

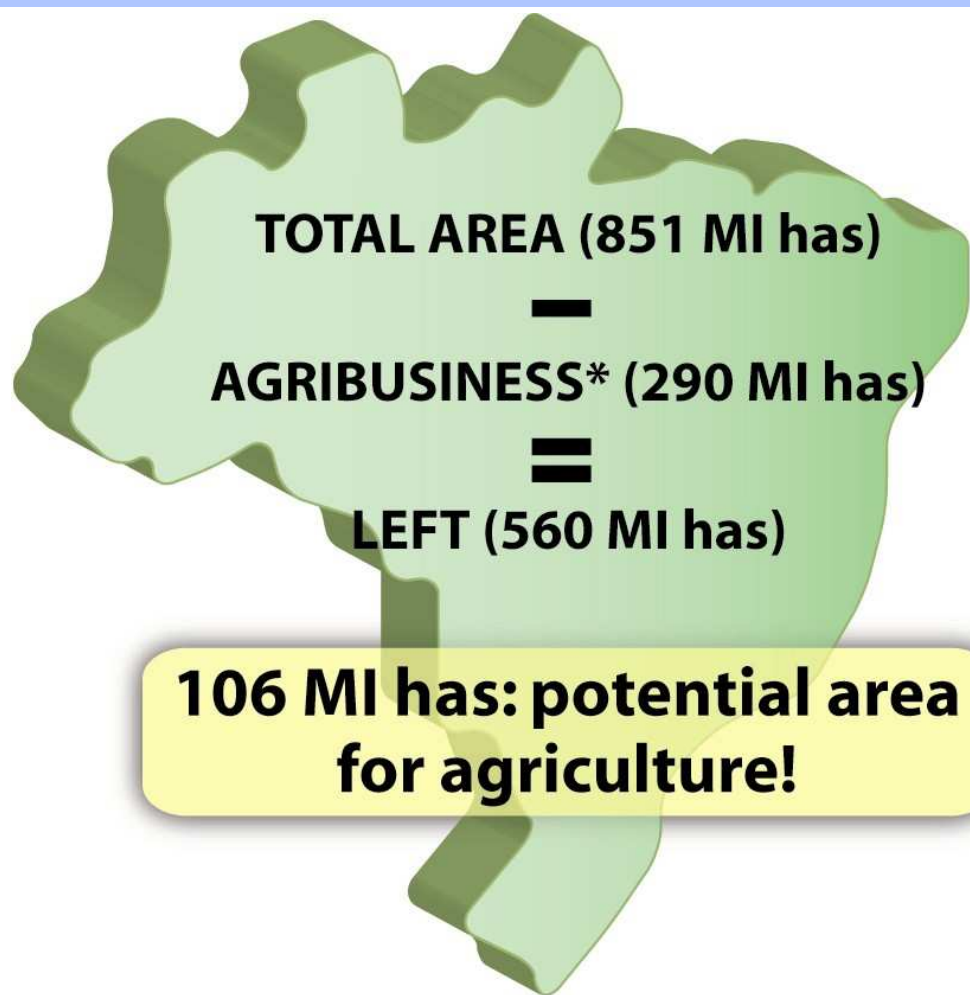


# **BRAZILIAN NEW BIOSAFETY LAW and GM LABELING**

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Daniela Contri

**Introduction – Agribusiness in Brazil**



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**USA**  
**Europe**  
**India, Russia and Canada**  
**China**

\* **Cattle and other animals (200 MI has)**  
+  
**Crops (90 MI has)**

**Introduction - Agribusiness in Brazil**

**Largest cattle and chicken stocks in the world**  
**Largest production of orange, coffee and sugarcane**  
**Second production of soy and third of maize**



**33% GNP**

**Biotech: to keep Brazilian competitiveness**

**GM crop area in Brazil = 9.4 MI hectares**

**N.3**

**Biosafety Law – clear rules for the right use of the  
biotechnology**

## *GMO Regulation Worldwide*

### ■ Substantial Equivalence

- USA

GMO are substantially equivalent to their conventional counterpart

### ■ Precautionary Principle

- EU

The acceptance of a new technology must be postponed until having enough evidence of their safety



