



## ***Functions of EFSA and its relationship with the scientific community***

*COST Workshop 5 Nov 2008*

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## EFSA in Parma

- December 2003: Parma selected by European Council as EFSA permanent seat
- October 2005: relocation to Parma completed



EFSA's official seat:  
Palazzo Ducale



EFSA's operational seat:  
"DUS" building

## Mission

EFSA is the keystone of EU risk assessment regarding food and feed safety. In close co-operation with national authorities and in open consultation with its stakeholders, EFSA provides independent scientific advice and clear communication on existing and emerging risks

## EFSA's tasks

1. Provide scientific advice, opinions (e.g. on applications), information, and technical support for Community legislation and policies
2. Collect and analyse data to allow characterisation and monitoring of risks
3. Promote and coordinate development of uniform risk assessment methodologies
4. Communicate risks related to all aspects of EFSA's mandate



**Scientists can contribute to these tasks**

## Who can task EFSA?



**European Commission**



**EU Member States**



**European Parliament**

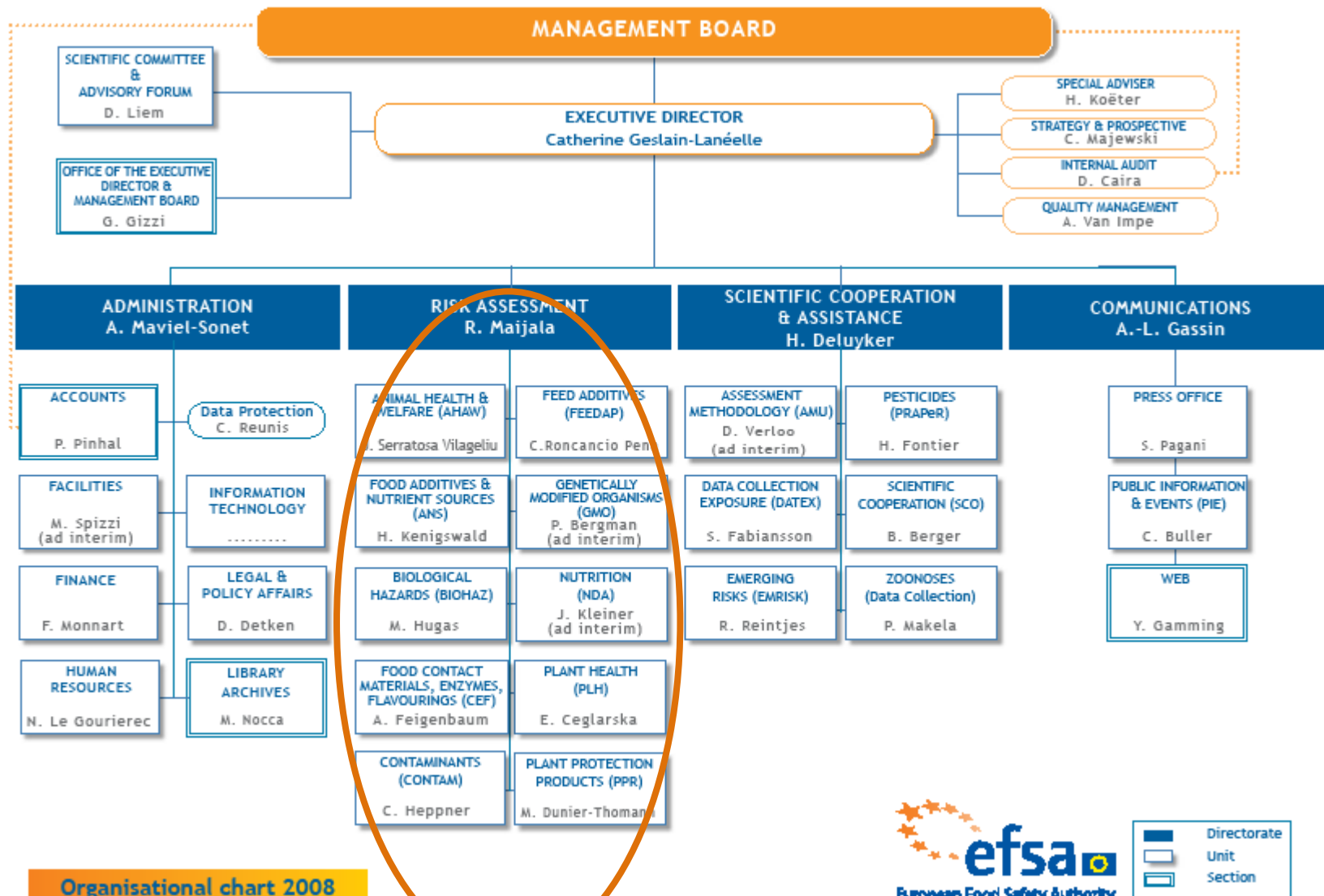


**EFSA itself**

# EFSA cannot

- **Be responsible for food safety legislation**
  - E.g. EFSA does not give authorisations for new products such as GMOs, Feed additives, Food additives, pesticides etc.
- **Take charge of food safety/quality controls (sampling), labelling or other risk management issues such as co-existence measure**
- **Act as a substitute for national authorities**

# EFSA structure



Organisational chart 2008

## Scientific Panels

- Animal health and welfare (AHAW)
- Food additives and nutrient sources added to food (ANS)
- Biological hazards (BIOHAZ)
- Food contact materials, enzymes, flavourings and processing aids (CEF)
