

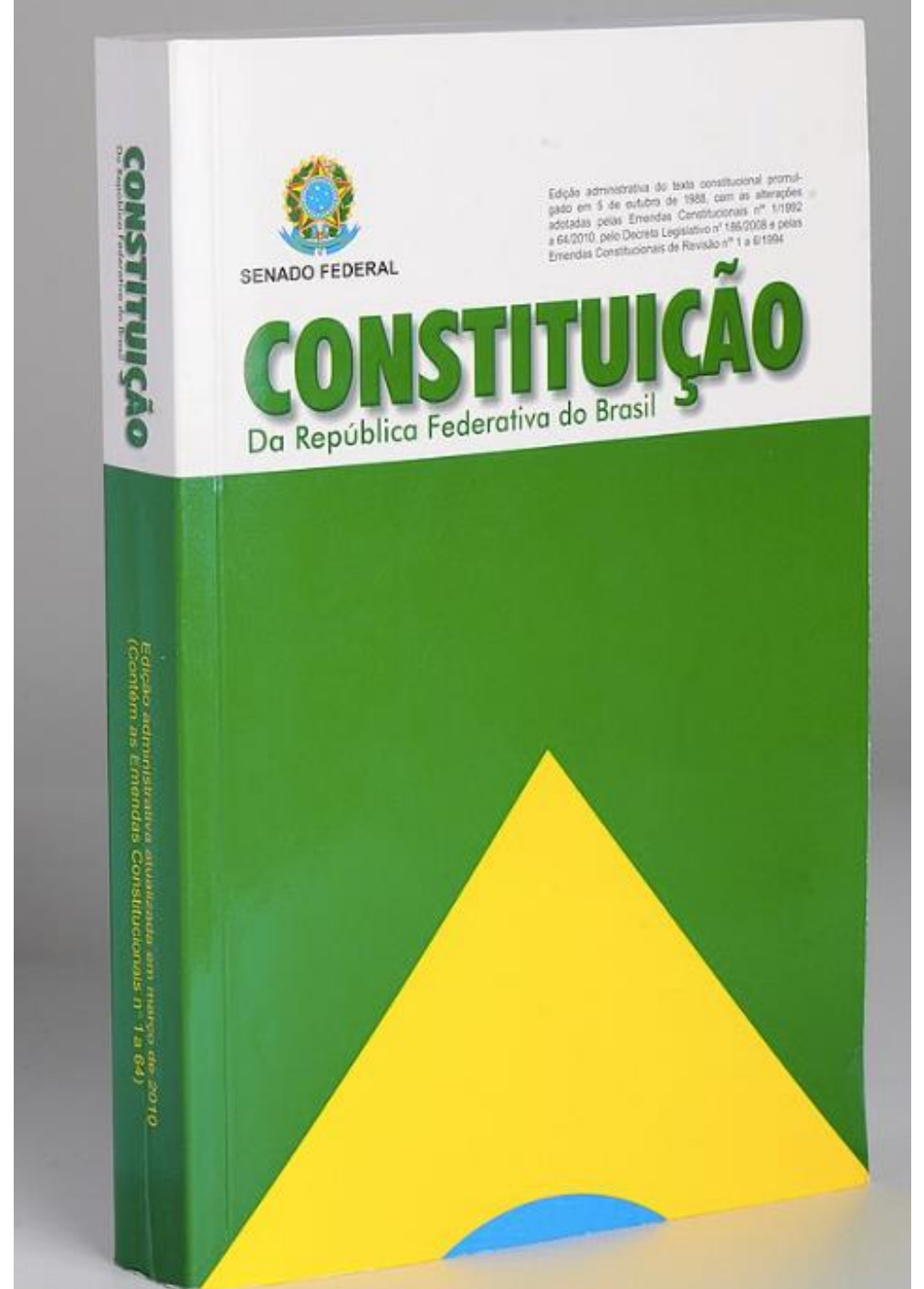
# How do agencies/ministries with shared responsibilities work together

**Session 3: Biosafety and conventionally-bred animals**

**4th International Workshop on Regulatory Approaches for Agricultural  
Applications of Animal Biotechnologies**

Maria Lucia Zaidan Dagli  
Brazil

- In the Brazilian Constitution of 1988, the Principle of Separation of Powers is set out in art. 2, under the title of fundamental principles, and constitutes one of the four essential clauses of the Brazilian legal system.
- In it, it is determined that “the Legislative, Executive and Judiciary are Powers of the Union, independent and harmonious with each other”.





