Scientific Panel on Genetically Modified Organisms (GMO Panel)

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Presentation to the EFSA Management Board
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Topics on the GMO Panel

1. Areas of work and Accomplishments
2. Interactions with the European Commission, Member States and other Stakeholders
3. Issues which need attention
4. Future challenges

1. Areas of work and Accomplishments of the GMO Panel

A. Scientific evaluation of GMO Applications for market release within the EU regulatory framework

B. RA Guidance Documents for applicants

C. Self-Tasking Activities

D. Scientific cooperations

E. Answering Questions from EC, MS, EP, public, stakeholders

F. Communication

A. EU Regulatory Framework for GMO applications

Two distinct legal bases:

- **Directive 2001/18/EC** on the deliberate release into the environment of genetically modified organisms
- **Regulation (EC) No 1829/2003** on genetically modified food and feed

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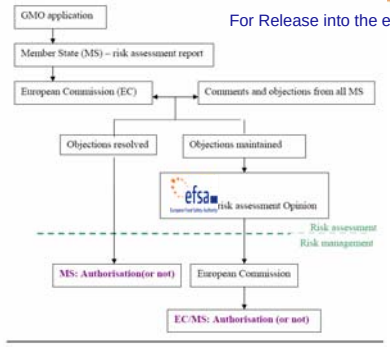
A. GMO applications under Directive 2001/18/EC

For Release into the environment



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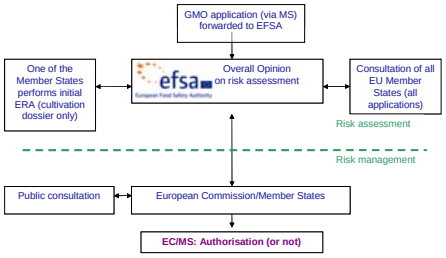
A. GMO application under Regulation (EC) No 1829/2003

For GM food & feed



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Working Procedures of the GMO Panel

- **GMO Panel (20 members, 1 vacancy)**
- **Standing Working Groups per application:**
  - **The high complexity GM plant evaluations require 3 parallel working groups:**
    1. Molecular Characterization
    2. Food and Feed Safety Evaluation
    3. Environmental Risk Assessment
  - **Evaluation of GM microorganisms**
- **Working Groups for specific issues and self tasking activities**
- **GMO Unit**
  - Drafting opinions/statements
  - Contribution Self-Tasking
  - Procedural Activities
  - Secretarial Activities

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Number of GMO applications

1829 GMO dossiers received by EFSA	46
Withdrawn	1
Under Completeness check	12
Valid in risk assessment	22
Scientific Opinions adopted	11
under consideration	**34**
Renewals dossiers	**20**
2001/18 dossiers considered by EFSA (1 withdrawn)	**12**
TOTAL number of dossiers	**78**
TOTAL pending and under considerations	**54**
Expected for coming 3 years (multiple stacks)	? (<60)

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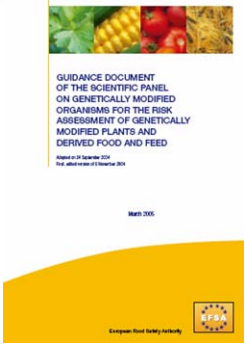
A. EFSA Guidance for GM Plants and derived Food and Feed



- Adopted on 24 September 2004,
- Updated in December 2005 (PMEM)
- Complemented in
  - December 2006 (Renewals)
  - March 2007 (Stacked events)

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A. Safety Assessment Strategy for GM Crops

Two-steps Procedure:

1. Identification of differences between the GM and non-GM crop
2. Assessment of the environmental and food/feed safety and nutritional impact of identified differences
   - *Substantial Equivalence*

Underlying assumption is that traditionally cultivated crops have gained a history of safe use for the environment, consumer and animals

CASE-by-CASE approach

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Elements of GMO Safety Assessment

- Molecular Characterisation:
  - look at the newly introduced DNA, expressed protein(s) and the consequences
- Food/feed safety assessment
  - particular focus on Toxicity, Allergenicity and Nutrition
- Environmental risk assessment
- Evaluation of the Post Market Monitoring Plan

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B. Guidance documents

- **Guidance Documents for Risk Assessment**
  - GM Plants and derived Food and Feed
  - GM Micro-organisms and their derived Products Intended for Food and Feed Use
  - Stacked Genes
  - Post Market Environmental Monitoring (PMEM)
  - Renewal dossiers
- **Guidance Documents under consideration**
  - GM crop for non-food/feed pruposes (e.g. phytoremediation, biofuels)
  - GM animals
    - Food/Feed
    - Environment

