GMOs – a risk communication from a regulatory perspective

Professor Tony Hardy
Central Science Laboratory
York, UK

JIFSAN June 13 2003
GM Situation in Europe 2003

Legislation

◆ Deliberate Release of GMOs to environment
◆ **Directive 90/220/EEC**
◆ 14 GM plants approved for commercialisation
  maize (4), osr (4), carnation (3), chicory (1), soybean (1), tobacco (1)
◆ None since October 1998
◆ Products derived from GMOs covered by
  Regulation on Novel Foods and Novel Food Ingredients (Regulation (EC) 258/97)
◆ Contained use of GMMs regulated for research
  and industrial use (Directive 98/81/EC)
GM Situation in Europe 2003

- Scientific Committee on Plants (SCP)
- 13 favourable RA s
- maize/sweet maize (5), osr (3), cotton (2), chicory (1), fodder beet (1), potato (1)

32 GMO opinions – on the internet
- 19 specific GM dossiers
- 3 GM micro-organisms
- 5 guidance documents
- 8 ‘Article 16’ opinions

By January 2003
**GM Situation in Europe 2003**

**Legislation**

- Updated Directive on deliberate release
  
  **Directive 2001/18/EC**

- October 17 2002, target date for local legislation in Member States

- 19 submitted dossiers – osr (5), maize (7), sugar beet (2), fodder beet (1), soybean (1), cotton (2), potato (1) (significant increase in GM plants with stacked traits)

**Mandatory information to the public**

**Mandatory post-market monitoring**

**Labelling and traceability requirements**

10 year approval then review
Risk Cycle
(SSC 2000)

Identification of concerns
Formulation of risk management questions

Human health and/or environment
RISK ASSESSMENT
Hazard identification
Hazard characterisation
Exposure assessment
Risk characterisation
Consolidated risk conclusions

RISK MANAGEMENT DECISION
Option selection
Regulatory/other control measures

Monitoring/surveillance
Implementation

Review

Cost/benefits
perception

RISK COMMUNICATION
Risk Communication

DG SANCO

- Scientific Committee on Plants (SCP)
- Scientific Steering Committee (SSC)

Opinions on internet
Guidelines for GM risk assessment
Q & A brief on the regulation of GMOs in the EU

DG JRC (Joint Research Centre, Ispra, Italy)

On internet - SNIF (Summary Notification Information Format) EU database of GMO field trials
Review of GMOs under R&D and in the pipeline in Europe
Current GM situation in Europe 2003

◆ ‘unofficial’ Moratorium
No new GMOs authorised for release into the environment since October 1998 pending new regulations. 6 Member States (Austria, France, Germany, Italy, Greece and Luxembourg) banned import and cultivation of some approved GM crops.

◆ New EU legislation

◆ Proposed new EU legislation
Labelling and traceability (to be approved ?July 2003). The 6 Member States have agreed to lift their bans when legislation in place.
GM labelling and traceability

- Since 1997 mandatory labelling of GMO presence as such or in product
- Additives and flavourings if DNA/protein of GMO origin is present in final product
- No requirements to label GM feed

Proposals leading to

- Harmonised system to trace GMOs
- Labelling of GM feed
- All GM food/feed to be labelled irrespective of detectability of GM DNA or protein
- Streamlined authorisation for GMOs in food, feed and deliberate release to the environment
European Food Safety Authority

- Set up under Regulation (January 2002), established 2003
- Aims:
  - Scientific evaluation of risks
  - Collection and analysis of scientific data
  - Safety evaluations of dossiers for Community level approval
  - Identification of emerging risks
  - Scientific support to the Commission particularly in the case of a food safety crisis

Direct risk communication to the public and other interested parties

- Responsibility for risk management or decision making remains with EU’s political institutions: the European Commission, the Council of EU Ministers and the EU Parliament.
EFSA – the Institutions

- The Management Board – independent control, not national representatives
- Executive Director (Geoffrey Podger, ex-Chief Executive of UK FSA)
- The Scientific Committee and 8 Risk Assessment Panels (160 independently appointed scientists)
- The Advisory Forum – network of National Food Authorities of Member States
- The staff of EFSA – scientific (permanent and seconded from national regulatory authorities and institutes)
EFSA Scientific Panels