**executive power**  
– enforces the laws



**legislative power** –  
creates the laws



**judicial power** –  
interprets the laws

Pode vetar leis  
- Pode votar impeachment  
- Pode derubar vetos após votação com maioria

- Indica juizes para a Suprema Corte  
- Concede indultos  
Pode declarar atos inconstitucionais

Analisa as indicações de juizes para a Suprema Corte



Pode declarar leis inconstitucionais



# The Public Ministry -

- The Public Ministry is an agency that is not part of any of these powers, but is directly related to all of them.
- The Public Ministry is an institution whose responsibility is to maintain the legal order in the State and to supervise the public authorities in various spheres.
- Its participation in Brazilian justice processes grants it a jurisdictional function – that is, it contributes to the good administration of justice.

# Ministries of Brazil - 23

- Ministry of the Environment;
- Ministry of Women, Family and Human Rights;
- Ministry of Agriculture, Livestock and Supply;
- Ministry of Education;
- Ministry of Science, Technology and Innovation;
- Ministry of Defense;
- Ministry of Health;
- Ministry of Tourism;
- Ministry of Infrastructure;
- Ministry of Mines and Energy;
- Ministry of Foreign Affairs
- Ministry of Citizenship;
- Ministry of Communications;
- Ministry of Agriculture, Livestock and Supply;
- Ministry of Regional Development;
- Ministry of Science, Technology and Innovation;
- Ministry of Economy;
- Ministry of Education;
- Ministry of Justice ;
- Ministry of General Coordination of the Union;
- Ministry of labor and pension;
- Institutional Safety

# Ministries of Brazil

- **Ministry of the Environment;**
- **Ministry of Agriculture, Livestock and Supply;**
- **Ministry of Health;**
- **Ministry of Science, Technology, Innovations and Communications;**

# Ministry of Environment

- responsibility to preserve Brazil's natural resources
- controls the IBAMA (Brazilian Institute of the Environment and Renewable Natural Resources)





MEIO AMBIENTE E CLIMA  
Encontro Nacional dos Cetos é realizado em Goiânia



ibama capacita 50 militares em prevenção e combate aos incêndios florestais

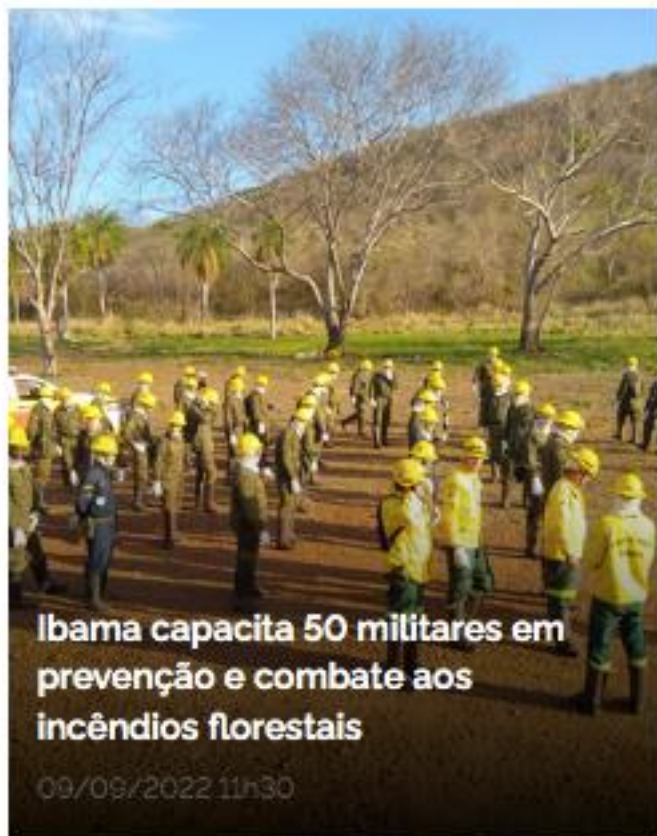


Operação Floresta Pública combate crime de exploração irregular de madeira



ibama interrompe criação ilegal de gado em Terra Indígena do Para





# Ministry of Agriculture, Livestock and Supply

- The Ministry of Agriculture, Livestock and Supply (MAPA) is responsible for managing public policies to encourage agriculture, promoting agribusiness and regulating and standardizing services linked to the sector.
- **Plant and animal products, including the GMO products approved by CTNBio for commercial release.**

# Ministry of Health

Fundamental role for the public health of Brazilians

- I – national health policy;
- II – coordination and inspection of the Unified Health System;
- III – environmental health and actions to promote, protect and restore individual and collective health, including that of workers and indigenous peoples;
- IV – health information;
- V – critical health supplies;
- VI – preventive action in general, surveillance and sanitary control of borders and sea, river, lake and air ports;
- VII – health surveillance, especially regarding drugs, medicines and food; and
- VIII – scientific research and technology in the health area.

