



Scientific evaluations of environmental impact before approval of GM crops





Prof. Dr. Joachim Schiemann

Environmental impact of Bt-maize varieties in Spain

Madrid, 04 December 2007

Joachim Schiemann
Madrid, 04 December 2007
Federal Biological Research Centre for Agriculture and Forestry
Institute for Plant Virology, Microbiology and Biosafety


Agenda


GMO Regulation in the EU

European Food Safety Authority (EFSA)

Environmental Risk Assessment


Opinion on Bt11

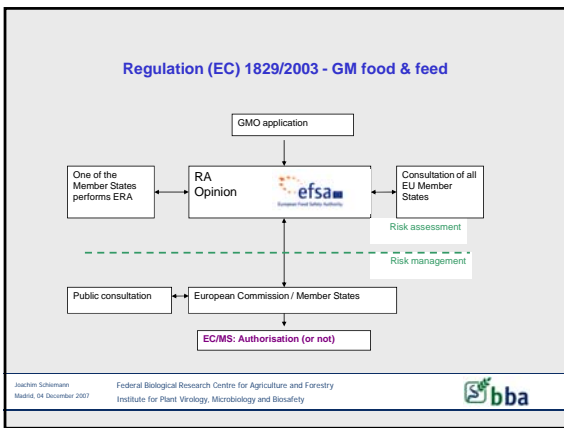
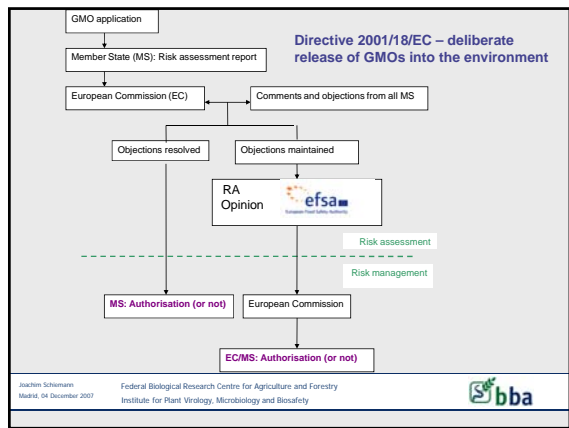
Recent Developments

Joachim Schiemann
Madrid, 04 December 2007
Federal Biological Research Centre for Agriculture and Forestry
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GMO Regulation in the EU

- ➔ **EC-Directive on Deliberate Release of GMOs**
(Directive 2001/18, implemented since 10/02, Adaptation into national laws necessary)
- ➔ **EC-Regulation 1829/2003 on GM Food/Feed**
- ➔ **EC-Regulation 1830/2003 on Labelling and Traceability of GMOs and GM Food/Feed**
(both regulations implemented 4/04, directly binding laws)
- ➔ **EC-Regulation 65/2004 on a System for the Development and Use of unique identifiers for GMOs**

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EFSA in Parma

European Council:
EFSA permanent seat decided on 13/12/2003



EFSA's official seat
Palazzo Ducale



EFSA's operational seat
"DUS" building

EFSA's Mission

Risk assessment
Provision of scientific advice and scientific opinions
Scientific and technical support for the Communities legislation and policies in all fields which have a direct or indirect impact on food and feed safety
Provision of independent information on all matters within these fields

Risk communication
Risk communication related to food and feed safety

Not risk management

Joachim Schiemann
Madrid, 04 December 2007
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EFSA's Credo

Given the known history of accepted use of food crops and their biology,
and the availability of analytical, toxicological, nutritional and environmental assessment tools,
the GMO Panel is of the opinion that an assessment process can be put in place for GM plants and derived food and feed, which provides an internationally accepted level of safety for the consumer, animals and the environment.