- Scientific Committee
- Food additives, flavourings, processing aids and materials in contact with food
- Additives and products or substances used in animal feed
- Plant health, plant protection products and their residues
- **Genetically modified organisms**
- Dietetic products, nutrition and allergies
- Biological hazards
- Contaminants in the food chain
- Animal health and welfare
EFSA’s role in Risk Communication

- Independent of political process
- Open and transparent
- Co-ordination with national food safety and regulatory authorities
- Support to the Commission over food ‘scares’/emergencies

Europe-wide reference service largely via website (www.efsa.eu.int)
- Timely and accurate public announcements on key EU-wide food safety issues
- Close co-ordination of communications with Member States
GMOs in Europe – re-engaging

Commission
Aims to get the ‘Moratorium’ lifted
Revised Directive and local Member State legislation in place
2 legislative proposals (July 2001) provide framework of labelling and traceability, include food and feed.
6 Member States lift their bans?

DG Research – open Research Roundtables, Consensus workshops for stakeholders
Consumer Organisations (e.g. Bureau Europeen des Unions de Consommateurs) Consensus Workshops
EU roadmap if re-engaged?

- GM crops unlikely to be > 10% arable farming by 2008
- 2 / 3 years before GM maize seed available
- 3 / 4 years before GM osr and sugar beet available
- GM wheat seed not marketed until 2010?
- By 2013, GM wheat and potato crops < 10% area
- By 2013, GM osr, sugar beet and maize may be 40-50% of area

GMOs in the UK – re-engaging

◆ Farm Scale Evaluation Trials
3 year programme to study environmental impact of herbicide applications to GM Herbicide Tolerant crops – osr (spring and winter), beet (sugar and fodder), maize. Results to ACRE.

Peer-reviewed publication of results late 2003 (spring sown) and 2004 (winter sown).

◆ Agriculture and Environment Biotechnology Commission

Technical workshops, consultations
GMOs in the UK – the big debate

Government responsibilities to fulfill and decisions to be taken against background of:

- Existing public attitudes to GM, to the potential impacts of GM and to institutions involved in promoting and regulating GM technology
- The ethical, social and environmental implications of GM
- Scientific evidence on the impacts of GM
- Economic analysis of the costs and benefits associated with GM applications
- The wider international context, including the legal and regulatory framework at the EU and international level
UK GM public debate 2003

Aim
Promote innovative, effective and deliberative programme of debate on GM issues, framed by the public, against the background of possible commercial production of GM crops in the UK and options for possibly proceeding with this. Through the debate, provide meaningful information to Government about the nature and spectrum of the public’s views, particularly at grass roots level, to inform decision-making.
GMOs in UK – re-engaging

- GM Dialogue – the different strands
  - Independently run Public Debate
    
    GM Nation? The public debate (regional meetings, website)

- Science Review
  

- Costs and Benefits Study
  
  The PM’s Strategy Unit analysis of different commercial scenarios of GM crops in the UK – (June 2003) website
GM Issues for European consumer

- Lack of confidence in regulatory control
- Lack of consumer benefits from first generation GM crops
- Choice
- Proximity and environmental spatial mosaic of cropped and non-cropped areas
- Co-existence of agricultural systems (GM, conventional and organic)
- Liability
- Post-marketing monitoring
‘Although we’re not sure, a small percentage of North American cattle probably have BSE and people could develop vCJD from eating them. But the risk is low, and you are better off worrying about something else – *E.coli*, for instance, or cholesterol.’

New Scientist
Key websites

- [http://europa.eu.int/comm/food/fs/sc/scp/index_en.html](http://europa.eu.int/comm/food/fs/sc/scp/index_en.html) SCP (opinions)
- [http://gmoinfo.jrc.it](http://gmoinfo.jrc.it) JRC (EU GMOs)
- [www.efsa.eu.int](http://www.efsa.eu.int) EFSA
- [http://europa.eu.int/comm/food/fs/gmo/gmo_index_en.html](http://europa.eu.int/comm/food/fs/gmo/gmo_index_en.html) EU GMOs
- [http://www.gmpublicdebate.org.uk](http://www.gmpublicdebate.org.uk) UK debate
- [http://www.gmsciencedebate.org.uk](http://www.gmsciencedebate.org.uk) UK science
- [http://europa.eu.int/comm/research/biosociety/index_en.html](http://europa.eu.int/comm/research/biosociety/index_en.html) EU GMOs
- [http://defra.gov.uk/environment/gm/index.htm](http://defra.gov.uk/environment/gm/index.htm) UK GMOs