



GM insect regulation in Europe

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EUROPEAN AND MEMBER STATE REGULATIONS

European Union: Directive 2001/18/EC

- GMOs: Plants; Fish; Insects; Mammals and Birds
- Technical and scientific advice to risk managers
 - EFSA is the EU risk assessment body
 - EFSA GMO Panel of independent experts
 - EFSA liaises with Member State authorities
- Decisions by European Commission, based on technical advice and social/economic considerations
 - Political issues influence this level

Directive (EU) 2015/412

- From 2015 some national decisions on GM *plants* allowed

EUROPEAN AND MEMBER STATE REGULATIONS

Member States:

Legislation implementing the Directive 2001/18/EC

- UK example:
 - Environmental Protection Act 1990
 - General provisions for release of organisms
 - Genetically Modified (Deliberate Release) Regulations 2002
 - Detailed national rules for GMO use
- Advisory Committee on Releases into the Environment (ACRE)
 - Independent expert group gives technical and scientific advice
- Department of Environment, Food and Rural Affairs
- Health and Safety Executive

EFSA GIVES GUIDANCE ON DIRECTIVES

Guidance on environmental risk assessment for Directive 2001/18/EC

- **Scientifically sound and transparent process**, based on relevant scientific data
 - Highly structured in accord with technical concerns outlined in the Directive
- **Case-by-case**, considering each GMO individually
- **Compares** characteristics of GMO with potential to cause adverse effects using appropriate comparator(s)
- **Step-by-step**, starting with a robust problem formulation
- **Relevant to diverse insect applications**
- **Consistent across different animals**
- **Genuine guidance** “The Applicant should....”
- Working Group of independent experts



EFSA GM INSECT GUIDANCE

Areas of environmental concern covered

Persistence and invasiveness

• 4.0 pages

Horizontal gene transfer

• 4.5 pages

Pathogens, infections and disease

• 4.5 pages

Target organism effects

• 8.5 pages

Non-target organism effects

• 9.5 pages

Impacts of specific management techniques

• 2.5 pages

Impacts on human and animal welfare

• 4.0 pages



EFSA GM INSECT GUIDANCE

Some significant issues for GM Insect Working Group

- Choice of individual, population or system **comparators**
- Important role of **modelling**
- Implication that **persistence** is a problem
- Limited evidence for **HGT**, except in microbial systems
- **Pathogens** mainly related to rearing and release process, incidental to GM trait
- **Preventative release** is a special case, no Target Organism present
- **Short-term increase** in Target Organism with release
- Difficult keeping **benefits or efficacy separate from risk** when target organism is a noxious pest
- **Quality control** is particularly significant in permanent releases



PUBLIC CONSULTATION PROCESS

EFSA Guidance has a public consultation

- More than 700 comments received on the GM Animal Environmental Risk Assessment Guidance
 - Half from Germany; a third from UK
 - German public institutes and UK NGOs
 - Around 5% from USA and Canada
- 60% of comments were on specific animal chapters
 - Greatest number were on insects
- Some criticism that guidance is too directed
 - Policy by the back door?
- Some criticism of the consultation process
 - Duration and timing
 - Complexity of issues



PUBLIC CONSULTATION PROCESS

Comments and Response to public consultation

■ General comments

- EFSA competence and remit
- Member State authorities welcomed the Guidance
- Detail obscures the message in places
- More consistent terminology needed, less repetition, clearer scope for each section

■ Specific comments on insect section

- Request for more references
- Concern about accidental ingestion of GM insects

■ Response

- Editorial and technical improvement
- Agreement that risk-benefit assessment, socio-economics and ethics were out of EFSA remit
- Comments summarised and all comments listed in report on EFSA website



EUROPEAN GMO APPROVAL PROCESS

Technical, risk-driven system from EFSA advises European Commission and Member States

- **Rigorous and technically demanding** process
 - Difficult for smaller companies
- Risk benefit and ethical issues are **outside the EFSA mandate**
 - Normative values dealt with at political levels
- **Transboundary concerns** influence all of Europe
- **No GM insect applications** for field release have been formally made
- **Some national discretion** on GM plants already in place
 - Maybe some extension to GM insects in future



EFSA GM INSECT ERA GUIDANCE WORKING GROUP

Independent technical experts and EFSA GMO Unit

- Jeffrey Bale, Romeo Bellini, Michael Bonsall, George Christophides, Patrick du Jardin, Achim Gathmann, Marc Kenis, Jozsef Kiss, Esther Kok, Anna Malacrida, John Mumford, Kaare Magne Nielsen, Steve Sait, Jeremy Sweet
- Yann Devos, Christina Ehlert, Yi Liu, Sylvie Mestdagh, Nancy Podevin, Stefano Rodighiero, Elisabeth Waigmann

<http://www.efsa.europa.eu/en/efsajournal/pub/3200.htm>

<http://www.efsa.europa.eu/en/supporting/pub/428e>