Joachim Schiemann
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Scientific Committee and Panels

SC	Scientific Committee
AFC	Food additives, flavourings, processing aids and materials in contact with food
AHAW	Animal health and welfare
BIOHAZ	Biological hazards
CONTAM	Contaminants in the food chain
FEEDAP	Additives and products or substances used in animal feed
GMO	Genetically modified organisms
NDA	Dietetic products, nutrition and allergies
PPR	Plant protection products and their residues
PH	Plant health (since 2006)

Joachim Schiemann
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Guidance Documents

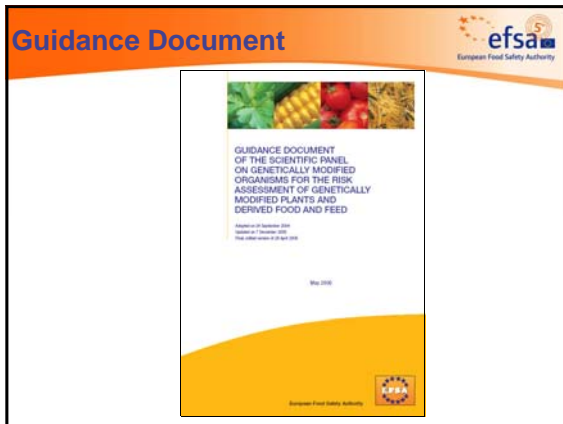
Guidance Documents for Risk Assessment

- GM Plants and derived Food and Feed
- GM Micro-organisms and their derived Products Intended for Food and Feed Uses
- Stacked Genes
- Post Market Environmental Monitoring
- Renewal Dossiers



Guidance Documents under Consideration

- GM Plants for non-Food/Feed Uses
- GM Animals (Food/Feed, Environment)

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Principles of Environmental Risk Assessment

EFSA guidance document
makes use of **previous guidelines developed by SCP**
adopted on **24 September 2004**
updated on **December 2005 (section 11: monitoring)**
updated on **July 2007 (section Annex: Hybrid document)**

EFSA guidelines follow requirements under Regulation (EC)
No. 1829/2003
but following the principles of Directive 2001/18/EC
(Annexes II, III and VII) regarding the deliberate release of
GMOs into the environment (= commercialisation)

Joachim Schiemann
Madrid, 04 December 2007

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Objectives of Environmental Risk Assessment

Identify and characterize potential adverse effects that the
GMO might have on the environment

Assess the magnitude of the consequences of the adverse
effects

Joachim Schiemann
Madrid, 04 December 2007

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Types of Potential Adverse Effects

Direct effects
Impact of Bt toxin on target organisms


Indirect effects ('chain reaction' effects)
Development of herbicide resistance in weeds

Immediate//delayed effects
Death of target pests feeding Bt crops//invasive
behaviour of GM crops after several generations of
cultivation

Cumulative long-term effects

Joachim Schiemann
Madrid, 04 December 2007

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Basis of the Environmental Risk Assessment

The **crop** (maize, oilseed rape, cotton, potato, soybean)
The transgenic **trait** (e.g. PAT, EPSPS, Bt)
The receiving **environment** (EU)
The potential **interactions** between the GM crop and the
environment = essence of ERA
Management/**monitoring** measures

Joachim Schiemann
Madrid, 04 December 2007


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The Crop


Biology of the crop
self/cross-pollination
survival structure(s): seeds
cold/heat sensitivity
dissemination ways (seeds, pollen)
wild relatives in EU
distribution in EU

What is the potential effect(s) on the level of exposure to the environment?

Joachim Schiemann
Madrid, 04 December 2007 Federal Biological Research Centre for Agriculture and Forestry
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The Transgenic Trait


Its specificity in the GM plant:
Changes in metabolic pathways (PAT, EPSPS)
Bio-activity in target organisms (toxicity of Bt proteins)
 Specificity of the toxin (CRY1Ab on Lepidoptera, CRY34/35Ab1 on Coleoptera)

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Madrid, 04 December 2007 Federal Biological Research Centre for Agriculture and Forestry
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Issues to be Considered in the ERA

Persistence/invasiveness of the GMO crop:
The likelihood of the GM plant to become more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats
The likely consequences of this increased persistence to be assessed

