

An Overview of the Brazilian Biosafety Regulatory System.

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Today's Agenda

Regulatory System

Law

Regulatory
Decree

Normative Resolution

Communication

Agencies and Committee

Composition

How its Works

Operating Mechanisms

Administrative Support

Publication

Forms

Executive Secretary



CTNBio

**Normas de
Biossegurança e
avaliação de
risco**



ORFs

**Registro e
Fiscalização**



CIBios

**Manutenção da
Biossegurança**



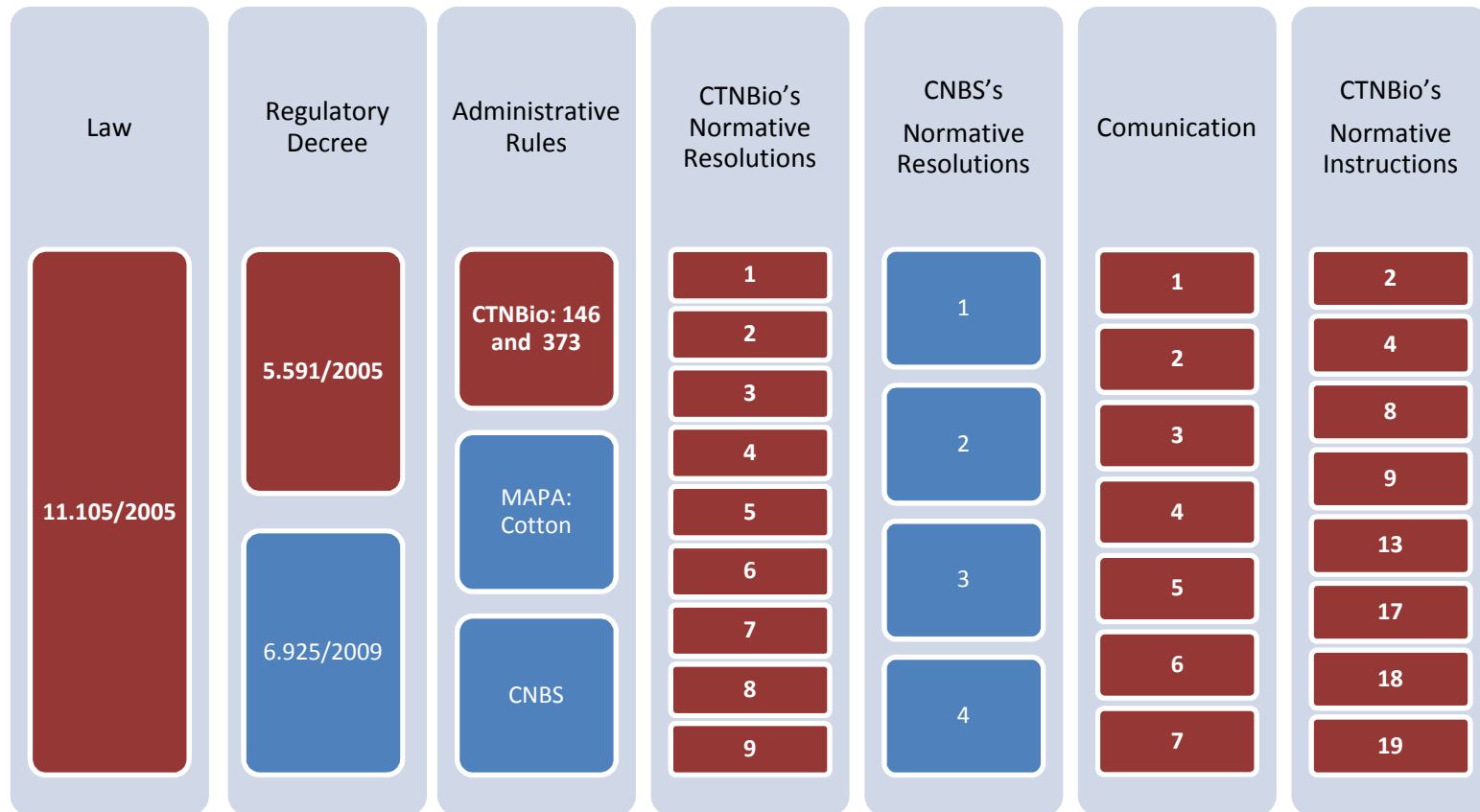
CNBS

**Sócio-
econômica e
interesse
nacional**



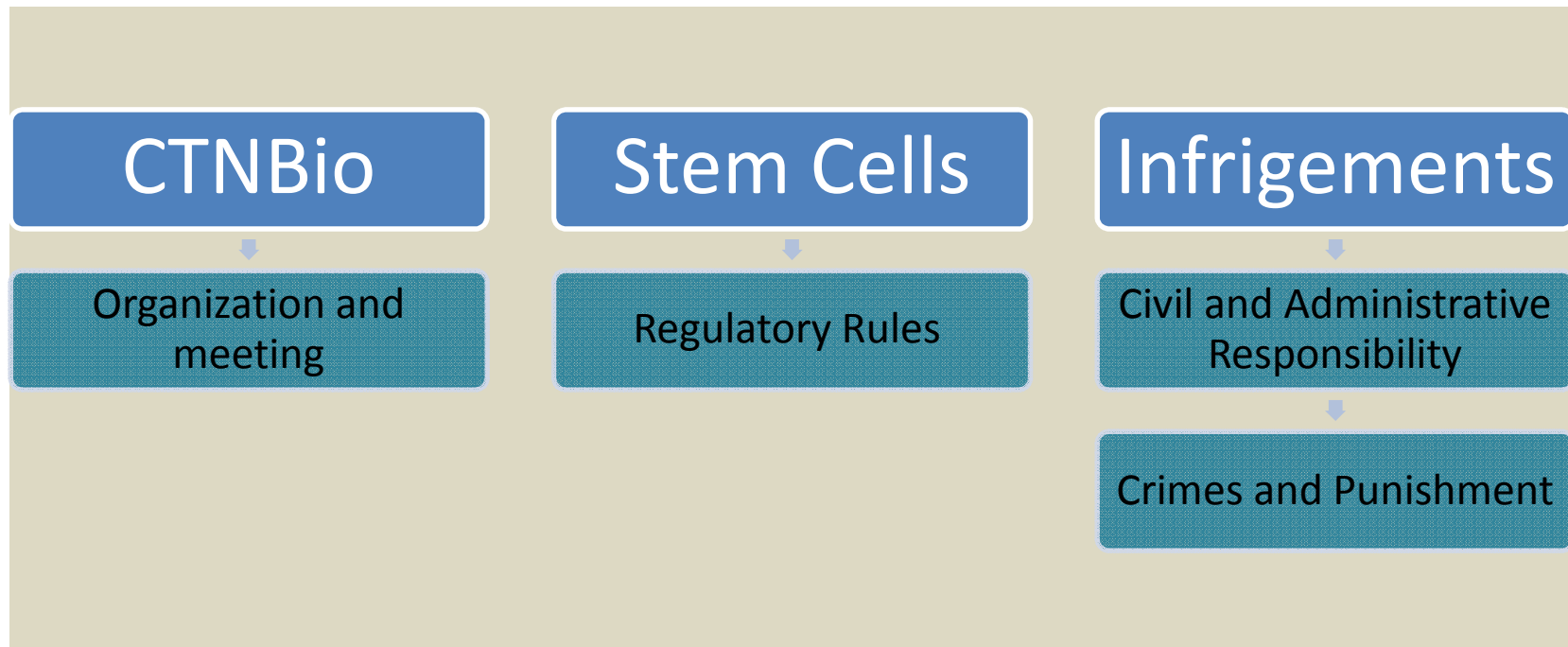
Brazilian Biosafety System

Brazilian Regulatory Biosafety Summary



- Release March 2005;
- Regulates Article 225 of the Federal Constitution;
- Provides safety norms and inspection mechanisms for activities involving GMOs and their by-products;
- Implements the National Biosafety Council (*CNBS*);
- Re-structures National Biosafety Technical Commission *CTNBio*;
- Create Biosafety Information System (*SIB*);
- Provides for the National Biosafety Policy (*PNB*).

Decree 5.591/2005



Normative Resolutions

- NR 01 – Criteria and procedure for Biosafety Quality Certificate (CQB)
- NR 02 - Risks classification of GMO and biosafety levels
- NR 03 – Replaced by # 09
- NR 04 – Coexistence between commercial GM and non-GM corn
- NR 05 - Rules for commercial release
- NR06 – Plant Environmental release
- NR 07 – Micro-organism and Animals release
- NR 08 – Plant Enviromental release – Simplified Rules
- NR 09 - Post-Market Environmental Monitoring of GMO

Administrative Rules

MCTI 146,
06/03/2006

- Bylaw

MCTI 373,
06/06/2011

- Change bylaw
- Confidentiality

MAPA 21/2005

- Cotton Area

CNBS's Normative Resolution

- CNBS's Bylaw
- Ratify and Approval CTNBio's decisions.