# Ministry of Science, Technology and Innovation

- The objective is the promotion of scientific production strategies, the inspection of initiatives and materials and the promotion of technology in the country.
- The functions are:
  - I – national scientific and technological research and innovation incentive policies;
  - II – planning, coordination, supervision and control of science, technology and innovation activities;
  - III – information technology and automation development policy;
  - IV – **national biosafety policy**;
  - V – space policy;
  - VI – nuclear policy;
  - VII – export control of sensitive goods and services; and
  - VIII – articulation with the governments of the States, the Federal District and the Municipalities, with society and with federal government agencies, with a view to establishing guidelines for national policies on science, technology and innovation.

# Regulatory agencies in Brazil

- Created recently in Brazil – 1990's
- Regulatory agencies are governmental bodies whose purpose is to regulate and/or supervise the activity of a particular sector of the economy.
- They interconnect interests of **users, providers of services and the Executive Power**

# Regulatory Agencies of the Brazilian government





# ANVISA – National Agency for Sanitary Surveillance

- Its institutional purpose is to **promote the protection of the population's health, through the sanitary control of the production and consumption of products and services subject to sanitary surveillance**, including the environments, processes, inputs and technologies related to them, as well as the control of ports, airports, borders and customs facilities.
- COSMETICS, HUMAN VACCINES, TOBACCO, DRUGS,
- LABORATORIES
- **ALL PRODUCTS FOR HUMAN USE, including the GMO products approved by CTNBio for comercial release.**

Serviços mais acessados do govbr

Serviços em destaque do govbr



**Tudo sobre as vacinas**  
Acompanhe aqui os pedidos, status das análises e mais informações sobre as vacinas contra Covid-19.