**BRASIL**

## **Background – OLD BIOSAFETY LAW**

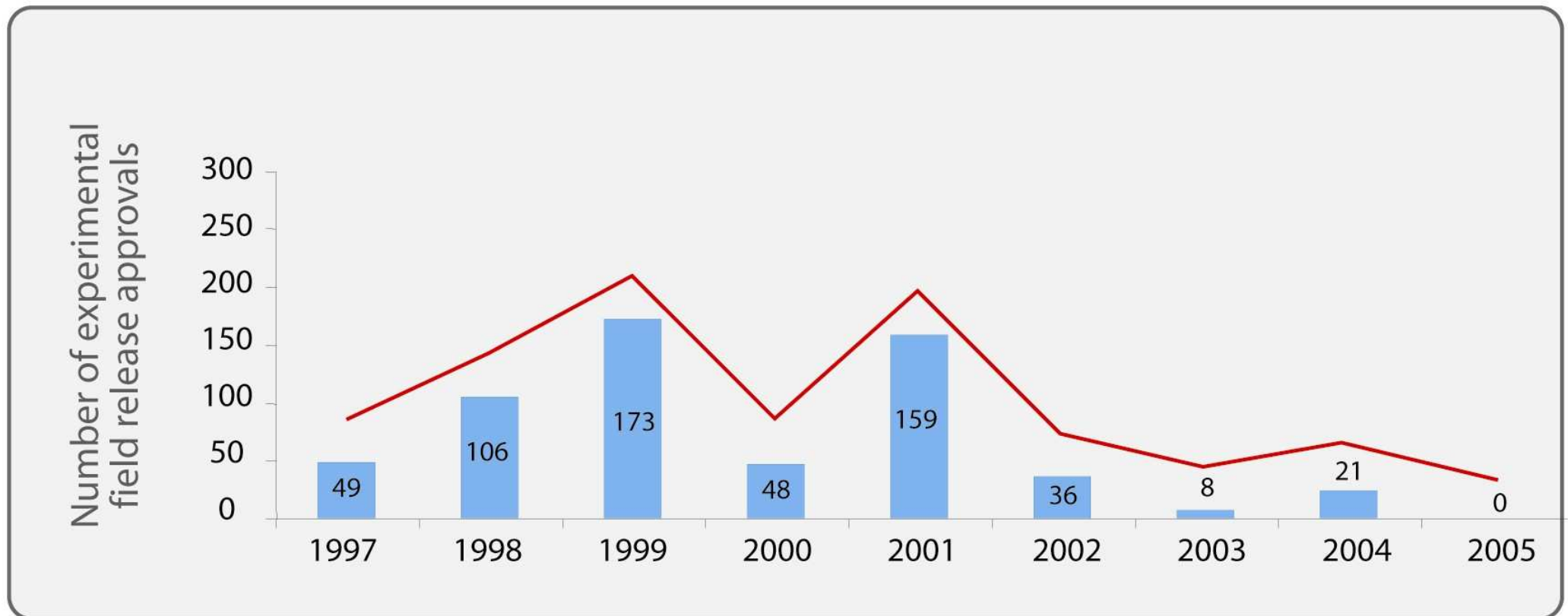
- **Precautionary Principle → Law 8.974: 1<sup>st</sup> Biosafety Law (05 Jan 1995)**
  - **Proper and modern legislation** in terms of biosafety in accordance with the international market
  - **Set up the CTNBio** (National Biosafety Technical Commission) to coordinate and authorize activities with GMO
  - **Legal Loopholes** allowed Governmental Agencies under the Ministries of Agriculture and Environment to create additional authorizations and licences

**Decision → to elaborate a NEW Biosafety Law**

**HOW TO GET AN APPROVAL??**



## Experimental Field Release Approvals



**NEW BRAZILIAN BIOSAFETY LAW: 11.105 (24 March 2005)**

- Re-structures the National Biosafety Technical Commission ([CTNBio](#)) and restores its power
- Implements the National Biosafety Council ([CNBS](#))
- Provides for [safety norms and inspection mechanisms](#) for activities\* that involve **GMOs and their by-products**

