



## Food Safety aspects of regulations for genetically engineered/modified (GM) animals in Brazil

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## CTNBio

### National Technical Commission on Biotechnology

- Governamental agency to evaluate biosafety on biotechnological process and products
  - Humans and animals
  - Plant and environmental protection
- Ministry of Science, Technology & Innovations
- Composition (PhD requirement)
  - 27 Effective members
  - 27 Substitute members

<http://ctnbio.mctic.gov.br/a-ctnbio>

## CTNBio procedures follow

### ☐ Biosafety law

#### ☐ Decrees

#### ☐ Normative Resolutions (28)

Parameters to proceed the evaluations (members)

How to demand a petition (companies)

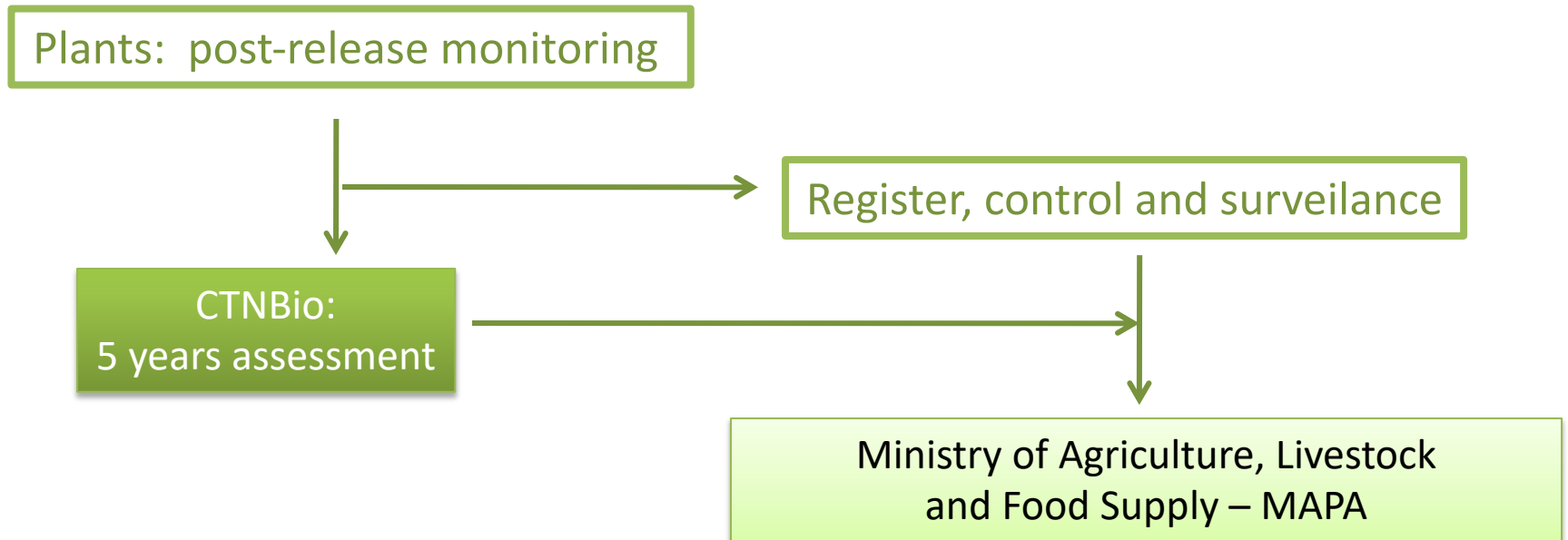
Case by case analysis

## GMO approvals in Brazil

|                      | Approvals         | %            | TIMP-NBT          |
|----------------------|-------------------|--------------|-------------------|
| <b>Plants</b>        | <b>107</b>        | <b>58.79</b> |                   |
| <b>Vaccines</b>      | <b>44</b>         | <b>24.18</b> |                   |
| <b>Microrganisms</b> | <b>26</b>         | <b>14.29</b> | <b>[3]</b>        |
| <b>Drugs</b>         | <b>2</b>          | <b>1.10</b>  |                   |
| <b>Insects</b>       | <b>3</b>          | <b>1.64</b>  |                   |
| <b>Animal</b>        |                   |              | <b>[1]</b>        |
| <b><i>Total</i></b>  | <b><i>182</i></b> |              | <b><i>[4]</i></b> |

\* TIMP = NBTs – Regulated by NR 16

## After the commercialization approval



# After the commercialization approval

Vaccines – register, control and surveillance

Animals

Ministry of Agriculture, Livestock  
and Food Supply – MAPA

Humans

Brazilian Health Regulatory Agency  
ANVISA

# Approvals in restrict area or under contention

Normative Resolution #18

Plants

Green house

Depends on the  
level of  
biosafety risk

Microrganisms

Batch

Insects

Laboratory

Animals

Animal house

## Normative Resolution for animals

- None of NR are specific for animals
  - Scarce demands
    - Few cases abroad
      - Easier to control (?)





Thank you

Muchas gracias

Obrigado

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