Opinion of the EFSA GMO Panel on the Post Market Environmental Monitoring (PMEM) of GM plants

Opinion adopted on 25 January 2006

EFSA PMEM Opinion

1. Introduction
2. Methodology
3. Guidance for the applicants
   (equal to EFSA Guid. Doc. Risk Assessment
4. Views expressed during consultation
5. Wider issues to be consideed by applicants and risk managers
6. Conclusions and recommendations

EFSA PMEM Opinion - Chapter 1 + 2

EFSA GMO Panel self tasking activity

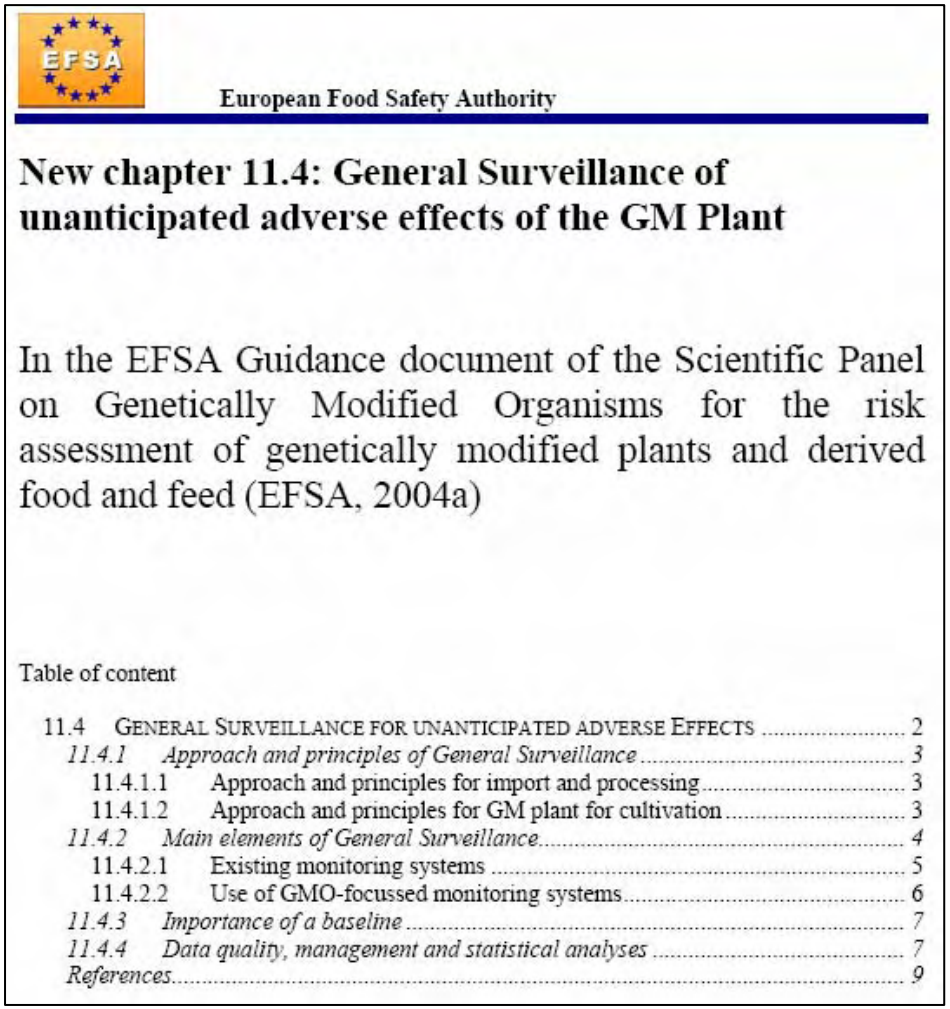
- Mandate adopted by EFSA in April 2004
- Task: advice GMO Panel, act as interface to Commission and CA, organise workshops, prepare guidelines
- 8 Panel members supported by 8 external ad hoc experts
- 10 meetings with 3 consultation workshops

EFSA PMEM Opinion - Chapter 3

Guidance for the applicants

- Presentation of chapter 11 of the EFSA guidance document on risk assessment

PMEM opinion includes new GS chapter



European Food Safety Authority

New chapter 11.4: General Surveillance of unanticipated adverse effects of the GM Plant

In the EFSA Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed (EFSA, 2004a)

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The diversity of views on GS expressed during the consultation process

1. Definition CSM / GS
2. Feasibility of testing hypotheses
3. Use of historical knowledge
4. Difference monitoring / biosafety research
5. Monitoring at landscape level for protection goals
6. Intensive monitoring of environmental exposure
7. Good monitoring practice
8. Monitoring effects on human health
9. Responsibilities

CSM / GS differentiation by Sanvido et al. 2005

Table 1. Objectives of a monitoring program for genetically modified plants (GMPs) according to EU Directive 2001/18/EC, plus a judgment on the possibilities and limits of case-specific monitoring and general surveillance.

	Case-specific monitoring	General surveillance
Objectives according to 2001/18/EC	– To assess, if anticipated adverse environmental effects related to a specific GMP do occur (confirm assumptions of environmental risk assessment - ERA)	– To detect unanticipated adverse environmental effects which were not identified in the ERA
Approach	– Detection of changes related to GMP cultivation during a defined time period	– Assessment of state of the environment independent from any preconception and time period
What the program can provide	– Case-specific confirmation or rejection of a previously formulated hypothesis in comparison to a reference system – Draw conclusions on the cause of detected changes	– Provide information on the state of the environment and of possible environmental changes – Provide fundamentals to forecast the likely development of the environment (early warning system)
What the program can not provide	– Draw conclusions on the long term development of the environment	– Determine the cause of an environmental change – Draw conclusion on the effects of GMP cultivation

Clarification: GS borderline to CSM

1. CSM is hypothesis driven, whereas GS not.
2. CSM depends directly on the outcome of ERA, whereas GS not (but on uncertainty whether unforeseen effects might occur).
3. CSM may use experiments, whereas GS not.
4. CSM is focused and limited in time and space, whereas GS is in principle unlimited

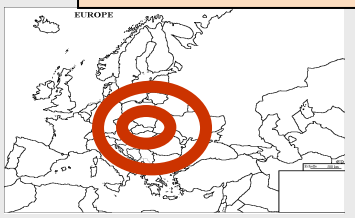
The principles of general surveillance

Largely based on routine observation
(e.g. by existing systems or new questionaires)

- **Proportionate scale, costs, and burden**
- **Environmental exposure as starting point**
  - **risk equation: hazard not known**
  - **differentiation between cultivation and import only dossiers**
- **Protection goals as focus point**

Monitoring responsibility

Where is assistance by risk managers needed?



Impacts at National Levels and evaluation of EU Impacts

Impact at Regional Level

Landscape

Impact at the farm level

Farming system

Crop and management Impacts

Field

Where does the capacity of an applicant end?

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Wider issues to be considered by applicants and risk managers

1. Involvement of CAs
2. Implementation of monitoring
3. Use of existing networks
4. Use of GMO cultivation registers
5. Data reporting and analyses
6. Systems for data reporting and analyses
7. International harmonization

EFSA PMEM Opinion - Chapter 6

Conclusions and recommendations

1. How to use CSM
2. How to implement GS
3. Risk managers working with applicants on specific monitoring measures
4. Considering the interactions of several different GM plants subject to different applications
5. Development of reporting mechanisms and collating monitoring data both at MS and EU level

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GMP PMEM summary