

# Evaluation of environmental risks of GMOs: a view from Spain

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Original Extent (km <sup>2</sup> )	2.085.292	Area Protected (km <sup>2</sup> )	90.242
Vegetation Remaining (km <sup>2</sup> )	98.009	Area Protected (km <sup>2</sup> ) in	
Extinct Species <sup>†</sup>	5	Categories I-IV*	28.751
Population Density (people/km <sup>2</sup> )	111	Total Population	232.200.000
Plant Species	22.500	Endemic Threatened Birds	9
Endemic Plant Species	11.700	Endemic Threatened Mammals	11
		Endemic Threatened Amphibians	14

# Basic Principles in Spanish Legislation

- Precautionary Principle
- Evaluation based on scientific data:  
transparency
- "case by case"
- "step by step"

Laboratory/  
Greenhouse



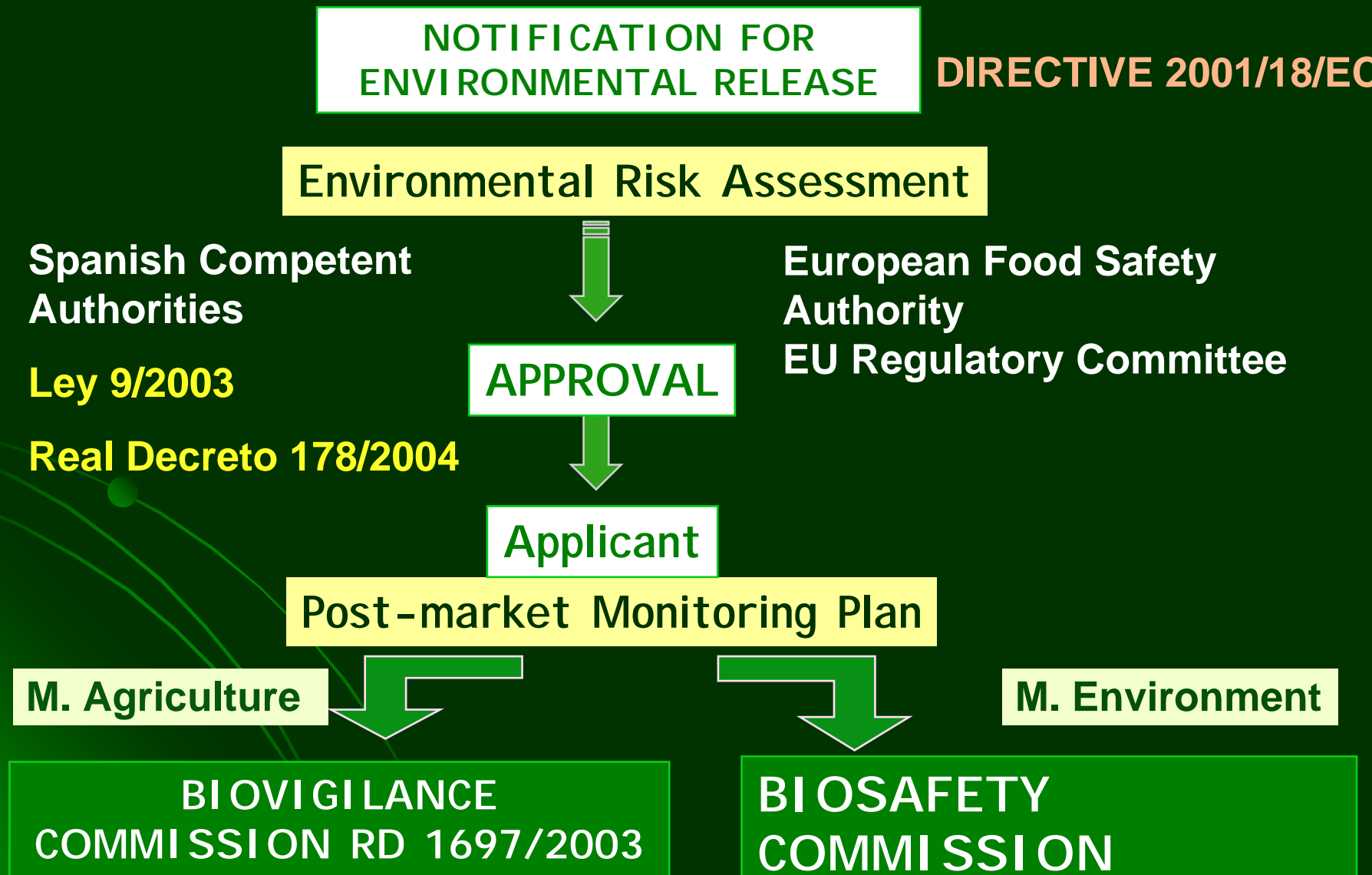
Controlled Assays



Marketing



# REGULATORY FRAMEWORK IN SPAIN



# INTERMINISTRY COUNCIL FOR GENETICALLY MODIFIED ORGANISMS

Responsible for the authorizations assigned to the General Administration of the Spanish State.