- Contaminants in the food chain (CONTAM)
- Additives and products in animal feed (FEEDAP)
- **Genetically modified organisms (GMO)**
- Dietetic products, nutrition and allergies (NDA)
- Plant health (PLH)
- Plant protection products and their residues (PPR)

## Scientific Panels

- 10 Scientific Panels, each composed of 21 scientists
- Independent scientists selected based on their proven excellence
- Open meetings as appropriate
- Mandatory commitment of independence
- Declaration of Interest (annual and per meeting)

## Mandate and legal framework



- **To deliver scientific opinions on scientific questions regarding the safety of genetically modified organisms such as micro-organisms, plants and animals for human and animal health and the environment**
- **Questions can be related to GM food and feed including derived products** (e.g. applications under Regulation (EC) No 1829/2003)
- **Questions can be related to the deliberate release into environment – cultivation** (e.g. applications under Directive 2001/18/EC or Regulation (EC) No 1829/2003)

## Risk assessment activities

- **Scientific evaluation of GMO applications for market release within the EU regulatory framework**
- **Development of guidance documents for applicants (a legal requirement)**
- **In-depth analysis of scientific issues related to risk assessment in self-tasking activities and special mandates from the EU commission (e.g. effect of GM crops on non-target organisms; use of antibiotic resistance marker genes)**

# GMO applications

## scope of applications (Regulation 1829/2003)

### Food

- GMO for food use
- Food containing or consisting of GMOs (e.g. cob)
- Food produced from or containing ingredients produced from GMO (e.g. oil, lecithin)



### Feed

- GMO for feed use
- Feed containing or consisting of GMOs (e.g. maize plant as fodder)
- Feed produced from GMOs (e.g. soya meal)

