European Food Safety Authority

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

What EFSA does

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

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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

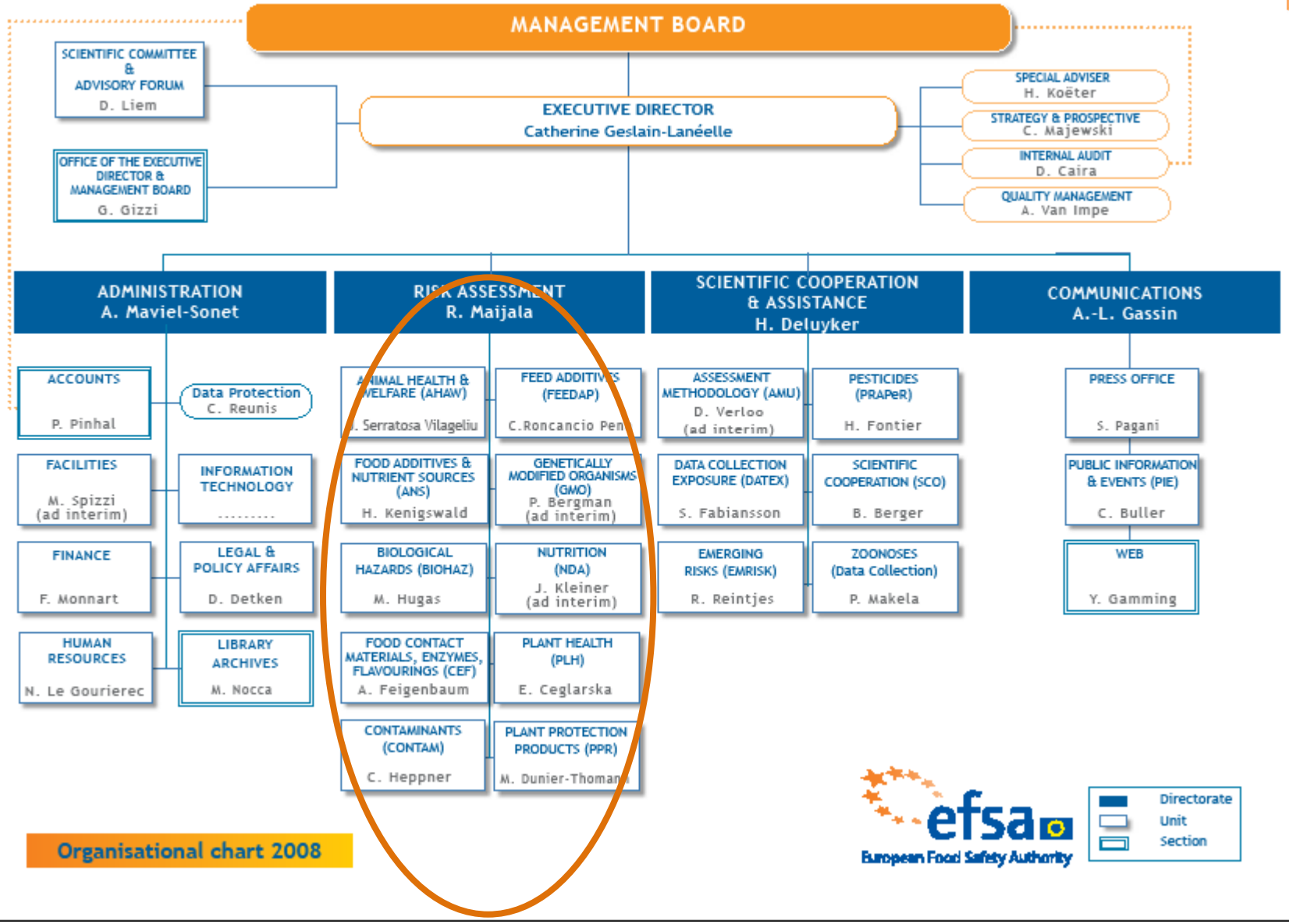
European Parliament

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

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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)

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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