REPRESENTATIVES FROM THE MINISTRIES OF

THE ENVIRONMENT

HEALTH AND CONSUMERS

AGRICULTURE, FISHING & FOOD

EDUCATION AND SCIENCE

INDUSTRY, TOURISM AND BUSINESS

INNER AFFAIRES

# NATIONAL BIOSAFETY COMMISSION

Consulting organism, must report every authorization request to the General State Administration and Autonomous Communities.

## COMPOSITION:

REPRESENTATIVES FROM THE MINISTRIES OF

THE ENVIRONMENT

HEALTH AND CONSUMERS

AGRICULTURE, FISHING & FOOD

EDUCATION AND SCIENCE

INDUSTRY, TOURISM AND BUSINESS

INNER AFFAIRES

REPRESENTATIVES FROM THE AUTONOMOUS COMMUNITIES

EXPERT AND SPECIALIST SCIENTISTS

## EXPERT SCIENTISTS IN THE BIOSAFETY COMMISSION

Dr. Fernando González Candelas. Population and Evolutionary Genetics.

Dr. Rafael Pérez Mellado. Molecular Microbiology and Biotechnology.

Dr. Rafael Rotger Anglada. Clinical and Molecular Microbiology.

## SPECIALIST SCIENTISTS IN THE BIOSAFETY COMMISSION

Dr. Pedro Castañera Domínguez. Plant-insect population biology.

Dr. Pere Puigdomènech. Plant molecular biology.

Dr. Florentino Juste. Plant breeding.

Dr. Ramón González García. Food biotechnology.



# RELEASE INTO THE ENVIRONMENT



Experimental assays

Marketing

GOAL: Identify and evaluate, case by case, potential harmful effects of GMOs, *direct or indirect, immediate or delayed*, on human health and the environment resulting from their voluntary release or marketing.

# Release notification/application

1. Features of donor, recipient or parental organisms.
2. Vector features.
3. Features of the genetically modified organism.
4. Release conditions and recipient environment.
5. Interaction between GMOs and the environment.
  - Features affecting GMO survival, establishment and dissemination.
  - Monitoring plan.
6. Control, treatment of residues and action and emergency plans.

Assessment of risks for the environment and human health (ERA)

Post-Market Monitoring Plan

# METHODOLOGY: ERA Phases

*Phase 1:* Determination of features that might cause damaging effects

*Phase 2:* Evaluation of the scale of every damaging effect, if they actually happen.

*Phase 3:* Evaluation of the probability of occurrence for each identified damaging effect

*Phase 4:* Estimation of the risk for each identified trait in the GMO

*Step 5:* Application of management strategies to risks resulting from the release or marketing of the GMO.

*Step 6:* Determination of the global risk of the GMO.

# Evaluating the potential impact of a GMO on the environment - I

1. Increased invasibility in natural habitats or persistence in agricultural habitats;
2. Any acquired advantage or disadvantage;
3. Gene transfer to other species and any selective advantage or disadvantage transferred to other species.
4. Potential impact, immediate or delayed, of direct and indirect interactions or between the GMO and target and non-target organisms.
5. Possible effects on human health.

# Evaluating the potential impact of a GMO on the environment - II

6. Possible effects on animal health and its consequences on the food chain.
7. Possible effects on biogeochemical processes due to a potential direct or indirect interactions between GMOs and target and non-target organisms.
8. Possible direct or indirect effects of GMO culture, management or harvest techniques.
9. Possible immediate and/or delayed effects on biogeochemical processes resulting from interactions.
10. Assessment of the global risk for the GMO.

# Monitoring plans (Part B)

## Experimental releases in the field

### NOTIFICATION:

- Information on monitoring (tracing methods, specificity, duration)
- Control (methods and procedures to minimize dissemination)
- Waste disposal (type, volume, treatments)
- Emergency plans (methods and procedures for control, elimination, decontamination, isolation, protection)

### REPORT ON ASSAY RESULTS

# Field Trial releases (notifier)

- The National Biosafety Commission (CNB) has always pushed notifiers to conduct further scientific studies adapted to local conditions. Some examples are:
  - “Gene flow between transgenic, wild relatives and non-transgenic rice (*Oryza sativa* L. *japonica*)”. Institut de Recerca i Tecnologia Agroalimentàries (IRTA). (Notification B/ES/01/07).
  - “Spread of herbicide-resistance genes from wheat and foxtail millet to weedy species”. Instituto Nacional de Investigaciones Agrarias y Alimentarias (INIA). (Notification B/ES/99/41)
  - “Effects on dairy cows feeding with insect resistance and herbicide-resistance maize (MON810-GA21): milk composition and milk production”. Dr. Casamiglia, Universidad Autònoma de Barcelona. (Notification B/ES/00/09)
  - “Impact of Roundup Ready genetically modified maize (NK603 line) of Monsanto on soil insect populations”. Dr. M. Campos Estación Experimental del Zaidín (CSIC). (Notification B/ES/00/06).

# Monitoring plans (Part C)

## Goals

1. Verification of potential negative effects of GMOs or their use detected in the ERA: Monitoring of specific cases.
2. Identification of any negative effects of GMOs or their use not included in the ERA: General vigilance.