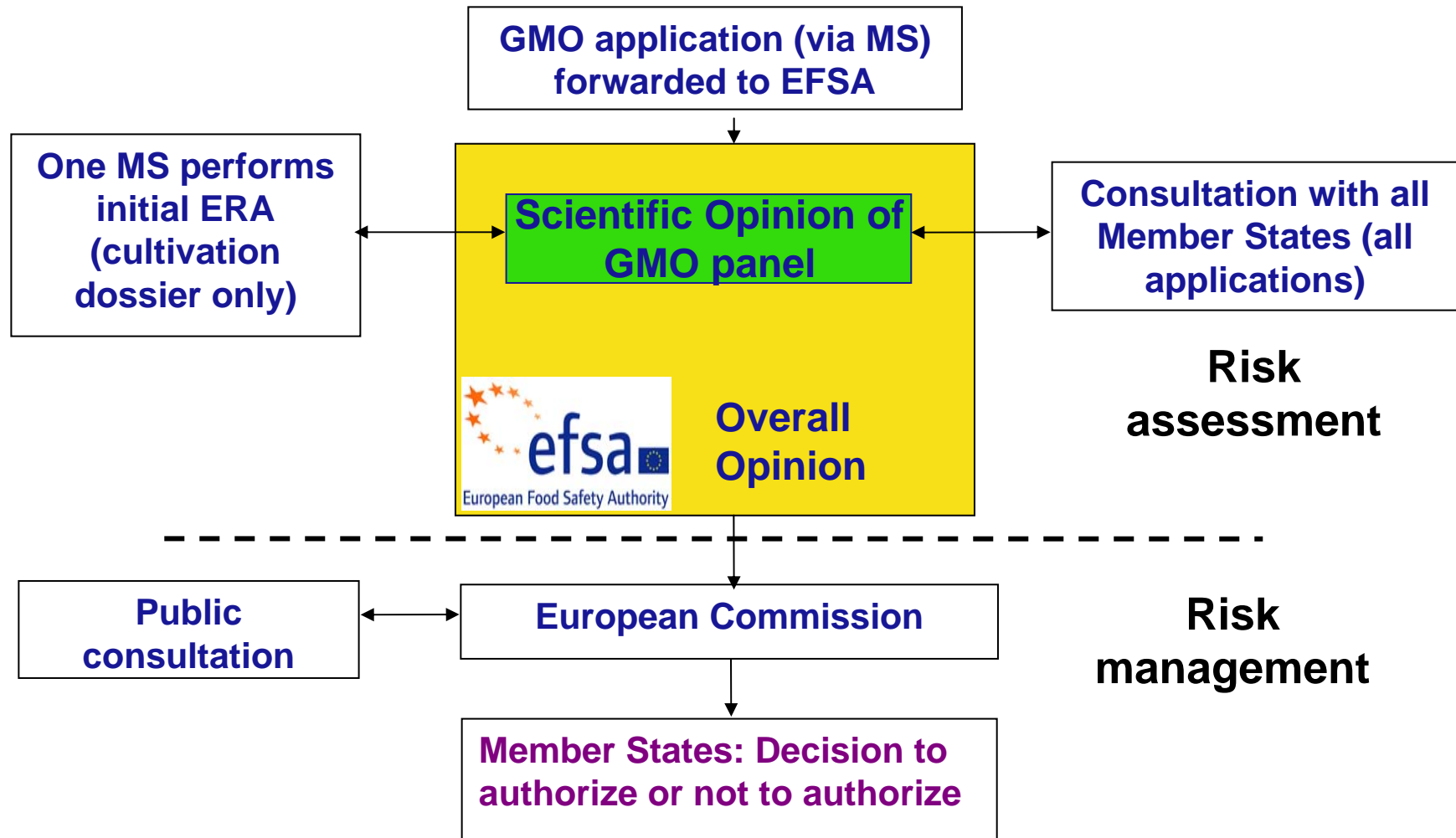
### Deliberate release into the environment

- Import and processing (shipping, making silage)
- Seeds and plant propagation material for cultivation



# GMO Applications: Order of events

## GMO applications under Regulation (EC) No 1829/2003 for GM food & feed



## How is GMO risk assessment carried out

**Comparative approach  
= compare the GMO with the non-GMO**



### For plants:

- Traditionally cultivated crops are well known (***Concept of familiarity***) and have a history of safe use for the environment, consumers and animals.
- These crops can serve as a *baseline* for the environmental and food/feed safety assessment (***Concept of Substantial Equivalence or Comparative Safety Assessment***)

