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**“GM Crops in Argentina:  
Overview of the Regulatory Framework,  
Current Status and Challenges”**

**Eurofins International Seminar**

**Paris, France – February 20, 21 & 22, 2008**

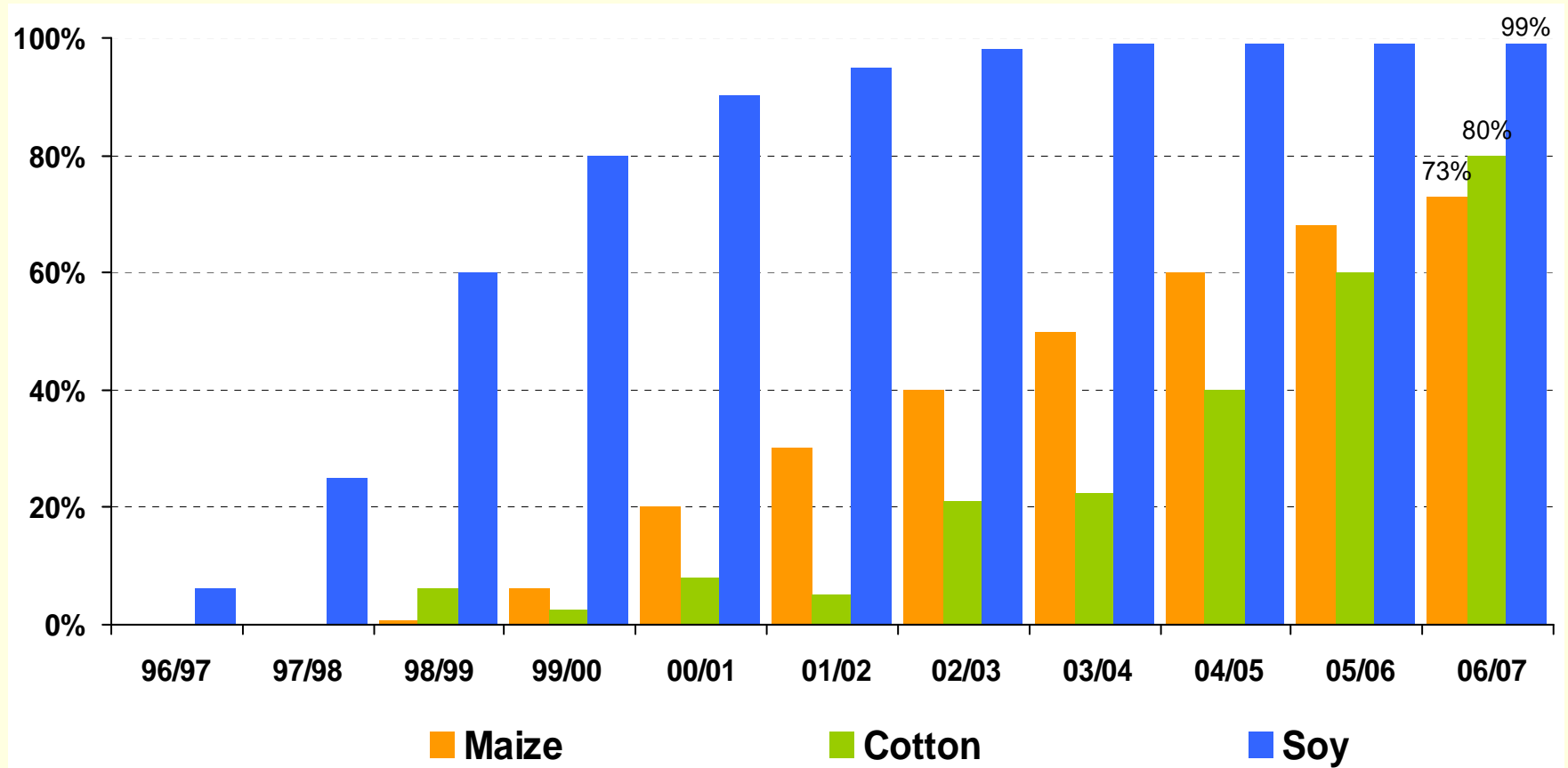
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Secretariat of Agriculture, Livestock, Fisheries and Foods***

# Agricultural Biotechnology in Argentina

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- **Agricultural production** strong and well-established (~60% exports)
- **Strategic technology**
- International **leading position** (area planted with GM crops: 18 million ha, **2nd. place worldwide**)
- Regulatory system for GM crops **since 1992.**
- Successful application of the **Precautionary Approach**
- Participation of the **scientific community** in regulatory activities
- **Transparency** in the technical and scientific inputs in the decision making process
- Regulatory framework **acknowledged** in relevant international fora

# Argentina: Evolution of the GMO cultivated area



Area planted with GM crops (as % of total for each crop)  
Maize, Cotton, Soybean