Selective advantage and disadvantage
Potential for gene transfer to plants
Considering the biology of the crop/environment/trait
Transfer to cultivated/wild relatives/feral crops
to microorganisms (e.g. soil/gut bacteria)

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Madrid, 04 December 2007 Federal Biological Research Centre for Agriculture and Forestry
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Issues to be Considered in the ERA

Interaction with **target and non-target organisms**
 Laboratory and field data
 Field tests carried out on EU representative species
 Adequate statistical analysis of the data

Effects on **biogeochemical processes** (e.g. soil)

Effects on **human and animal health**

Effects due to changes in **agricultural practices** (for HT crops)

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Madrid, 04 December 2007 Federal Biological Research Centre for Agriculture and Forestry
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Role of EFSA with Regard to PMEM

Risk assessment / risk management

PMEM plan has to be part of the application for market authorization (legislative requirement since 2001)

EFSA to assess GMO applications (since 2003)
 → **import, processing, food/feed use**
 → **cultivation**

EFSA provides opinion and recommendations on the scientific quality of PMEM plans
 → Decision is taken by the risk managers (EU level)


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Madrid, 04 December 2007 Federal Biological Research Centre for Agriculture and Forestry
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Objectives of PMEM

identify unanticipated adverse effects on human and animal health or the environment which could arise directly or indirectly from GM plants

case-specific monitoring (CSM)
 to confirm the assumptions of the environmental risk assessment if scientific evidence that a potential adverse effect is linked to the genetic modification


general surveillance (GS)
 to identify the occurrence of unanticipated adverse effects of GM plants or their use on human and animal health or the environment that were not anticipated in the environmental risk assessment

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EFSA Scientific Colloquium

Environmental Risk Assessment of Genetically Modified Plants - Challenges and Approaches
20-21 June 2007, Tabiano, Parma, Italy


DG 1: Testing non-target organisms;
DG 2: Upscaling;
DG 3: Long-term effects;
DG 4: Broadening the scope of environmental risk assessment (risk-benefit analysis)


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EFSA Opinion Bt11




Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the notification (Reference C/F/96/05.10) for the placing on the market of insect resistant genetically modified Bt11 maize, for cultivation, feed and industrial processing, under Part C of Directive 2001/18/EC from Syngenta Seeds

- Bt11 maize, genetically modified to provide protection against specific lepidopteran pests; the maize also contains a gene providing tolerance to the herbicide glufosinate
- Scientific assessment made initially by the Competent Authority of France and evaluated subsequently by all other Member States
- Assessment of Bt11 maize was requested by the Commission because of questions raised by several Member States following the evaluations at the national level

Joachim Schiemann
Madrid, 04 December 2007 Federal Biological Research Centre for Agriculture and Forestry
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EFSA Opinion Bt11




The scientific assessment included:

- Examination of the DNA inserted into Bt11 maize
- Nature and safety of the newly expressed proteins produced by the transgenic plants with respect to toxicology and allergenicity
- Comparative analysis of agronomic traits and composition
- Safety of the whole product
- Nutritional and an environmental assessment, including monitoring plan

Though the applicant considered that the *pat* gene for HR was a marker gene and would only be used for that purpose, the Panel considered it likely that farmers would grow Bt11 maize with glufosinate herbicide applications. The Panel therefore decided that the environmental risk assessment and the post marketing environmental monitoring should also consider the direct and indirect impacts of the herbicide tolerance trait.


Joachim Schiemann
Madrid, 04 December 2007 Federal Biological Research Centre for Agriculture and Forestry
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EFSA Opinion Bt11 - ERA




Issues raised by the Member States (selected)


- Direct and indirect effects of the Cry1Ab toxin on non-target organisms, specifically soil biota, arthropods, butterflies, and other invertebrates, should be addressed.
- Further data on the effects and persistence of Bt toxin in soil is requested.
- More information on the general surveillance and monitoring of non-target effects is needed.
- Concerns about potential harm to endangered Lepidopteran species are expressed and the possible need to protect endangered butterfly species is emphasised.
- It is recommended that potentially altered lignin contents and the biodegradability of plant litter as well as possible long-term persistence of the Cry1Ab protein should be considered.