**Regras para entrada no Brasil**  
Entenda o que é necessário para entrar no país por via aérea, marítima ou terrestre.

**Autotestes**  
Saiba mais sobre a regulamentação de autotestes para Covid-19 e os produtos autorizados.

SAÚDE E VIGILÂNCIA SANITÁRIA

Novas regras para rotulagem

SAÚDE E VIGILÂNCIA SANITÁRIA

Anvisa proíbe uso em alimentos de lotes de ingrediente suspeito de ter

SAÚDE E VIGILÂNCIA SANITÁRIA

Anvisa realiza eventos internacionais sobre farmacovigilância

# GMO Policy in Brazil

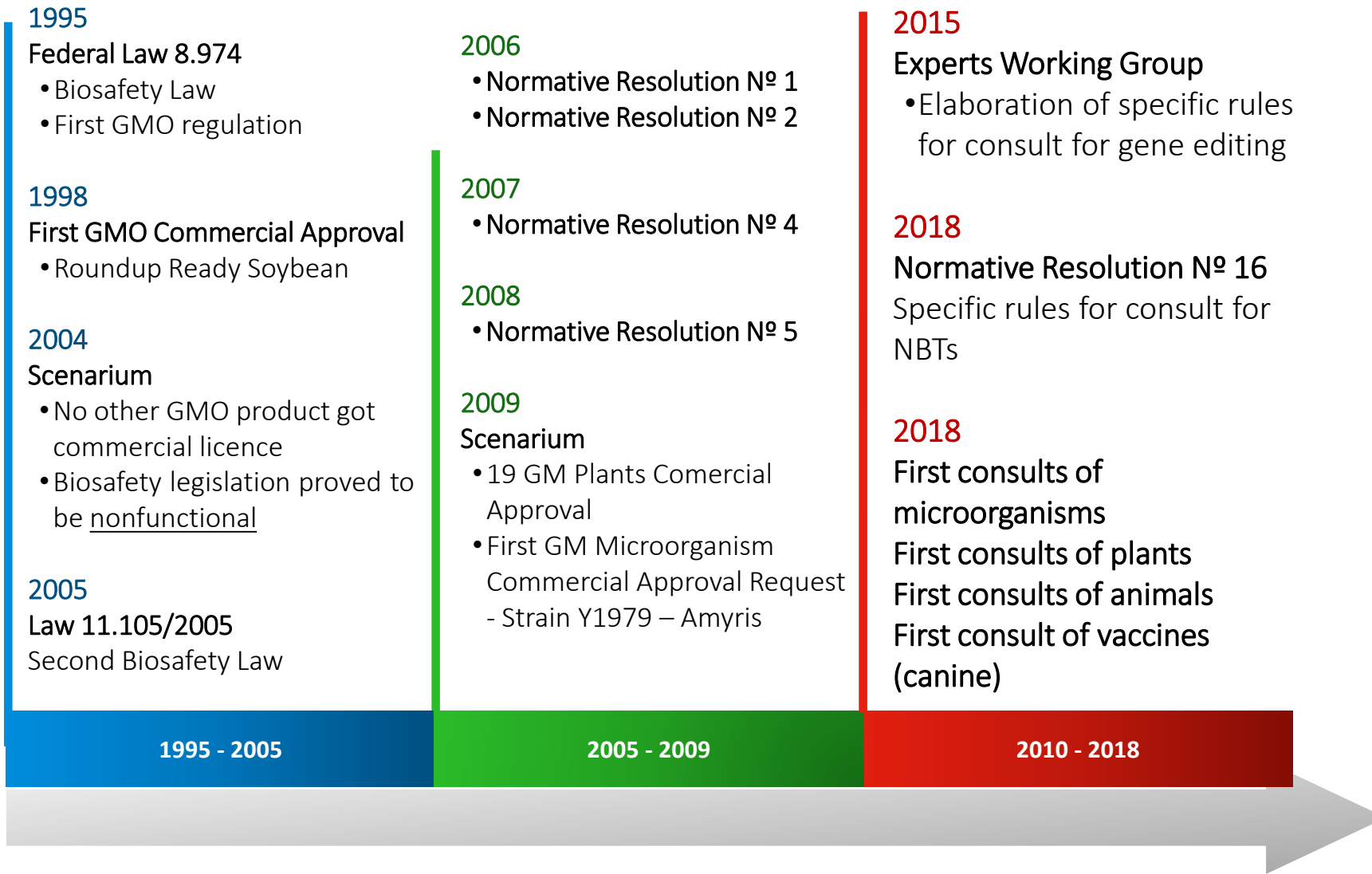
## CTNBio

### linked to the MCTI

- Law 11.105/2005
- Decree 5.591/2005
- CTNBio Resolutions

# Brazilian Biosafety Regulation

## Historical context of GMO and Gene-editing Regulation



**Law nº 11.105, dated March 24th, 2005**

***“Biosafety Law”***

Provides for safety norms and inspection mechanisms for activities with GMOs and their by-products