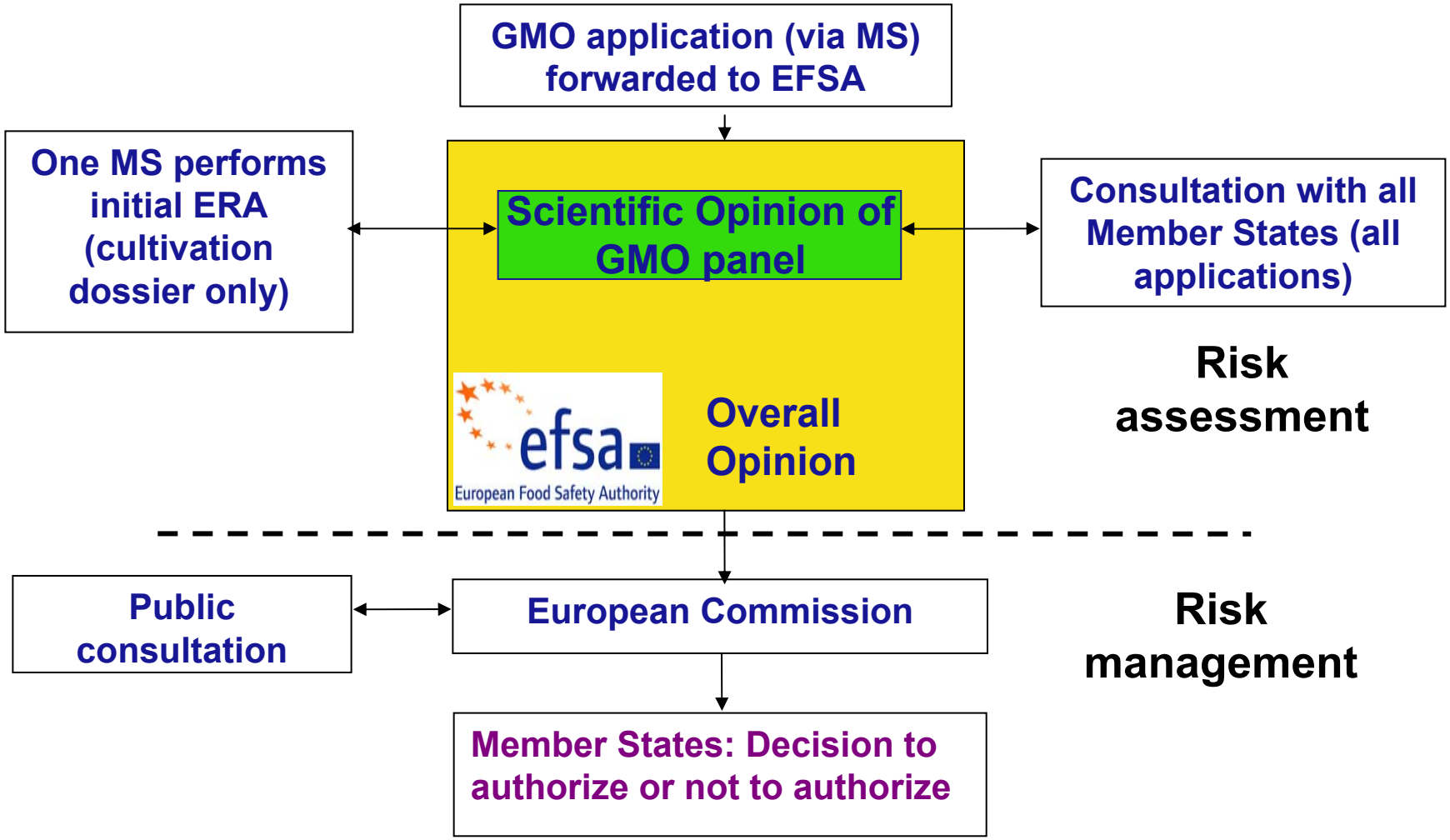
- GMO for feed use
- Feed containing or consisting of GMOs (e.g. maize plant as fodder)
- Feed produced from GMOs (e.g. soya meal)