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C. Self-Tasking Activities

1. Antibiotic marker genes in GM plants
2. Post-market environmental monitoring
3. Stacked events (GM plants combined by crossing
4. Interplay GMO and pesticide legislation
5. Allergenicity assessment of GM plants
6. Animal feeding trials with GM plants
7. GM plants for non-food/feed purposes (e.g. phytoremediation, biofuels)
8. Statistics in comparative assessment of GMOs

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D. Scientific Cooperation

Currently ongoing or under consideration:

- Art 36 project:
  Cry proteins and their expression in micro organisms and genetically modified plants (CFP/ EFSA/GMO/2007/01)
- Art 36 project:
  Study on the state-of-the-art on the impact of Genetically Modified Herbicide Tolerant plants on **non-target organisms** (CFP/ EFSA/GMO/2007/02)
- Art 36 project proposal:
  Genetically Modified Animals – Review and environmental risk assessment (CFP/EFSA/GMO/2007/xx)
- Follow-up Colloquium on ERA

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E. Answering questions

EFSA addresses questions and concerns from

- European Commission
- Member States Authorities
- European Parliament Members
- General public
- Environmental NGO's, applicants and other stakeholders

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Types of Questions

- Specific questions regarding dossier applications
- Safe guard clauses
- Studies appearing in peer reviewed scientific journals/internet (MON 863)
- Petitions (rec DNA in products of animals fed GM feed)
- Newspaper notes (inadvertent presence of GMOs)
- Press statements (antibiotic resistance marker genes)

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MON 863, an example (1)

- GMO Panel issued an opinion and statement (2004) on the safety of MON 863 maize
- Séralini *et al.* (2007) published a *statistical re-analysis* of the original data of a 90-days rat feeding study with maize kernels
- Conclusion Seralini: '*with the present data it cannot be concluded that GM corn MON 863 is a safe product*'
- The European Commission asked EFSA to consider, in cooperation with the Member States, what impact the re-analysis might have on the earlier EFSA opinion and statement

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MON 863, an example (2)

- EFSA set up a Task Force to assess the statistical methodology applied by Séralini *et al.* and to perform its own statistical analysis
- Extensive exercise with experts involved from:
  - Members of the GMO Panel and Working Group Food/Feed
  - Members of the Self-Tasking Working Group on Statistics
  - GMO Unit
  - SCA Unit (Scientific cooperation and assistance)

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MON 863, an example (3)

- Conclusion of the EFSA Taskforce:
  - the statistical approach taken by Seralini et al. showed a number of deficiencies, not allowing conclusions that there were significant adverse effects on biological parameters of rats fed with MON863 kernels
- Consultation of the EU Member States through the EFSA Advisory Forum
- The GMO Panel reconfirmed its earlier conclusion on the safety of MON863 maize

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Number of meetings

	2003	2004	2005	2006	2007	Total
Plenary meetings	**2**	**9**	**8**	**7**	**7**	**33**
Applications Food Feed	4	7	13	8	10	42
Applications Mol. Charact.	4	8	13	6	10	41
Applications Environment	3	8	11	7	7	36
GM Plant Guidance document		7				7
GMM Guidance		4	5	1		10
GMM feed additives			1	1	6	8
Hybrids				1	1	2
Antibiotic Resistance Marker Genes	3				1	4
PMEM		4	3			7
Animal feeding trials			5	5	3	13
Non food feed			1	5	4	10
Statistics			1	3	2	6
Allergenicity			1	3	4	8
Others (CA, colloquium, etc.)				6	7	13
Total	14	47	62	53	62	196

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Number of published documents

From 2003 - 2007 (Q3)

GM plants RA opinions (Reg. 1829/2003 + Dir. 2001/18 applications)	**23**
General topics (contained use GMM, ARMs, PMEM)	**3**
Safeguard clauses on GM plants (AU, GR, AU, HU, 5 MS, GR)	**6**
GM microorganisms RA co-opinions (with FEEDAP)	**4**
Statements (fate DNA, MON863 stats, NptII, LLRICE601, MON863 feeding study)	**5**
Guidance (GM plants, GM Microorganisms, renewal dossiers, stacks)	**4**
TOTAL	**45**

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2. EFSA interacts with the European Commission

- EFSA interacts with DG SANCO and DGENV on GMO issues + occasionally with DGRTD, DGAGRI and JRC
- EC is informed about all the details on the GMO applications
- Attendance of EFSA and scientific support to EC in e.g. standing Committee meetings
- Attendance of the EC at plenary meetings and self-task meetings

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GMO Panel Interacts with EU Member States

- Direct contact with Member States' experts via the online **GMO EFSAnet** system for exchanging information on GMO dossiers
- **Internet Consultations** on all Guidance documents and Self-task documents
- **Consultation meetings** with Member States:
  - GM Plant Guidance consultation meeting (25/04/2004)
  - Workshop with Member States experts on post-market environmental monitoring (20/01/2004)
- **Meeting with national experts** from Member States (Austria, France) on specific issues of toxicology and allergenicity assessment (March and July 2004)
- **GMO Forum meeting** on risk assessment approaches (Brussels, 15 May 2006)
- **Meeting** with Greek competent authorities on the safeguard clause under Directives 2001/18 and 2002/53 (3 July 2006)