# GMO applications: required information

**For GM plants, dossiers from applicants must provide information on**

## **1. Molecular characterisation**

- characteristics of the donor and recipient organisms
- the genetic modification and its functional consequences

## **2. Comparative analysis of the GM plant with non-GM plant**

- agronomic characteristics (yield, plant morphology...)
- the compositional, nutritional characteristics (proteins, sugars, ..., toxins, allergens...)
- influence of processing on properties of food or feed

## **3. Food/feed safety in relation to intake of the GM plant**

- potential for changes in dietary intake
- the potential toxicity and allergenicity of gene products, plant metabolites and the whole GM plant
- potential for long-term nutritional impact



Cotton – generic image

# GMO applications: required information

**For GM plants, dossiers from applicants must provide information on**

## **4. Environmental impact of the GM plant compared to non-GM plant**

- **Persistence and invasiveness**
- **Selective advantage/disadvantage**
- **Potential for gene transfer**
- **Interactions between GM plant and target organisms/non-target organisms**
- **Effects on human/animal health**
- **Effects on biogeochemical processes**
- **Impacts on cultivation, management and harvesting techniques**
- **Potential interactions with abiotic environment (e.g. altered sensitivity/tolerance to mineral toxins, salinity etc..)**

## **5. Environmental monitoring plan for the GM plant**

# GMO applications: evaluation of information

- **the GMO panel evaluates all these aspects for:**
  - **Intended and unintended effects** due to the modification
  - Effects in **Short- mid- and long-term periods**
- **the GMO panel works in a CASE-by-CASE approach**



# Overall opinion on applications

- **Overall opinion of EFSA in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003**
  
- **List of annexes**
  - Annex A: Scientific opinion of the GMO Panel (EFSA)**
  - Annex B: Cartagena Protocol**
  - Annex C: Labelling**
  - Annex D1: Validation report (CRL)**
  - Annex D2: Validated detection method (CRL)**
  - Annex E: Certified reference materials**
  - Annex F: Monitoring plan**
  - Annex G: Member States comments**

# Status of applications October 2008

GMO dossiers	Adopted opinion	Withdrawn	Pending	Total
Regulation (EC) No 1829/2003 GM food and feed placing on the market (may include cultivation of GMOs)	15	4	42	61
Regulation (EC) No 1829/2003 (renewals)	2	0	23	25
Directive 2001/18/EC Deliberate release of GMOs into the environment (cultivation)	12	2	0	14
Regulation (EC) No 1831/2003 GMO derived additives in animal nutrition	10	0	4	14
<b>Total</b>	<b>37</b>	<b>6</b>	<b>71</b>	<b>114</b>

# GMO applications: scope cultivation

## 12 applications include scope cultivation

MS competent authorities  
carry out environm. RA

UK-2005-17	1507 x NK603 maize	Spain
NL-2005-22	NK603 maize	Spain
NL-2005-23	59122 maize	The Netherlands
NL-2005-24	40-3-2 soybean	Germany
NL-2005-26	MON810 x NK603 maize	Spain
NL-2005-28	1507 x 59122 maize	The Netherlands
UK-2006-30	59122 x 1507 x NK603 maize	Belgium
NL-2007-46	T25 maize	UK
CZ-2008-54	MON88017 maize	Belgium
UK-2008-60	GA21 maize	Czech Republic
RX-MON810	MON810 maize	Spain
RX-T25	T25 maize	UK

All GM plants are herbicide tolerant and/or insect resistant crops

- 1. GM plants and derived food and feed**
- 2. Renewal of authorisations of existing GMO products**
- 3. GM plants containing stacked transformation events**
- 4. Post Market Environmental Monitoring (PMEM)**
- 5. GM microorganisms and their derived products intended for food and feed use**