# CTNBio

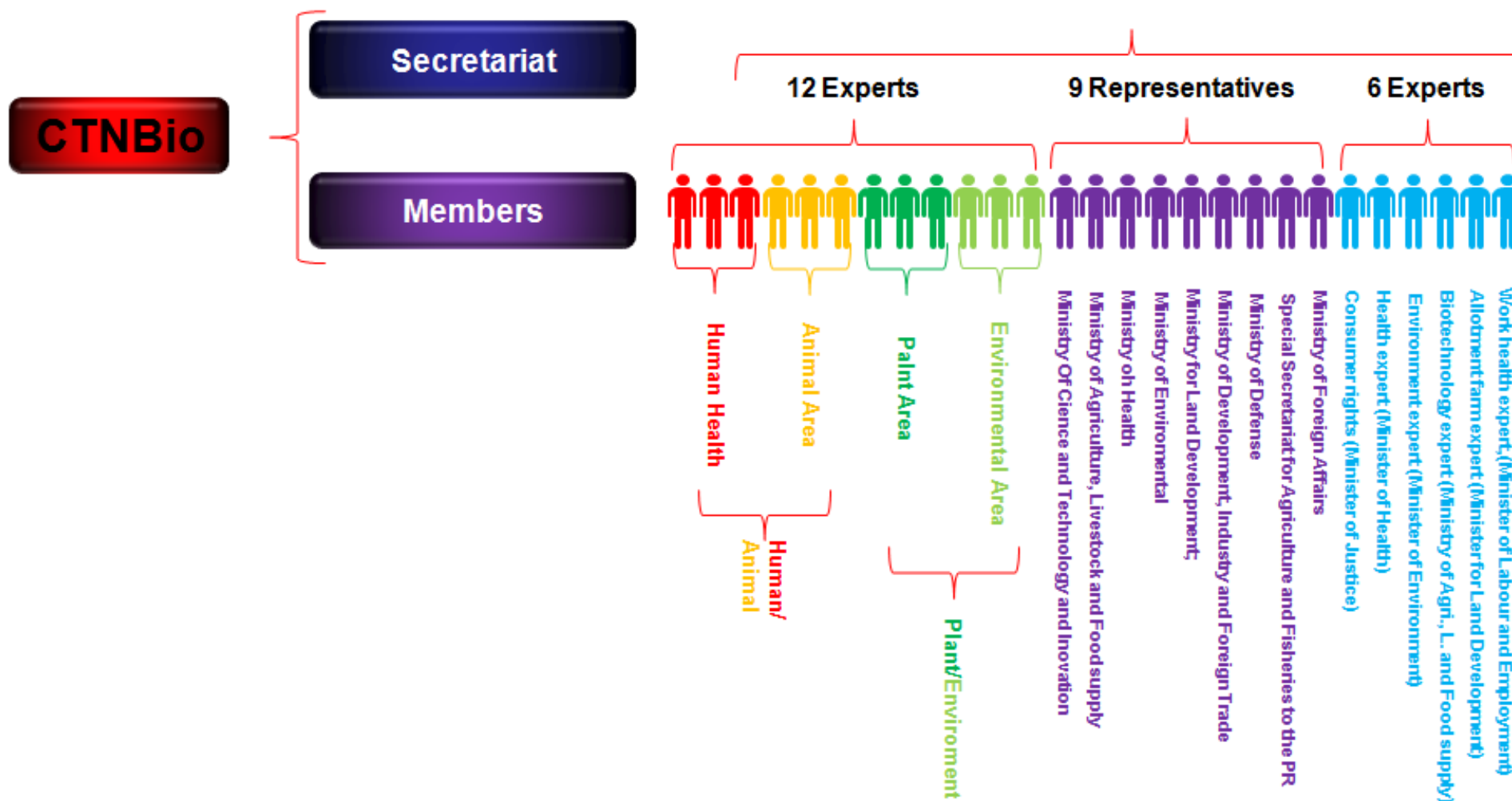
- **Created by laws 8974 and renewed by Law 11.105 – March 24, 2005**
- 54 members (27 members and 27 alternates), all scientists holding a PhD title.
- All approvals need 14 votes



