



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)

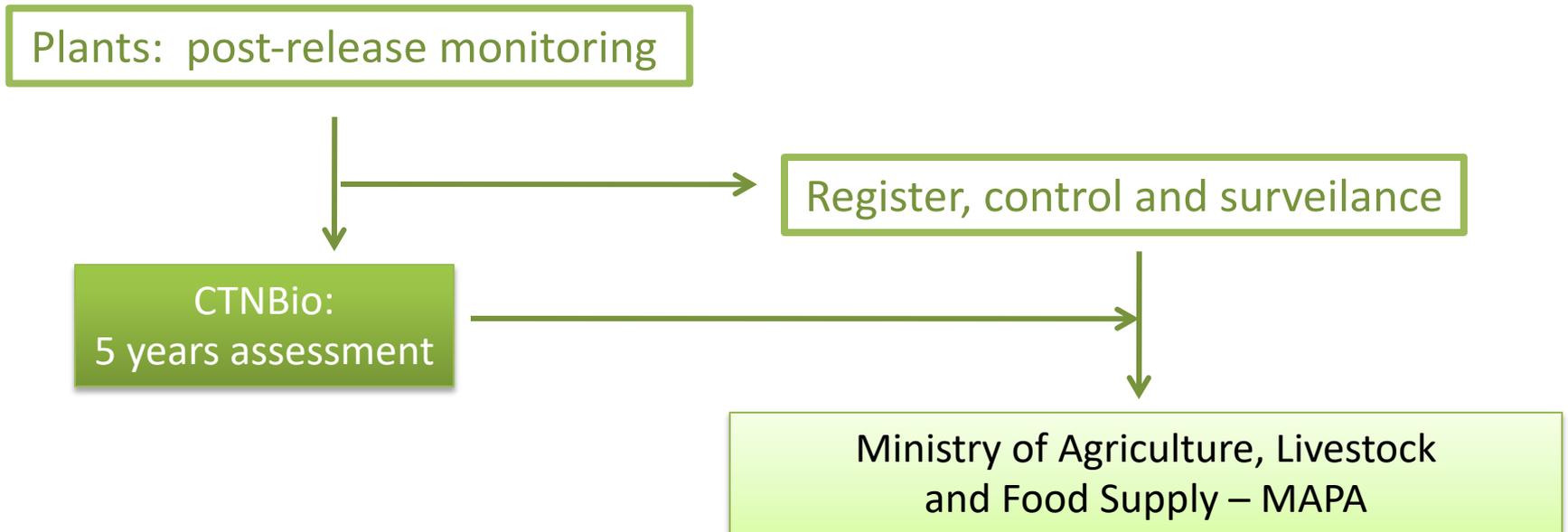
Case by case analysis

GMO approvals in Brazil

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

* 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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