Joachim Schiemann
Madrid, 04 December 2007 Federal Biological Research Centre for Agriculture and Forestry
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EFSA Opinion Bt11 - ERA




- No significant risk has been identified in the environmental risk assessment with the exception of resistance development of the target insects, which affects the case-specific monitoring plan.
- Bt11 maize has no altered survival, multiplication or dissemination characteristics except in the presence of glufosinate ammonium. The likelihood of unintended environmental effects due to the establishment and spread of Bt11 maize will be no different from that of traditionally bred maize.
- Judging from the available data delivered either by the applicant or by literature survey, the likelihood of adverse effects on non-target organisms or on soil function is foreseen to be very low.
- The Panel considers that the presence of the *pat* gene and the use of glufosinate ammonium are not likely to give an additional botanical diversity effect compared to other herbicides.

Joachim Schiemann
Madrid, 04 December 2007 Federal Biological Research Centre for Agriculture and Forestry
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EFSA Opinion Bt11



In conclusion, the Panel considers that the information available for Bt11 maize addresses the outstanding questions raised by the Member States and considers that Bt11 maize will not have an adverse effect on human and animal health or the environment in the context of its proposed use.

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Open Letter EFB

**European Federation of Biotechnology
Open letter to Commissioner for the Environment Dimas
Stavros, Nov. 28, 2007**
<http://www.efb-central.org>
- Citations of some paragraphs -

Dear Commissioner Dimas,
The European Federation of Biotechnology, EFB, is very concerned to read about your draft decisions to reject two Bt maize product submissions based on discredited scientific arguments that have not been reviewed by your own independent scientific body, the European Food Safety Authority.


Joachim Schiemann
Madrid, 04 December 2007 Federal Biological Research Centre for Agriculture and Forestry
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Open Letter EFB

Concerning the scientific studies contained in your draft decisions, that claim to demonstrate environmental risks presented by Bt maize, nine out of the eleven publications actually confirm the environmental safety of Bt maize cultivation and in fact do not identify any environmental risk with respect to the cultivation of Bt maize in the EU.

Only two of these publications (Hilbeck et al., 2006, & Rosi-Marshall et al., 2007) allege potential environmental risks; the former being a philosophical approach, rather than scientific data, and the latter is a questionable extrapolation from laboratory tests.


There is no new scientific evidence to contradict the conclusions reached by the GMO Panel of the EFSA on the safety of Bt maize cultivation in the EU. Furthermore, in July 2007, the OECD published a consensus document (<http://www.agbios.com>) on safety information of transgenic plants expressing Bt.

Joachim Schiemann
Madrid, 04 December 2007 Federal Biological Research Centre for Agriculture and Forestry
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Open Letter EFB

Another inconsistency of your draft decisions is that they fail to draw on a substantial body of scientific data accumulated over several years and published in the last 12 months that highlight the economic, environmental and consumer benefits of Bt maize. A total of 63 peer-reviewed publications attest to the fact that Bt toxin does not accumulate in the soil and does not affect aerial and soil-based non-target organisms, on the contrary, there is ample evidence that non-target insects are severely threatened and reduced in their populations by spraying pesticides.

As European scientists we urge you to reconsider and return to a reasoning based on science and experience. The consequences of approving these draft Decisions and the precedents they would set would be the marginalisation of science in Europe, the discrediting of the European Food Safety Authority and the collapse of the EU-livestock industry.

Joachim Schiemann
Madrid, 04 December 2007 Federal Biological Research Centre for Agriculture and Forestry
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Those who want the world to continue as it is, do not want the world to continue

Joachim Schiemann
Madrid, 04 December 2007 Federal Biological Research Centre for Agriculture and Forestry
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