Source: ArgenBio, 2007

# Planting data - February 1, 2008

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- **Soybean: 16.9 million ha**  
Glyphosate tolerant: 99%
- **Maize: 4.1 million ha**  
Bt: 75%  
Glyphosate tolerant: 9%  
Both (stacked): 1.7%
- **Cotton: 0.32 million ha**  
Bt: 52%  
Glyphosate tolerant: 38%

**Total: 21.32 million ha**

# Main Regulatory Features

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- **Competent authority: the Secretary of Agriculture**
- **Scope: products of modern biotechnology (Cartagena Protocol definition)**
- **Precautionary criteria: scientific risk analysis, agro-ecosystem concept, comparator: non-GM**
- **Risk analysis data in decision making: WTO Agreement on SPS measures**
- **The usual: case-by-case, step-by-step**
- **Quality of supporting studies: peer-reviewed publications**

# Current Regulations

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**N° 39/03 Genetically Modified Crops**

**N° 57/03 Genetically Modified Animals. (includes pharma products)**

**N° 212/06 Production of regulated maize seeds**

**N° 60/07 Stacked events (interactions)**

**N° 412/02 Foods Derived from Genetically Modified Crops**

**Agricultural Biotechnology Biosafety Law (at Parliamentary stage)**

# Type of Releases

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- **First phase: Field trials**, early stages of development, small plots (detailed technical questionnaire)
- **Second phase: Comprehensive dossier, decision document** released on the Internet (already tested several times at the first phase): after approval, less information for planting, *but not commercial release*
- **“Off season” production. GMO not yet approved** in the country (special protocol, extreme containment measures, identity preserved, **all to export to countries where the GM crop is de-regulated**)
- **Commercial**

# Commercial Approval: A Three-step System

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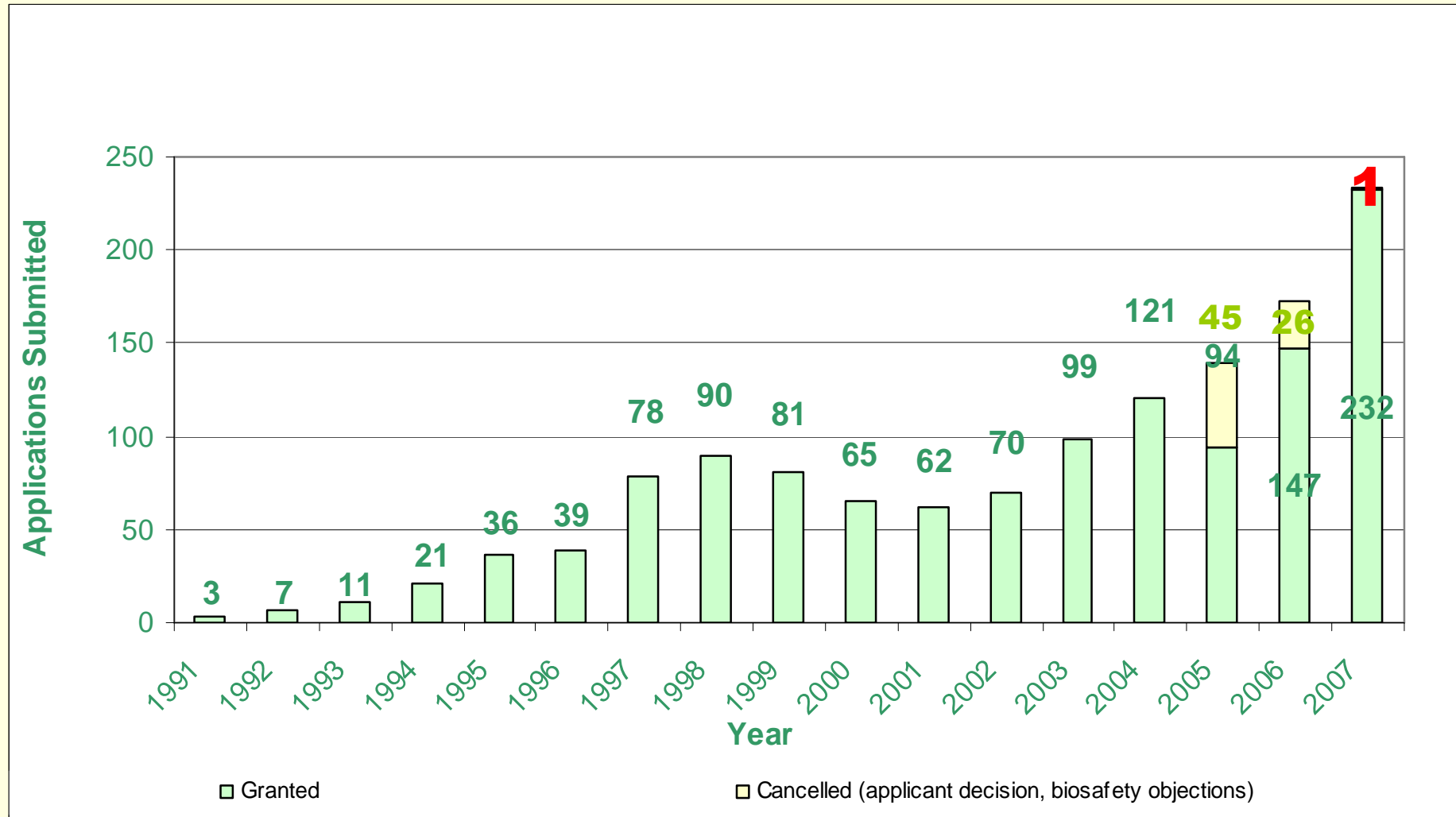
- **Environmental** safety (CONABIA)\*
- **Food** safety (CTAUOGM)\*
- Impact on international **trade** (Agrifood Market Directorate)\*\*