# Guidance for GM Plants and derived Food and Feed



GUIDANCE DOCUMENT  
OF THE SCIENTIFIC PANEL  
ON GENETICALLY MODIFIED  
ORGANISMS FOR THE RISK  
ASSESSMENT OF GENETICALLY  
MODIFIED PLANTS AND  
DERIVED FOOD AND FEED

Adopted on 24 September 2004  
First, edited version of 2 November 2004

March 2005



- **Adopted on 24 September 2004**
  - Updated in December 2005 (Post Market Environmental Monitoring)
- **Complemented in**
  - December 2006 (Renewals)
  - March 2007 (Stacked events)
- **Currently valid document!**

# New guidance/regulation on GM plants

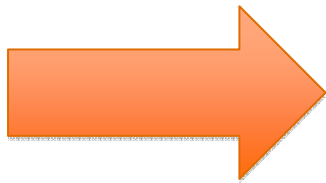


## In development

- **draft version launched for public consultation in July 2008**
- **updated sections on molecular characterization, compositional analysis and food/feed safety**
  - design of field trials for comparative assessment (initiated as self task)
  - standardized toxicity tests
  - role of the animal feeding trials (initiated as self task)
- **ongoing now: revision phase**
- **update of environmental risk assessment section foreseen within the next 2 years**
  - impact of GM plants on non-target organisms (initiated as self task)

# Guidance Documents under consideration and self tasks

- 1. Self task on allergenicity assessment of GM plants**
- 2. Use of antibiotic resistance marker genes in GM plants**
- 3. Self task on GM plants used for non-food/non-feed purposes**
- 4. Guidance on GM animals**



**Scientists with expertise in a broad range of areas are needed to accomplish these tasks**

# Scientific Committee and Panels: Background

- **EFSA is looking for Scientific Committee and Panel members to deliver high-quality scientific advice for Europe's risk managers**

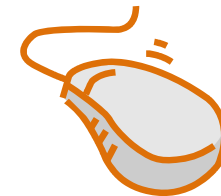


- **Experts sought to cover:**
  - Animal health and welfare
  - Biological hazards including TSEs
  - Contaminants in the food chain
  - Dietetic products, allergies and nutrition
  - Feedstuffs
  - **GMOs**
  - Plant health
  - Plant protection products

# Be an EFSA Scientific Committee or Panel member

- **Appointed for 3 years, renewable (beginning mid 2009)**
- **Selection based on proven scientific excellence**
- **Apply online from 23 Oct. till 7 Jan. 2009 to:**

**[www.efsa.europa.eu](http://www.efsa.europa.eu)**



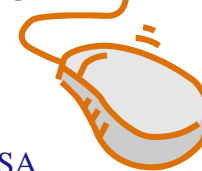
# Scientific expert database: Sign up and be an EFSA expert

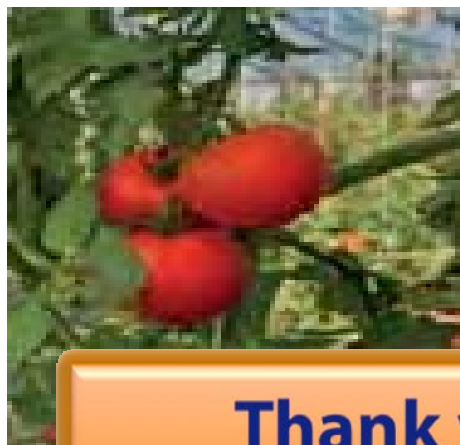
- **EFSA is looking for experts in a wide range of disciplines** (e.g. *Food and feed safety, nutrition, toxicology, chemistry and animal health & welfare, GMO, plant protection and health*)
- **Creating a database of experts to support EFSA or Member States**
- **Selected experts included in the database can be invited to participate in certain scientific activities to assist EFSA and Member States in their risk assessment work**

## Application process:

- **Experts are invited to fill in an online form:**

[www.efsa.europa.eu](http://www.efsa.europa.eu)





**Thank you for your  
attention!**