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



GMO Applications: comparative risk assessment

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

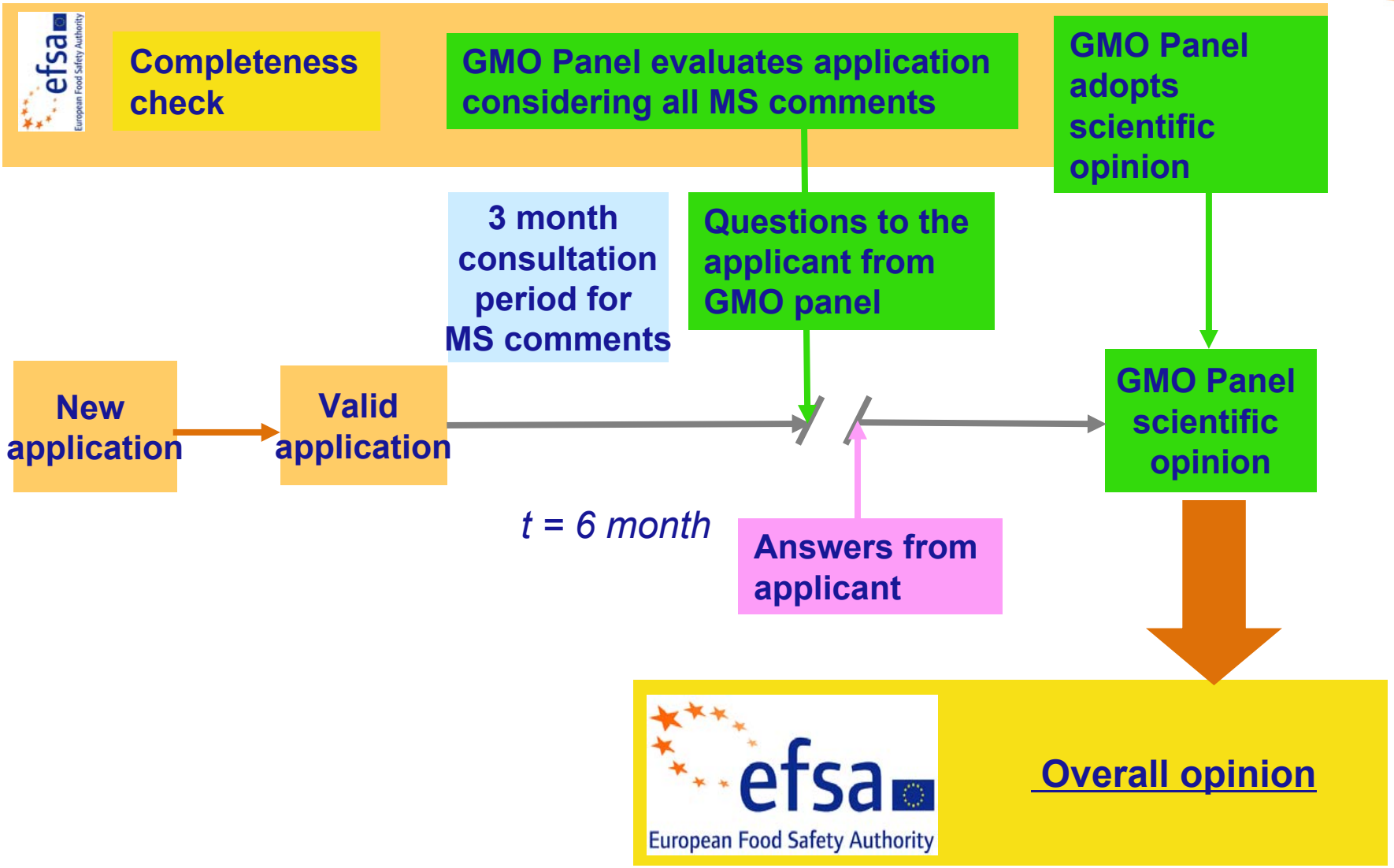
For GM plants, dossiers from applicants must provide information on

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**

GMO applications: procedure under regulation 1829/2003 (simplified)