\*construction, culture, production, manipulation, transportation, transfer, import, export, storage, research (containment or field regime), marketing, environmental release and discharge

**NEW law → must end several years of uncertainty  
creating a “smooth” process**

## **CTNBio (National Biosafety Technical Commission)**

- Under the Ministry for Science and Technology, is a consulting and deliberating multidisciplinary collegiate ([27 members](#))
- Main responsibilities:
  - providing [technical and assistance support](#) to formulate, update and implement the [National Biosafety Policy](#) for GMOs and their by-products
  - [authorizing, registering and monitoring research](#) activities using GMOs
  - [issuing the technical opinion](#), case-by-case, about the biosafety of GMOs and their by-products within the scope of [research and commercial use activities](#)

**CTNBio → Final word regarding technical opinion. Binding the other Governmental Agencies to it.**

**CTNBio: empowered referee**



**CTNBio is now poised to give the green light for experimental and commercial planting of GM crops.**

## **CTNBio composition**

### **Scientists**

**12**

Experts in Human Health (3)  
Experts in Animal Health (3)  
Experts in Plant Health (3)  
Expert in Environment (3)

### **Ministerial Representatives**

**9**

Science and Technology (1)  
Agriculture (2)  
Health (3)  
Environment (4)  
Land Development (5)  
Development (6)  
Defence (7)  
Foreign Affairs (8)  
Special Secretariat For Agriculture and Fisheries (9)

### **Specialists**

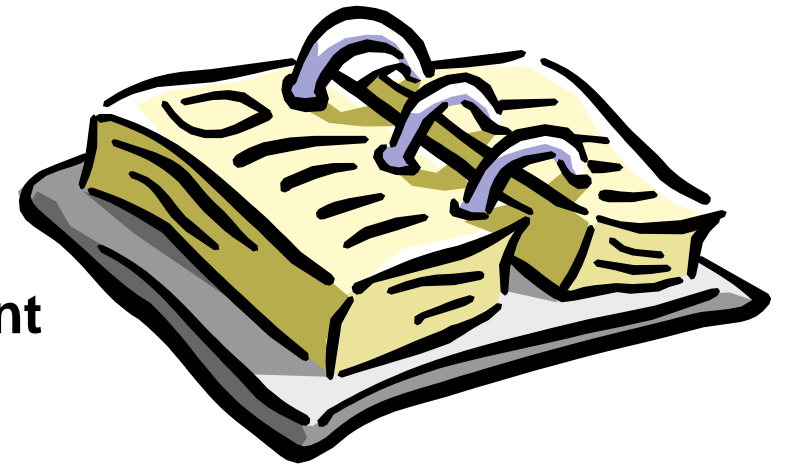
**6**

Consumer Rights Expert (1)  
Health Expert (2)  
Environment Expert (3)  
Biotechnology Expert (4)  
Allotment Farm Expert (5)  
Work Health Expert (6)