CTNBio's Normative Instructions

CTNBio

02

Import

04

Transport

08

Human Cloning

09

Genetic Intervention in Humans

13

Animals GM Import

17

GMO By-Products

18

Soya RR

Communications



National Biosafety Technical Commission - *CTNBio*

- Multidisciplinary Consulting and deliberating collegiate:
 - Provides technical and assistance support to the Government
 - formulate, update and implement the National Biosafety Policy
 - establishes safety technical norms regarding the authorization of research-related activities and the commercial use
 - evaluation of their zoo-phytosanitary, human health and environmental risk.

National Biosafety Technical Commission - *CTNBio*

- Belong to Ministry of Science, Technology and Innovation
- 27 Members and deputy,
 - Members: PhD and professionally active in the biosafety, biotechnology, biology, human and animal health areas and the environment, whereby:
 - I – 12 experts: human health; animal health; plant health; environment;
 - II – one representative from the following agencies:
 - the Ministry of Science, Technology and Innovation;
 - Agriculture, Cattle-Raising and Supply; Health;
 - Environment; f) the Ministry for the Development, Industry and Foreign Trade;
 - Defence; Agriculture and Fisheries; Foreign Office

National Biosafety Technical Commission - *CTNBio*

III – a consumer rights expert;

IV – a health expert;

V – an environment expert;

VI – a biotechnology expert;

VII – a family farm expert;

VIII – a work health expert.

National Biosafety Council - *CNBS*

“As a higher assistance agency of the President of the Republic for formulating and implementing the National Biosafety Policy (*PNB*)”

CNBS is responsible for:

Establishing principles and guidelines for the administration of federal agencies;

Analysing, upon *CTNBio*'s request, the social-economic convenience and opportunities and national interest entailed in the requests for clearing the commercial use of GMOs and their by-products;

Mandating and deciding, in the last and final prosecution stages, based on *CTNBio*'s opinion and whenever deemed necessary;