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GMO Panel Interacts with

Other Organizations

- Meeting with NGO representatives on risk assessment strategies for GMOs (Parma, 22 Feb 2006)
- Meeting with Applicants: Hearing on future products (Parma, 21 March 2007)
- Global organisations FAO/WHO
  - EFSA participation in Codex Task Force activities on Biotechnology
    - Nutritionally enhanced foods
    - Recombinant animals
    - Low level presence GMOs
- EMEA cooperation on Non Food/feed applications
- Global scientific community: Colloquium on Environmental Risk Assessment on 20-21 June 2007

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EFSA initiatives on strengthening interactions with Member States

- GMO Panel has substantially invested in meetings with experts and competent authorities of Member States regarding
  - Risk assessment strategies
  - Guidance documents
  - Specific issues
- Each Member States comment, for each application, is now answered individually in a published **Table with MS comments** (e.g. 38 comments per application)
- Meeting of the Advisory Forum with members from the Scientific Committee and the GMO Panel on GMO risk assessment principles (November 2007) with specific attention to:
  - the assessment of potential long term effects of GMOs
  - Use of test protocols

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Assessment of Potential Long-Term Effects of GMOs and the use of test protocols

- The assessment of potential long term effects is one of the fundamental pillars of EFSA's risk assessment work
- The EFSA Guidance Document refers to *validated* test protocols, where applicable, accepted globally (OECD protocols for single chemical substances)
- The pre-market safety assessment based on extensive molecular, compositional analysis, and on *in silico*, *in vitro* and *in vivo* testing should provide sufficient assurance on the safety of GM food/feed
- Short-, mid- and long-term effects of a GM crop on non-target organisms, soil micro-organisms, biogeochemical processes, or due to gene transfer, are considered and assessed by the GMO Panel
- In certain cases post market monitoring of GM foods/feed may be considered
- When not identified during the ERA, potential long-term effects to ecosystems might be managed or further monitored through the environmental post-market monitoring activities (PMEM)

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3. Issues which need further attention (1)

- Workload of the GMO Unit, GMO Panel and Working Groups is heavy
- Hardly enough manpower for prospective activities (guidance development for GM nutritionally enhanced plants, rec. animals, GM insects…)
- EU GMO authorisation process is challenged by WTO with respect to the timeframes and pressure is forwarded to the risk assessments of EFSA

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Issues which need further attention (2)

- Responding to questions on past opinions is relevant but time consuming
- There is a general support of risk assessors of Member States and of other International Organizations with the approaches taken by the Panel, but not always of national risk managers
- Panel should not be burdened with non-scientific issues (labeling, low level presence GMOs, rumours on the internet)

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Issues which need further attention (3)

- Time consuming activities with partly financial compensation
- Relatively low remuneration rates of EFSA
- Parma as location
- EFSA pied-a-terre Brussels?
- Paid work at home
- Art 36 networking (limited remuneration for Institutes)

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4. Future Challenges

- Wider recognition of GMO priorities for EFSA. Urgent need for priority setting
- Continuing communication with different stakeholders on risk assessment strategies for GMOs
- Further development of risk assessment strategies based on modern genomic and biotechnological methods
- Intensify role of EFSA in international activities regarding risk assessment strategies for GMOs

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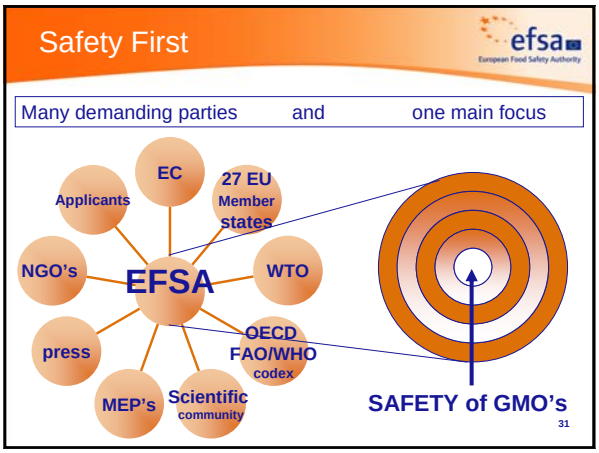
Safety First
efsa
European Food Safety Authority
Many demanding parties and one main focus
EC
27 EU Member states
Applicants
NGO's
EFSA
WTO
press
OECD
FAO/WHO
codex
MEP's
Scientific community
SAFETY of GMO's
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