release of GMOs and derivatives.
- **Ruling Instruction No. 06 of November 6, 2008.**
- Provides on rules for the planned release to the environment of Genetically Modified Organisms (GMO) of **plant origin and their derivatives.**

CTNBio

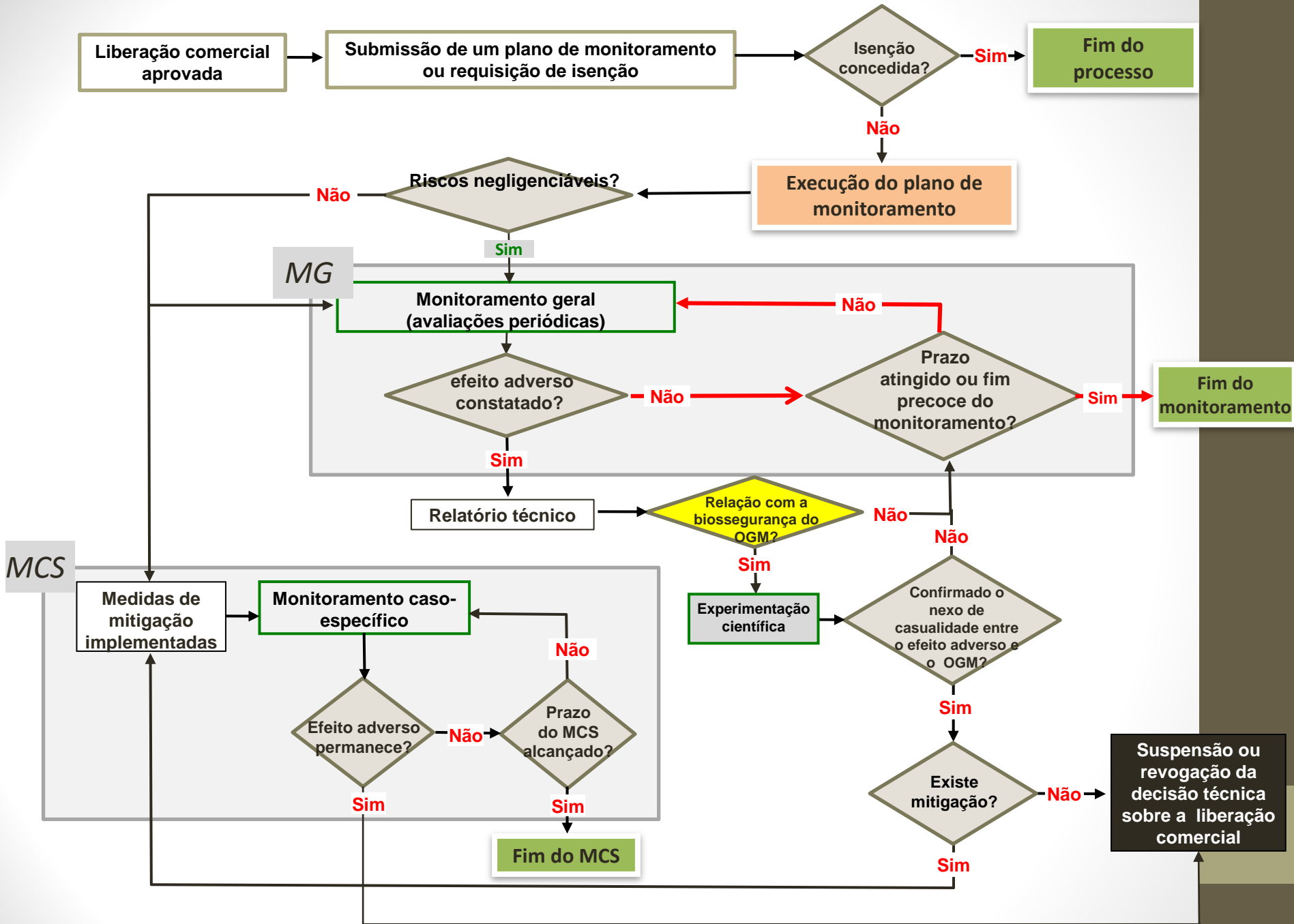
- **NORMATIVE RESOLUTION Nº 7, of April 27, 2009.**

Provides on rules for **planned release**
into the environment of Risk Class I
Genetically Modified Microorganisms
(GMM) and Genetically Modified
Animals (GMAn) and their derivatives.

- Obs: GMAn derivative – a product obtained from a GMAn that is unable to autonomously replicate itself or fails to contain a viable form of GMAn;

CTNBio

- **Post-commercial release (post market) monitoring system.**
- **Ruling Instruction nº 9, of December 2, 2011**
- Makes provisions on rules for genetically modified organisms post commercial release monitoring.
- **All commercial releases must be approved by the CNBS.





Top 10: área plantada no mundo com transgênicos em 2016

Confira quais são os países que mais adotam a biotecnologia agrícola no mundo. Brasil se destaca.