\* Advisory commissions, public and private participation, technical recommendations to the Competent Authority

\*\* Internal report (markets: share, regulatory status, public perception)

- **From Field Trials to Commercial Release: > 5 – 6 years**
- **Current policy: “mirror policy”**

# Applications for GMO Field Trials 1991-2007



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mburac\_mecon; 23/01/2008

# Commercially approved crops

| Species  | Trait                                | Applicant              | Year released |
|----------|--------------------------------------|------------------------|---------------|
| Soybeans | Glyphosate tolerance (40-3-2)        | Nidera S.A.            | 1996          |
| Maize    | Lepidoptera resistance (176)         | Ciba-GeigyS.A.         | 1998          |
| Maize    | Ammonium glufosinate tolerance (T25) | AgrEvo                 | 1998          |
| Cotton   | Lepidoptera resistance (Mon 531)     | Monsanto ArgentinaS.A  | 1998          |
| Maize    | Lepidoptera resistance (Mon 810)     | Monsanto ArgentinaS.A  | 1998          |
| Cotton   | Glyphosate tolerance (Mon 1445)      | Monsanto ArgentinaS.A  | 2001          |
| Maize    | Lepidoptera resistance (Bt 11)       |                        | 2001          |
| Maize    | Glyphosate tolerance (NK 603)        | Monsanto ArgentinaS.A  | 2004          |
| Maize    | Lepidoptera resistance & Ammonium    |                        |               |
|          | glufosinate tolerance (TC 1507)      | Pioneer Arg. & Dow Agr | 2005          |
| Maize    | Glyphosate tolerance ( GA21)         | Syngenta Seeds S.A.    | 2005          |
| Maize    | Lepidoptera resistance & Glyphosate  |                        |               |
|          | tolerance (NK603xMON810)             | Monsanto ArgentinaS.A  | 2007          |



# The Challenges

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- Do we need new *regulations* for complex phenotypes? **(a science issue)**
- In a free market economy, do we have *free international trade*? **(a political issue)**

# **The Regulation Issue: Genetic Engineering and Conventional Breeding Are Converging Technologies**

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## **Phenotypes:**

- **Yield-related properties** (total weight and number of seeds, harvest index)
- **Changes in plant architecture** (height, aerial biomass, ears, stems)
- **Increased tolerance to stresses** (biotic and abiotic)

## **Mechanisms:**

- **Modifying gene and cell cycle regulation** (transcription factors, hormone balance, signal transduction pathways)
- **Modifying physiology processes** (senescence, flowering time)
- **Modifying carbon partitioning**

# The regulation issue: Biosafety Questions

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- Development of GM crops and classical breeding are technologies having...
  - similar molecular mechanisms
  - different regulatory pressure
- Other technologies such as mutation breeding, somaclonal variation, chimeroplasty, have...
  - no regulatory pressure

**Should we change biosafety  
paradigms?**

# The International Trade Issue: The Dispute over GM Products

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## The Core of the Case

**Argentine position:** SPS Agreement (Article 5.7), “Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection ”

Scientific evidence needed for decision making

**EU's position:** Cartagena Protocol (Preamble)

“Reaffirming the precautionary approach contained in Principle 15 of the Rio Declaration...”

Lack of data will not prevent precautionary measures

# The International Trade Issue: The Dispute over GM Products

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- **1998.** The EU stops approving GM products against the opinions of their own scientists (EFSA)
- **2003.** Argentina, Canada and the EEUU submit a case before the WTO: 1) general moratorium, 2) moratorium of specific products, 3) national safeguards
- **2003 – 2005.** Negotiations. Both parties claim to be right. No agreement. The Panel proceedings start.

# The International Trade Issue: The Dispute over GM Products

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- **2006 (Sep. 29).** The Panel delivers the ruling (“implementation” > 2000 pages) after several deferrals (due to the complexity of the conflict).  
**Favors the complainants**
- **2006-2008 (Jan.).** The EU is still working on compliance
- **2008 (Jan.11).** A “roadmap” with a product approval schedule submitted to the EU.
- **2008 (Jun.11).** Compliance with “roadmap” achieved?

# Science and politics

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- **Regulations: science-based**
- **Safety: Environment, food, people**
- **Trade: political agendas?**

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***THANK YOU!***

**Biotechnology Office**  
**Secretariat of Agriculture, Livestock, Fisheries and Food**  
**[www.sagpya.mecon.gov.ar](http://www.sagpya.mecon.gov.ar)**