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
Total	37	6	71	114

GMO applications: scope cultivation

12 applications include scope cultivation

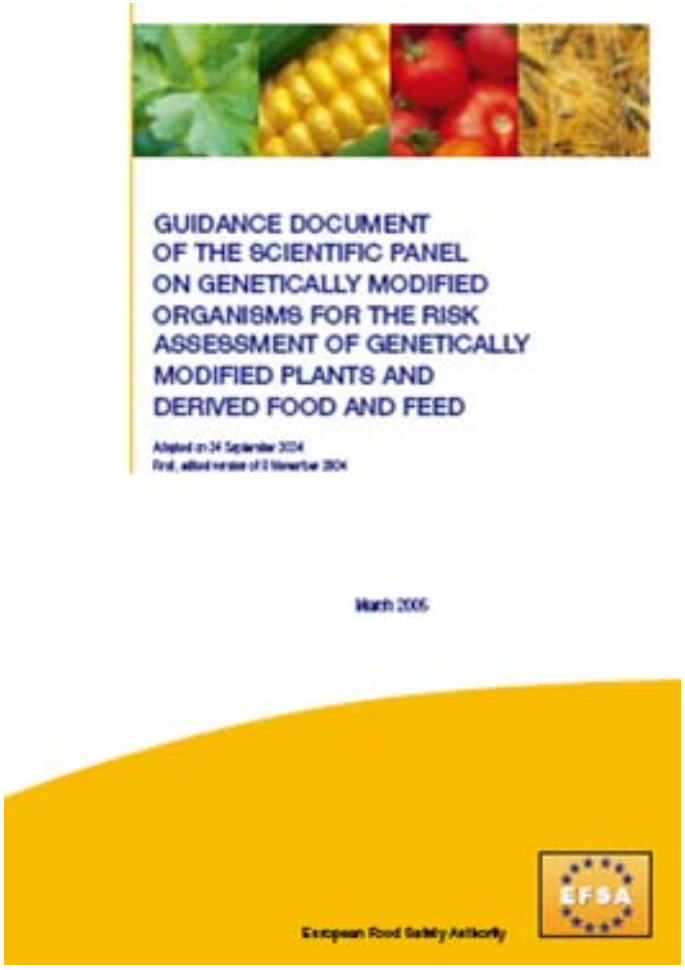
		MS competent authorities carry out environm. RA
UK-2005-17	1507 x NK603 maize	Spain
NL-2005-22	NK603 maize	Spain
NL-2005-23	59122 maize	The Netherlands
NL-2005-24	40-3-2 soybean	Germany
NL-2005-26	MON810 x NK603 maize	Spain
NL-2005-28	1507 x 59122 maize	The Netherlands
UK-2006-30	59122 x1507 x NK603 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

GMO Guidance Documents: adopted

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



- **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

- 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

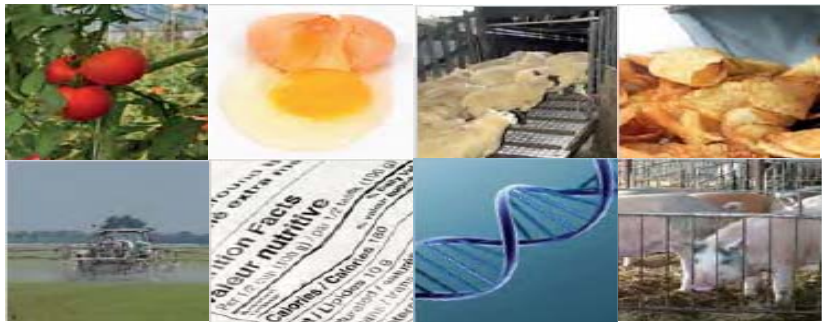
1. **Self task on allergenicity assessment of GM plants**
2. **Use of antibiotic resistance marker genes in GM plants**
3. **Self task on GM plants used for non-food/non-feed purposes**
4. **Guidance on GM animals**

GMO panel activities

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**

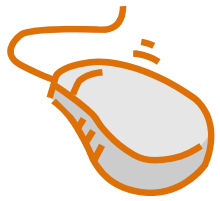


- **Experts sought to cover:**
  - **Animal health and welfare**
  - **Biological hazards including TSEs**
  - **Contaminants in the food chain**
  - **Dietetic products, allergies and nutrition**
  - **Feedstuffs**
  - **GMOs**
  - **Plant health**
  - **Plant protection products**

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



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


Thank you for your attention!