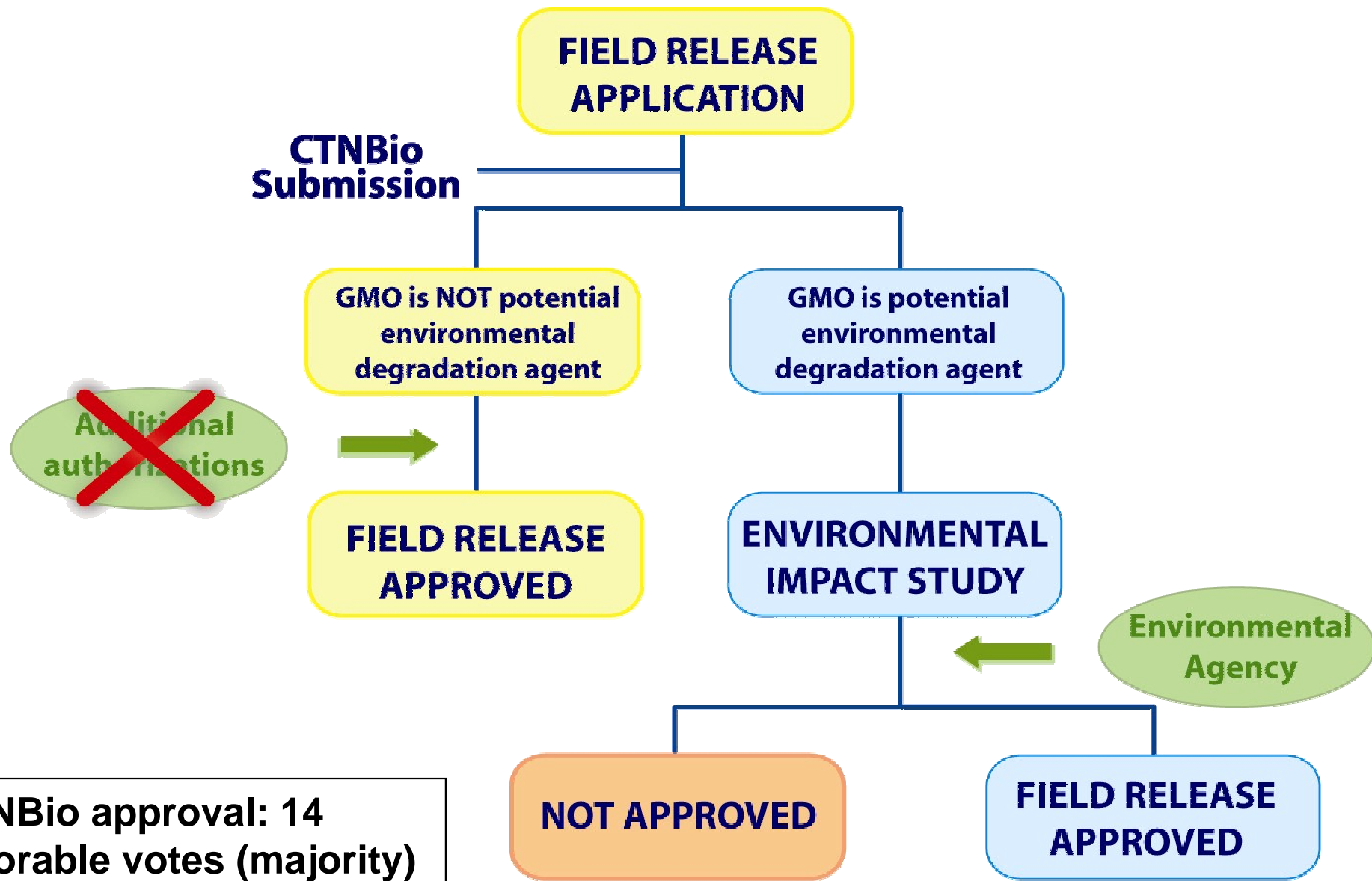
**CTNBio requires scientific qualification – PhD level**

## *How to get an experimental field release approval??*

- To prepare a field release application: CTNBio Guideline
- Key component: environmental risk assessment which considers the potential harm to human health, other organisms and the environment
- To provide responses to a profile of questions
  - Biosafety issues: weediness, gene transfer, effects on the wildlife, altered disease susceptibility, monitoring
  - Molecular characterization: method used for genetic modification, the nature and source of the vector, information about the donor organism