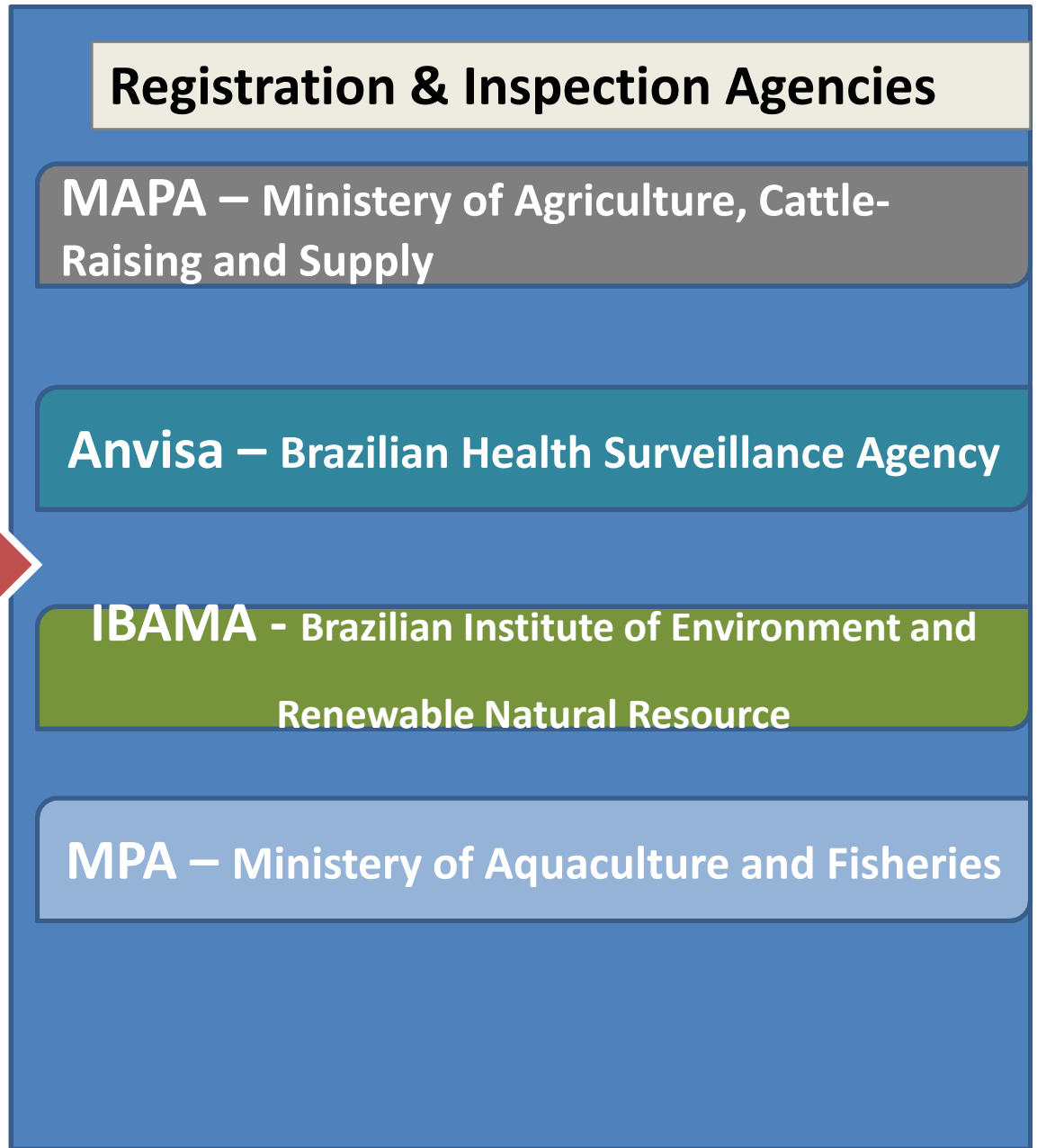
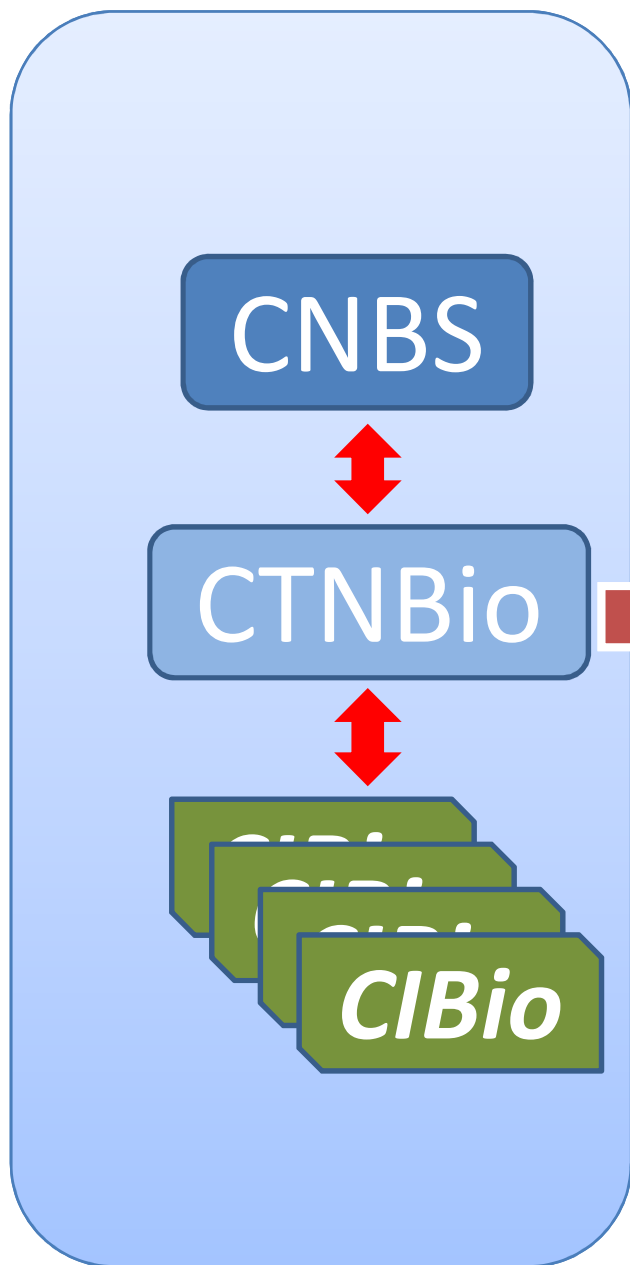
National Biosafety Council - *CNBS*

CNBS members:

Minister Chief of the Civil House - **Chairperson**;

Ministers:

- Science, Technology and Innovation;
- Land Development;
- Agriculture, Cattle-Raising and Supply;
- Justice;
- Health;
- Environment;
- Development, Industry and Foreign Trade;
- Foreign Office;
- Defence;
- Aquaculture and Fisheries



Registration & Inspection Agencies Role

- Inspecting research activities;
- Registering and inspecting;
- Authorization import for commercial use;
- Updated the Biosafety Information System (*SIB*);
- Enforce;
- Support to *CTNBio* definition biosafety assessment parameters for GMOs.