# Composition of The National Biosafety Technical Commission (CTNBio)







27 Professionals with Ph.D. Degrees

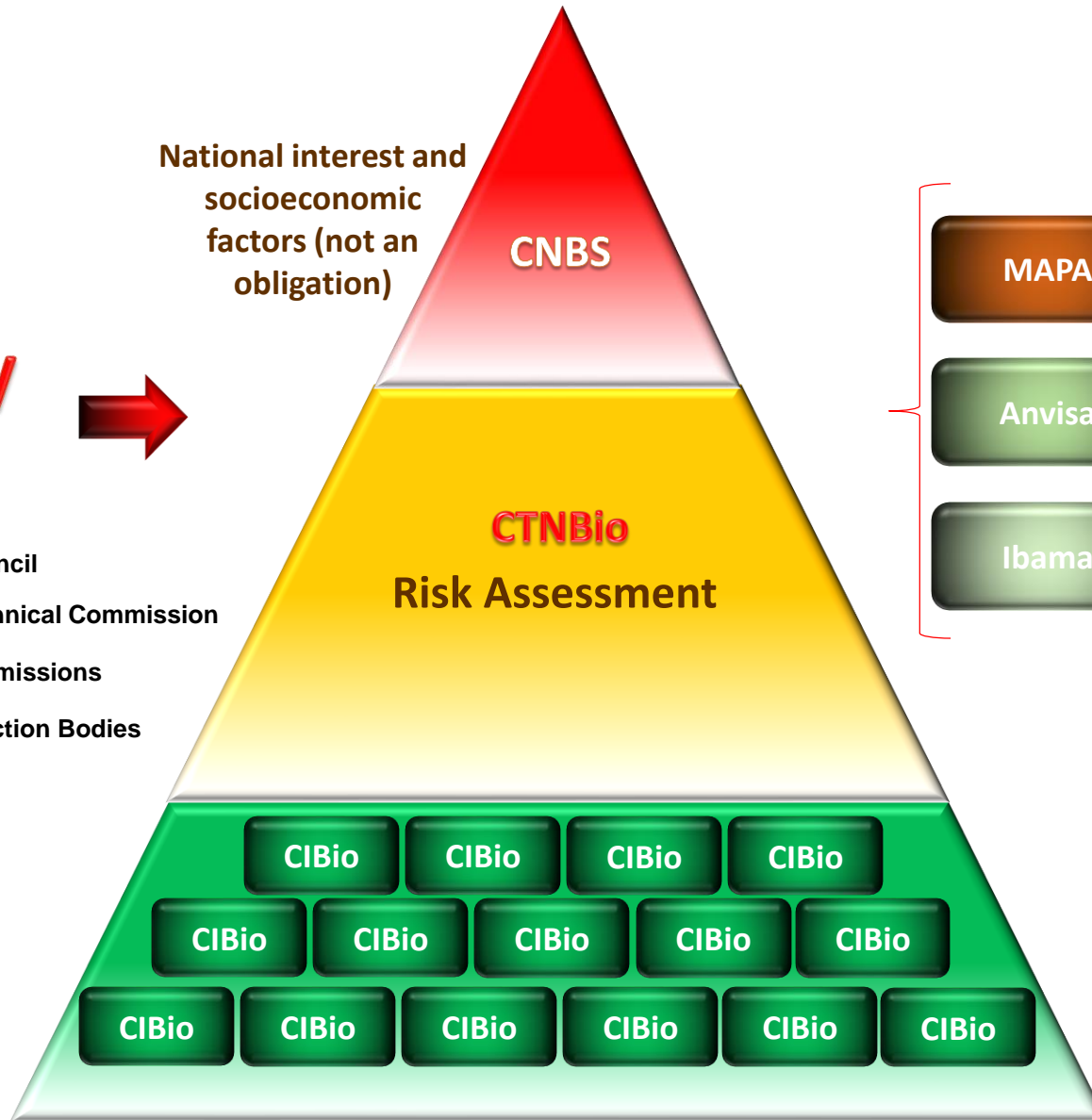


# Biosafety Law



-  National Biosafety Council
-  National Biosafety Technical Commission
-  Internal Biosafety Commissions
-  Registration and Inspection Bodies

National interest and socioeconomic factors (not an obligation)



CNBS

CTNBio

Risk Assessment

CIBio

CIBio

CIBio

CIBio

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Registration and Inspections