Aprovações CTNBio

Plantas
62,3%

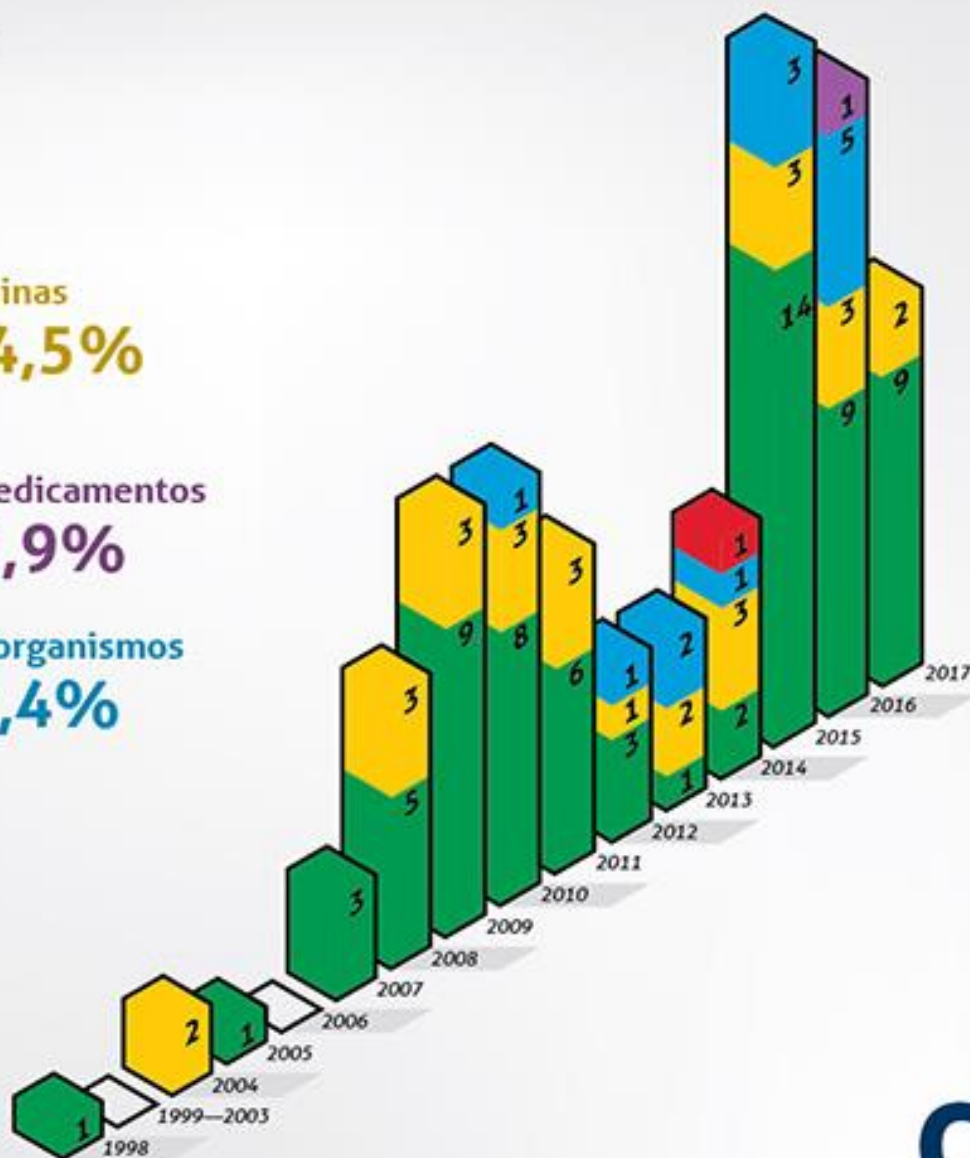
Vacinas
24,5%

Medicamentos
0,9%

Microrganismos
11,4%

Insetos
0,9%

Total:
114
aprovações



Fonte: CTNBio 2017.

CiB

Conselho de Informações
sobre Biotecnologia

CTNBio: rigor and transparency on GMO biosafety assessment in Brazil

Flavio Finardi Filho*

Science applied to agriculture has been increasing the food offer for many years, thus reducing the need to find new farming areas. In Brazil, the truth of such statement is proven by the fact that in the past 20 years the production volume increased by over 100%, while the total growing area increased only by 25%. In the period, the Brazilian primary sector became one of the most competitive, innovative agriculture in the world. Together with other methods, biotechnology made management easier and increased productivity. Most Brazilian cotton, maize and soy is genetically modified (GM) and helps the country to strengthen its farming industry.

The transgenic safety assessments follow international standards defined by the World Health Organization (WHO) and by the Food and Agriculture Organization of the United Nations (FAO/UN), institutions that already support GM food, as many others, such as the Pontifical Academy of Sciences. In Brazil, GMOs approved are submitted to toxicological, allergenic, nutritional and environmental testing that go through the National Technical Biosafety Committee (CTNBio), group connected to the Science, Technology and Innovation Ministry (MCTI).

Comissão Técnica Nacional de

Biossegurança

MINISTÉRIO DA CIÊNCIA, TECNOLOGIA E INOVAÇÃO



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INÍCIO

INSTITUCIONAL

[A CTNBio](#)

[Secretaria Executiva](#)

[Processo de OGM](#)

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[Atas](#)

[Pautas](#)

A **CTNBio** assessora o Governo Federal nas questões relativas a **Biossegurança** de **Organismos Geneticamente Modificados**

[Saiba mais...](#)

Avisos

Conheça o processo de um OGM dentro do CTNBio

ÚLTIMAS ATUALIZAÇÕES

03 - Abril 2017

ctnbio.mcti.gov.br/

THANK YOU!

QUESTIONS?

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