# MONITORING PLANS IN SPAIN

Notifier/Consent holder

Monitoring Plan

National Biosafety Commission +  
Ministry of Agriculture

National Biovigilance Commission (Part C)

*RD 178/2004*

- Part B-Art.23 2a)
- Part C-Art.32d),  
annex X.



# GM MAIZE IN SPAIN

1998-2002

2 varieties Bt176

2003-2005

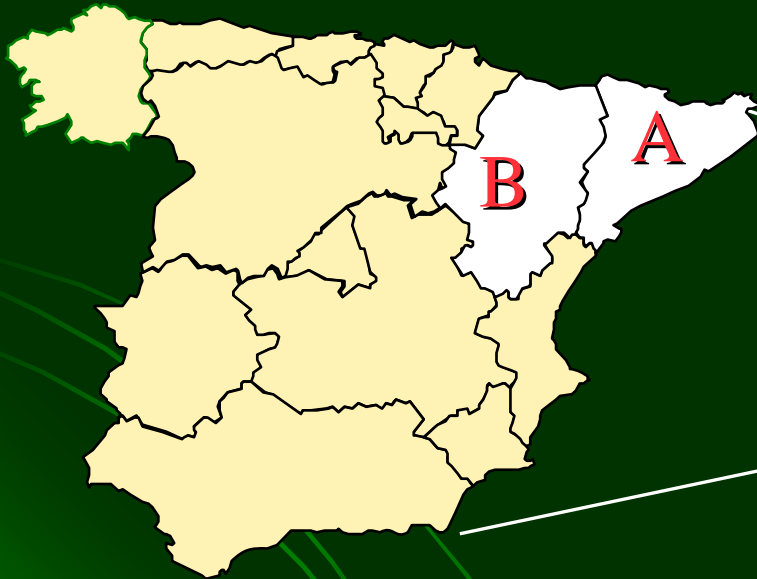
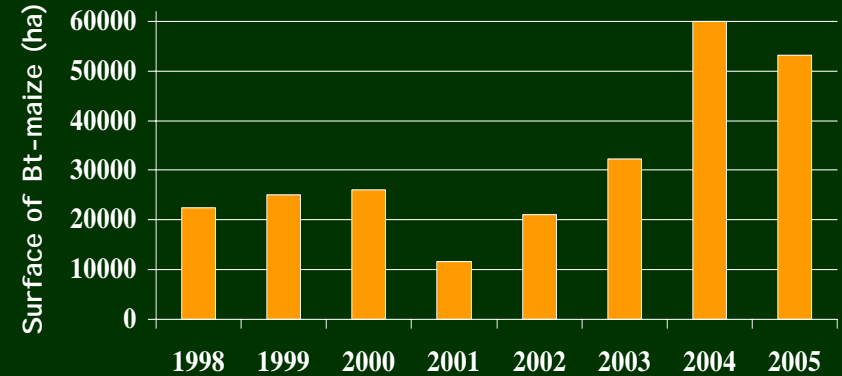
3 new varieties Bt176

11 varieties MON810

2006

Approved 14 new varieties MON810

Disallow further planting of Bt176



GMO 2005 - 53.225 ha  
(≈12% total)

A-Cataluña: GMO 16.830 ha/ 40.359 ha total (41,7%)

B-Aragón: GMO 25.547 ha/ 91.042 ha total (28,06 %)

≈70% GM  
maize in  
Spain

# Monitoring Plans

Annex VII, guidance notes (Decision 2002/811/CE)

## Monitoring strategy

1. Environmental risk assessment
2. Previous/background information
3. Approach (early detection, long term monitoring, adaptation)
  - 3.1. Case specific monitoring
  - 3.2. General surveillance (indirect, delayed or cumulative effects)
4. Baselines (GMO areas, non GMO areas)
5. Time period
6. Responsibilities
7. Existing systems

# Monitoring plans for GM maize in Spain

Monitoring plans (1998–2004) for Bt-176 and MON810 maize varieties (since 2004):

1. "Potential development of resistance in target insects to *CryIA(b)* toxin".
2. "Potential effects of maize on non-target arthropods".
3. "Transfer of genes (ampicillin resistance marker genes Bt-176) from transgenic maize to soil microorganisms".
4. "Effects on bacterial populations in the gut of Bt maize feeders, especially in relation to ampicillin resistance" (BT-176).

# Monitoring specific cases of Bt maize in Spain (2004-2007)

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Research in Public Research Centers sponsored by the Government (2004-2007): additional post-marketing studies with Bt maize (Bt-176 y MON810)

♣ "Assessment of ecological risks of genetically modified maize". Centro de Investigaciones Biológicas (CSIC) and Ministry for the Environment.

♣ "Gene transfer from GM maize to microbial populations in culture soils". Centro Nacional de Biotecnología and Ministry for the Environment.

♣ "Ecological effects of herbicide tolerant maize on weeds and arthropods and ecological effects of GM cotton". INIA and Ministry for the Environment.