MAPA

Agriculture

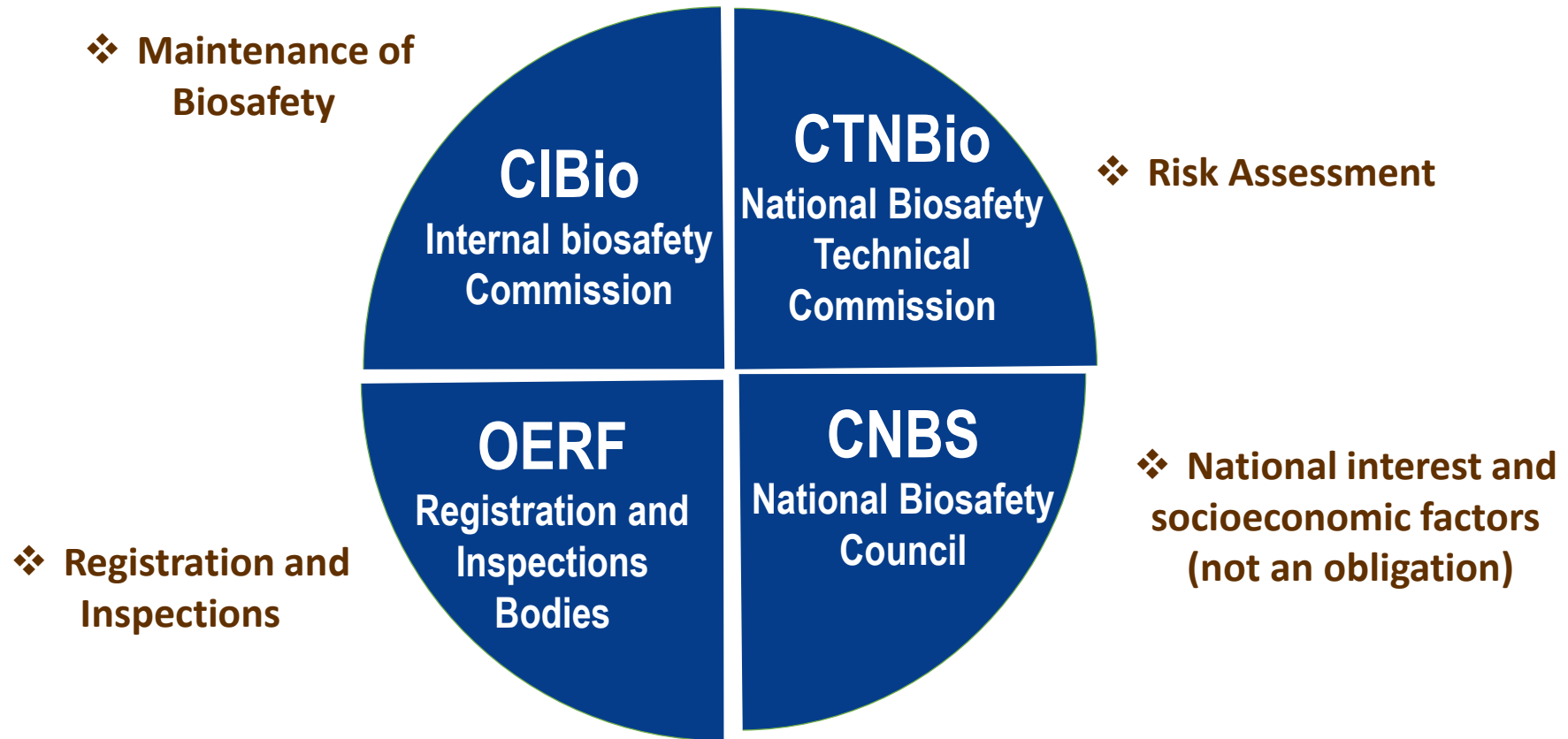
Anvisa

Human Health

Ibama

Environmental

Maintenance of biosafety



# Brazilian model of GMO regulation

- Process and product regulation
- Science-based and case by case assessment
- The same biosafety law for plants, microorganisms, vaccines, animals.
- Robust and transparent technical assessment.
- Evaluates labs, researchers, projects, planned releases in the environment, and commercial releases.

# Legal definition of GMO (Law 11.105/2005)

## Genetically modified organism

**Genetically modified organism** - GMO refers to an organism whose genetic material, DNA/RNA, has been altered by any **genetic engineering technique**;

## Genetic engineering

Genetic engineering refers to the production and manipulation of **recombinant DNA/RNA molecules**;

## Recombinant DNA/RNA

Molecules that are **manipulated outside living cells** by altering natural or synthetic DNA/RNA segments and that can **multiply themselves in a living cell**, or the DNA/RNA molecules resulting from this multiplication; they also refer to the synthetic DNA/RNA segments equivalent to natural DNA/RNA segments

# NORMATIVA BRASILEIRA SOBRE TIMP

(Técnicas Inovadoras de Melhoramento de Precisão)

QUERY



\*CTNBio – Comissão Técnica Nacional de Biossegurança, responsável por analisar e aprovar os transgênicos no Brasil

Publicação no Diário Oficial da União (DOU)