Cartagena Protocol on Biosafety - Decree 6.925/2009

- Foreign Office

National Focal
Point

Competent
National Authority

- CTNBio
- MAPA
- ANVISA
- IBAMA
- MPA



Commercial Release



Commercial Release



Vaccum

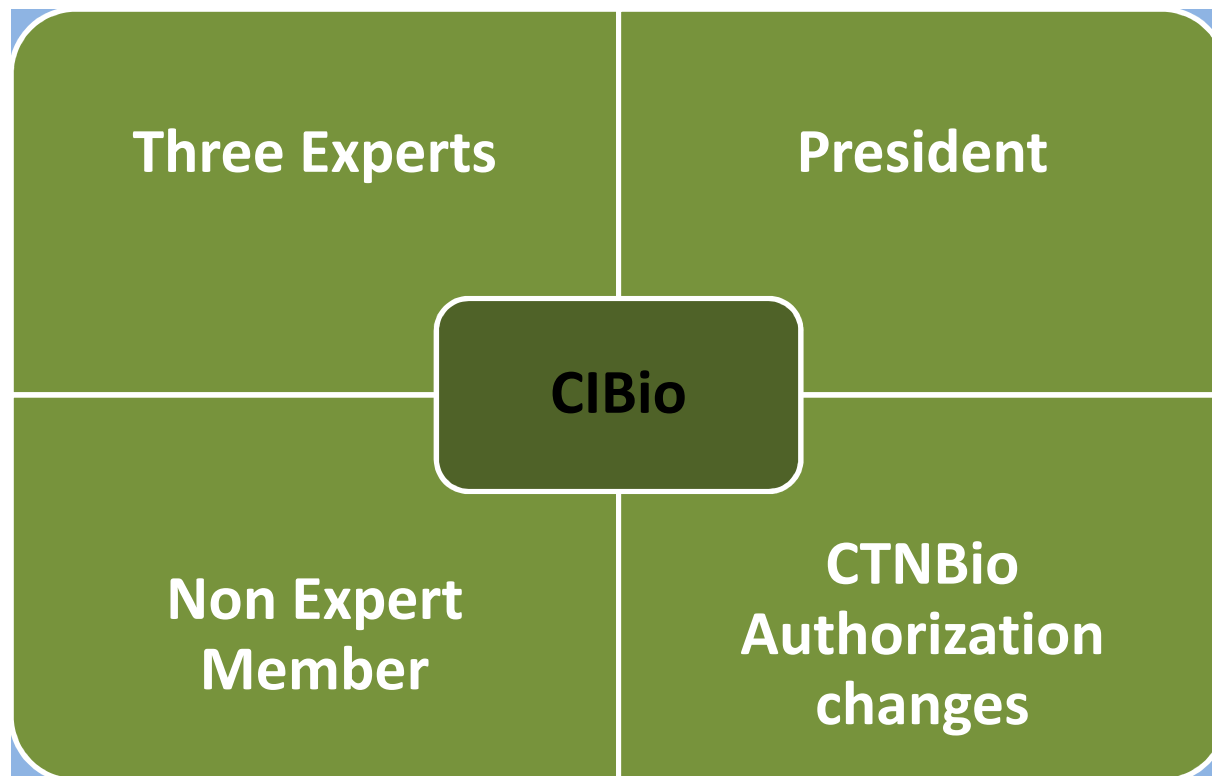


Yeast



INTERNAL BIOSAFETY COMMISSIONS – CIBio

CIBio is an essential component for the monitoring and surveillance of GMO activities;