# How to get an experimental field release approval??



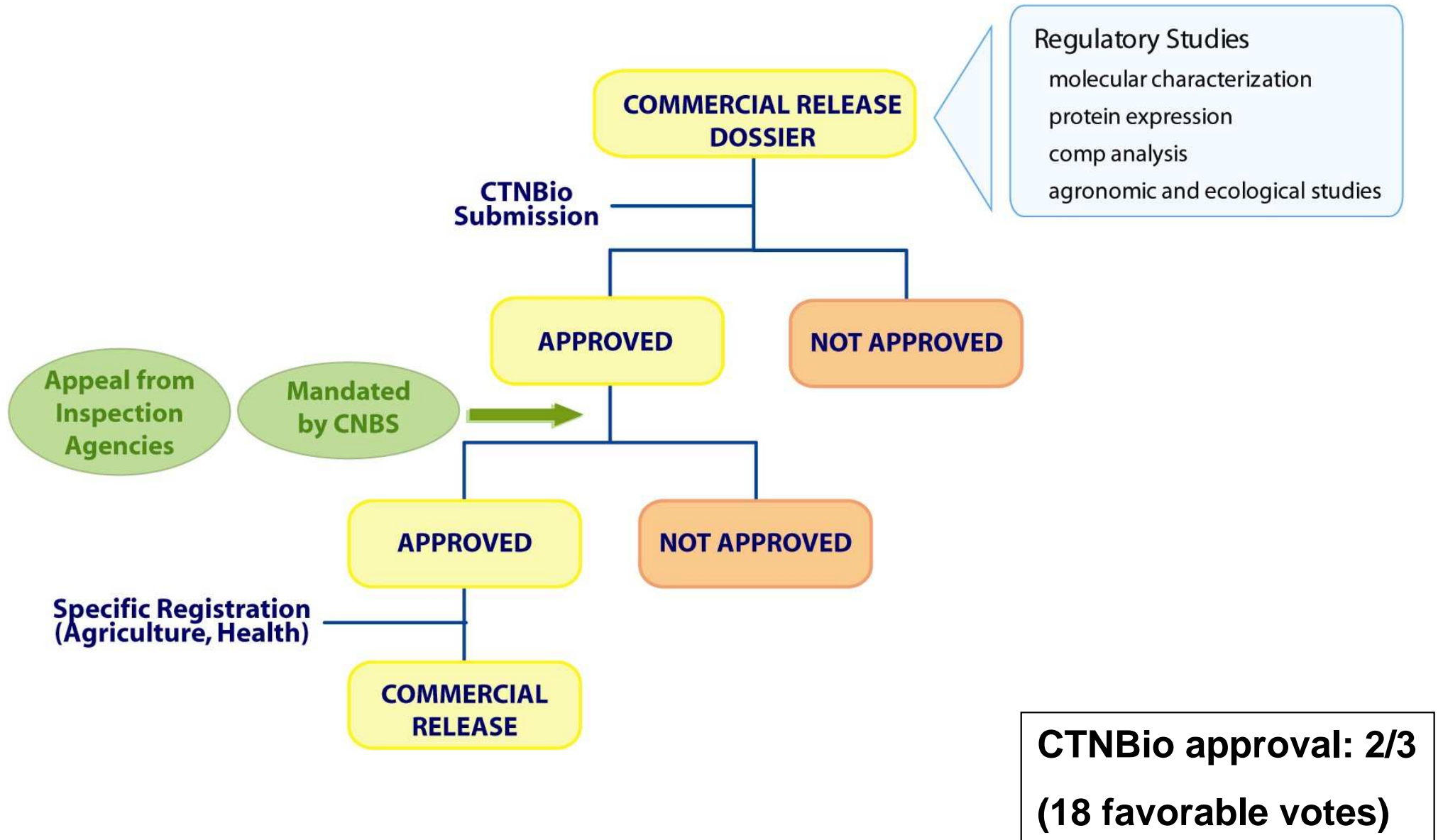
## How to move to the commercial approval?

- **Submission package**
  - **Molecular Characterization**
  - **Compositional analysis**
  - **Protein expression**
  - **Toxicological studies (rat, poultry, other animals)**
  - **Agro-ecological studies**

