GM insect regulation in Europe

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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
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
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
### Areas of environmental concern covered

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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
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
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
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
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