INTERNAL BIOSAFETY COMMISSIONS – CIBio

Liability

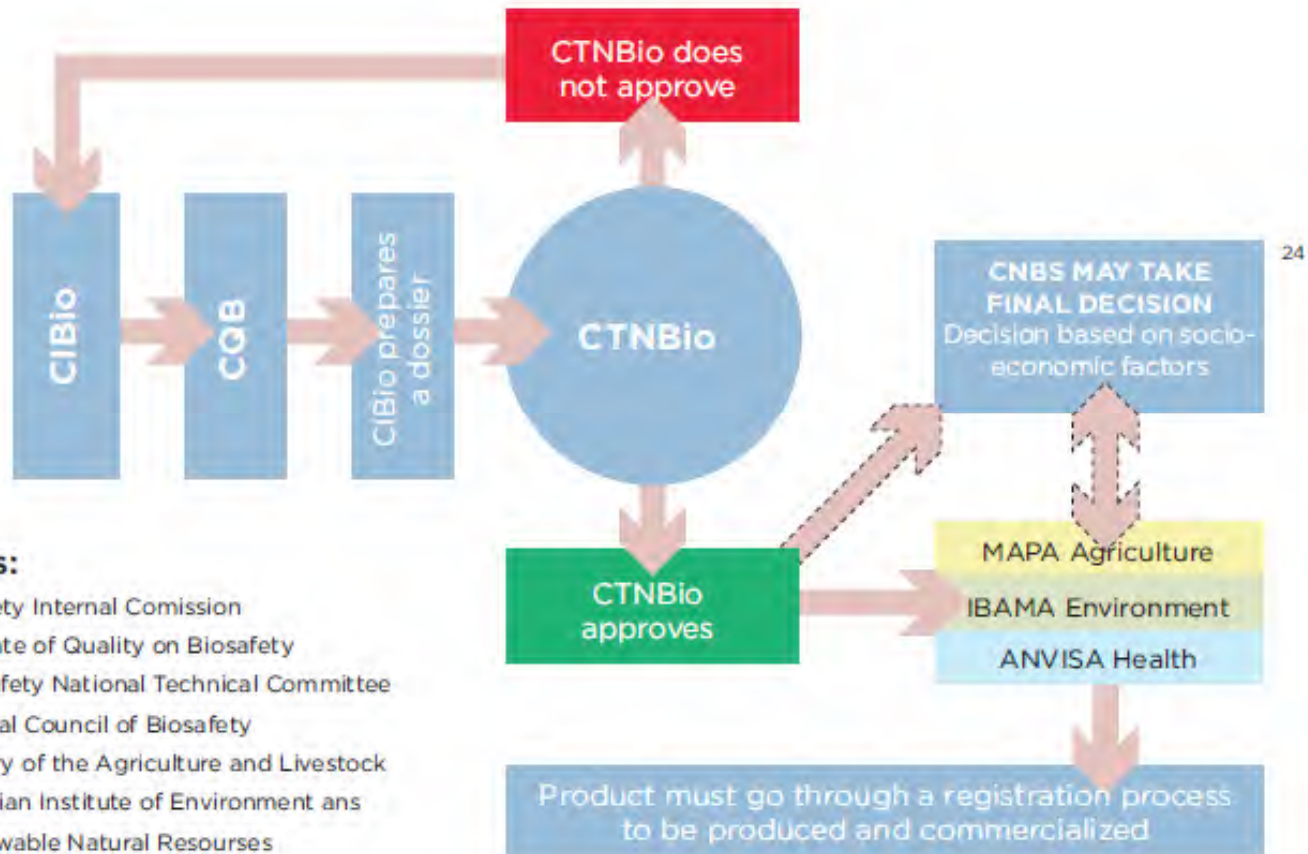
- I- Keep workers and community informed on issues related to health and safety, as well as on procedures in case of accidents;
- II- Set up preventive and inspection programs to secure the operation of facilities;
- III- Forward to CTNBio documents, forms annual report, permission;
- IV- Keep individual records of monitoring any activity or project ;
- VI- Investigate accidents and diseases likely to be related to GMO and by-product and notify CTNBio of conclusions and actions taken;

Executive Secretary

Team: Head, Technical & IT Advisory, Administrative Staff

- I- Provide technical and administrative support to CTNBio members;
- II- Receive document and cause to be processed the demands submitted to CTNBio deliberation;
- III- Forward CTNBio deliberations to government agencies in charge of their implementation and provide them the due disclosure
- IV – Publish Technical Decision - Federal Official Gazette

Executive Secretary



Acronyms:

CIBio: Biosafety Internal Commission

CQB: Certificate of Quality on Biosafety

CTNBio: Biosafety National Technical Committee

CNBS: National Council of Biosafety

MAPA: Ministry of the Agriculture and Livestock

IBAMA: Brazilian Institute of Environment and

Renewable Natural Resources

ANVISA: Health National Agency

The European Association for Biotechnology, October 2011: Approvals of GMOs in the European Union.

Conclusion

Ctnbio.gov.br

Legislation

ctnbio.gov.br/index.php/content/view/12840.html

Commercial

Executive Secretary Contacts

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Thank you...