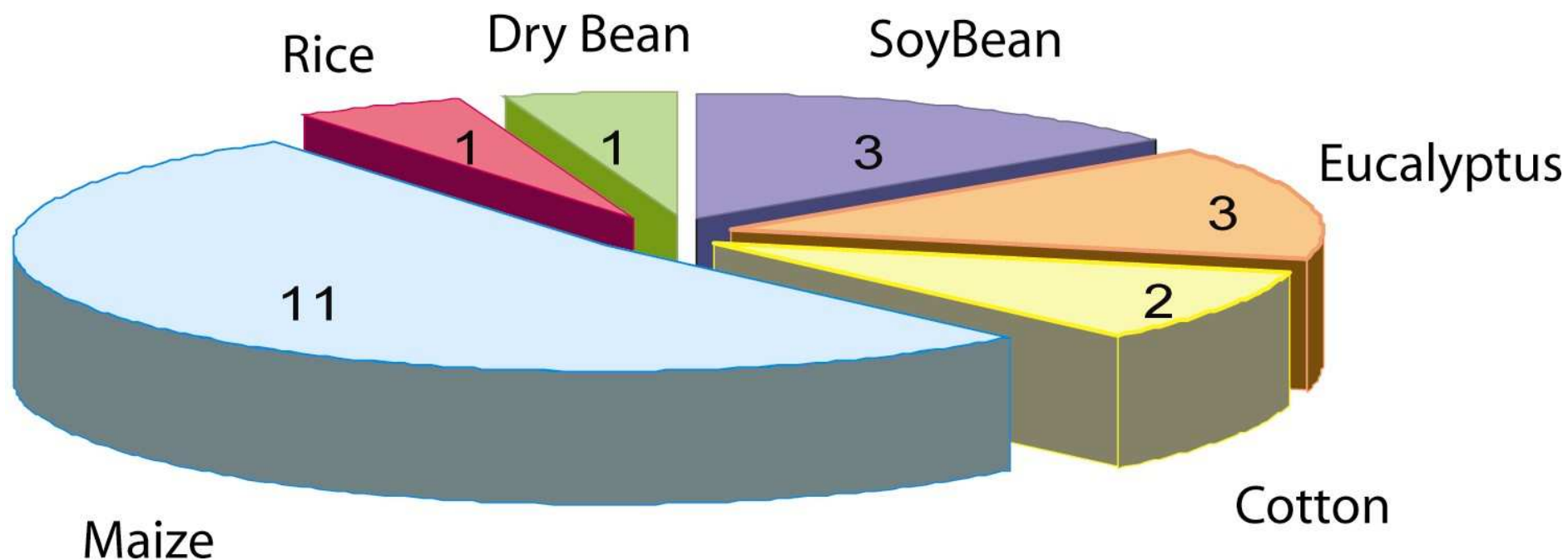


**Aiming the result → AS SAFE AS**

# How to get a commercial approval?



**Experimental Field Release Approvals by CTNBio in 2004**



**Approved Events for commercialization in Brazil**

**RR SOYBEAN**



- Monsanto
- event GTS 40-30-2, Roundup Ready®
- Tolerant to herbicide
- Approval: March 2005