Definição de relator para análise da consulta

90 dias, prorrogáveis por igual período

Parecer do relator submetido às subcomissões da CTNBio

CTNBIO SUBCOMMISSIONS

Deliberação em sessão plenária da CTNBio

CTNBIO PLENARY

**Não considerado um OGM**  
produto pode ser registrado



**Considerado um OGM**  
Submissão de dossiê à CTNBio

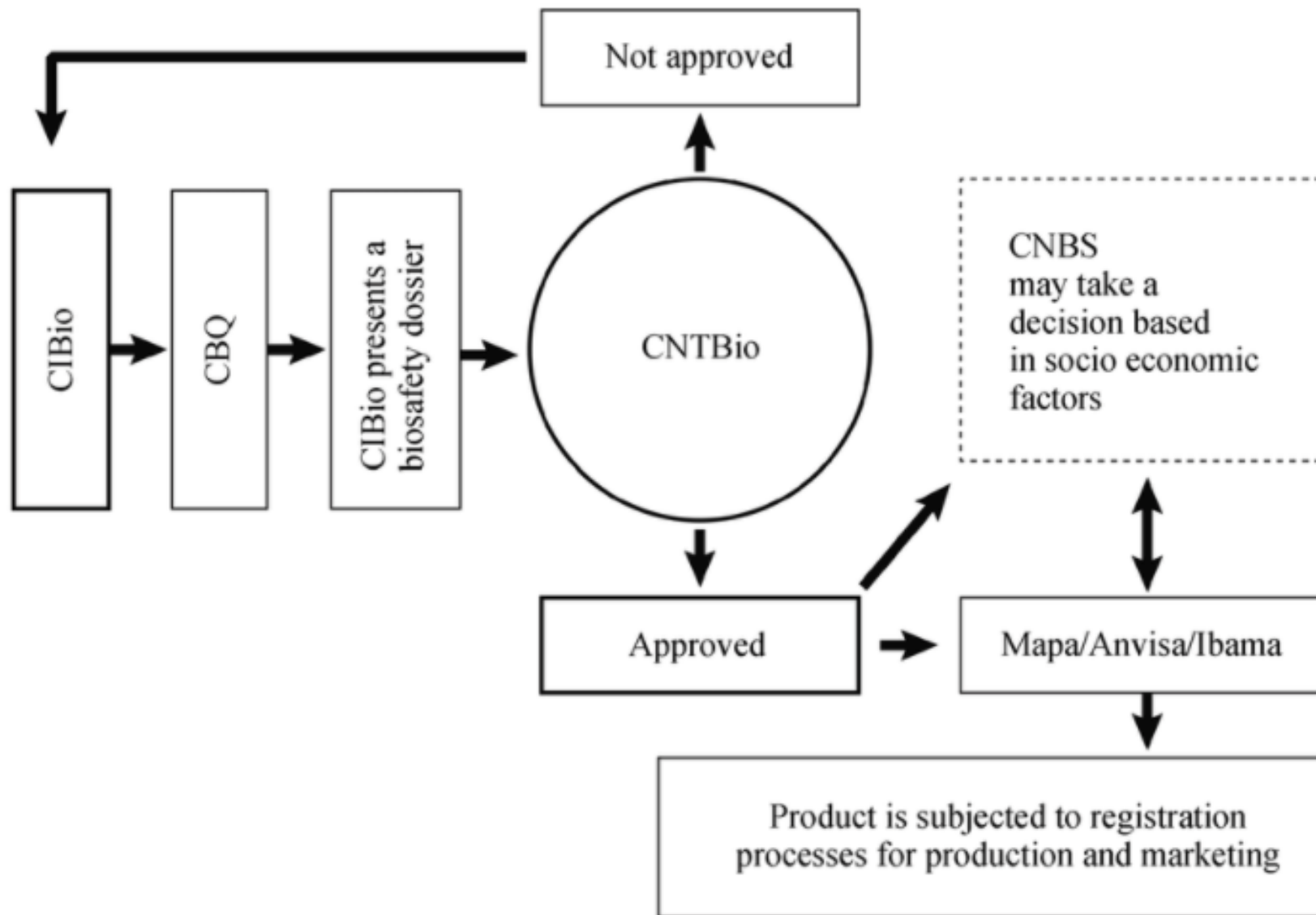


**CiB**

Conselho de Informações sobre Biotecnologia







## EXAMPLES

Mosquitos  
 Corn  
 Soybean  
 Cotton  
 Yeasts  
 etc

General procedure for a case-by-case consultation at CTNBio for a product generated by INIT, according to Normative Resolution No. 16. If the product is designated to be GM, the developer will have to go through all the biosafety requirements and will be approved only after the CTNBio risk assessment. If the product is designated as not GM (for the purposes of the legislation), it can be registered using the existing procedures.

Estes são Doutores favoráveis aos

# TRANSGÊNICOS

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"O que vemos na prática cotidiana da CTNBio são votos pré-concebidos e uma série de artimanhas obscurantistas no sentido de considerar as questões de biossegurança como dificuldades ao avanço da biotecnologia. A razão colocada em jogo na CTNBio é a racionalidade de mercado..."

Dra. Lia Giraldo, em sua Carta de Desligamento da CTNBio (17/05/07)

CTNBIO - COMISSÃO TÉCNICA NACIONAL DE BIOSEGURANÇA



Por um Brasil  
Livre de Transgênicos

Mais informações "Campanha Brasil Livre de Transgênicos"

www.feab.org.br