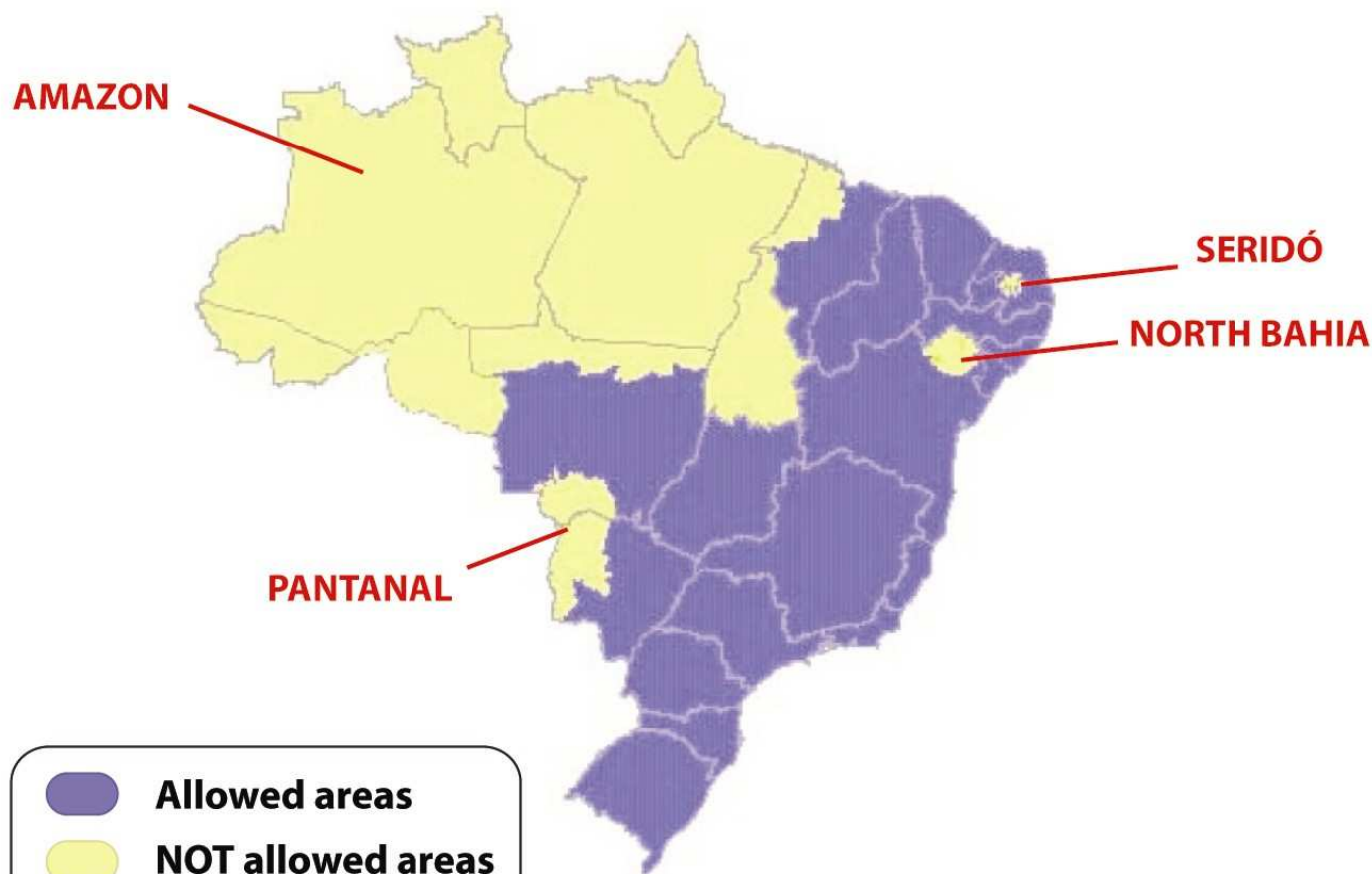
**Bt COTTON**



- Monsanto
- event 531, Bollgard®
- Resistant to insects
- Approval: March 2005
- Waiting for Ministry of Agriculture variety registration

## 3 Conditions for Bt Cotton Approval in Brazil

### 1- Zones of Exclusion for Bt Cotton



**Cotton distribution**  
**Biological importance of the population**  
**Mapping of the agri- zone**



**4 EXCLUSION AREAS**

## **1: Zones of Exclusion for Bt Cotton**

**2 - 20% of the cotton area must be a refuge area of conventional cotton at less than 800m from the transgenic crop**

**3 - CTNBio has also requested a mitigation plan from Monsanto with good agricultural practices such as destruction of the crop residue, crop rotation, use of trap crops and biological control.**

## *RR Soy history in Brazil*

- 1998: RR Soy Approval by CTNBio → subsequent suspension
- 1999: Brown Bagging – Argentine RR soybean
  - South area – high adoption rate
- 2002: provisional measure allowed the commercialization of the GM grain
- Up to 2005:
  - No segregation
  - No premium price for non GM soy
- 2006 (after approval by the new biosafety law):
  - Royalties collection: certified seed
  - Patent infringement fee: saved seed (strip test)



## GM labeling

- Decree 4680/03 (24 April 2003)
  - It mandates the labeling of foods or food ingredients with more than 1% genetically modified material.
  - Animals that had been fed with GMO must also be labeled
  - Information of the donor organism
- Ordinance 2658 (22 December 2003)
  - Label: Yellow triangle with a T in the middle



# GM label



## *Revision of Decree and label*

### **CAMPAIGN** **Food Industries**

- **Change the label, considered too alarming**
- **Review the information of the donor organism**
- **Review the animal label**



# Thank You!

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