Regulatory risk assessment of GMOs in the EU: where science, lobbying and politics meet

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Consumer awareness of risks related to food/feed:

- The consumer is *obviously aware* of the risk (avian influenza, Salmonella, BSE, saturated fatty acids);
- The consumer *may be aware* of the risk (dioxin, PCBs, methylmercury in fish);
- The consumer is *probably unaware* of the risk (‘organic’ food, natural toxins, botanical preparations);
- The consumer *has an opinion* on the risk (radiation, chemicals, GMOs).
Be careful with consumer opinions!

“Should the use of dihydrogen monoxide be banned or at least restricted in the EU?“

OK EVERYBODY—LISTEN CAREFULLY!
HERE’S THE PLAN... WE ALL PRETEND TO BE HARMLESS FOR A FEW YEARS, AND THEN WHEN THEY RELEASE US INTO THE ENVIRONMENT—WE GO WILD!
ANY QUESTIONS?..?
What is the relationship between risk assessors and risk managers?
## Regulatory authorities: risk assessors and risk managers

<table>
<thead>
<tr>
<th>Risk assessors</th>
<th>Risk managers</th>
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<tr>
<td>● Taking into account: science only;</td>
<td>● Taking into account: the risk assessed;</td>
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<td>● Evaluating <strong>all</strong> evidence;</td>
<td>● Consider social, economical, political and cultural aspects;</td>
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<td>● Consider the strength of the evidence;</td>
<td>● Making management decisions;</td>
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<td>● Providing options to RM;</td>
<td>● Communicate the management decisions.</td>
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<td>● Communicate risks.</td>
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Regulatory risk assessment authorities

- Risk assessment should not be influenced by risk management options;
- Risk assessors should have up-to-date knowledge of new scientific developments in the field;
- Risk assessors should have access to expert advisors;
- Risk assessors should be unbiased and not involved in risk management and certainly not in decisionmaking.
The EU situation today

● Regulatory RA at **national level** is hardly transparent and often interwoven with political elements: not clearly separated from RM;

● Regulatory RA at **EU and international level** has become increasingly more independent from RM, is generally unbiased and of high scientific quality.
The EU EFSA GMO Panel’s joint expertise:

- Biochemistry,
- Food and environmental microbiology,
- Molecular biology,
- Genetics, toxicology,
- Animal pathology,
- Immunology,
- Biotechnology,
- Food technology,
- Ecology, plant biology and agronomy.
GMO Panel: assistance

- Assisted by experts from other panels and *ad hoc* experts on a case by case basis
  - e.g. nutrition, pesticides, natural toxins, animal feed, biometrics, environmental monitoring…
- Networking with national GMO risk assessment bodies (e.g., Netherlands, Spain, UK);
- Scientific support from GMO Unit staff;
- Panel working groups.
GMO panel: working groups

- 3 permanent working groups to deal with marketing applications:
  - Molecular characterisation
  - Food&feed safety (comparative analysis, toxicology, allergenicity, nutrition)
  - Environmental risk assessment
- *ad hoc* working groups to deal with specific issues
International Risk Assessment Strategies for GMO’s

- OECD Task Force on the Safety of Novel Foods and Feed, 1998-present
- Codex Task Force on Foods Derived from Biotechnology, 1999-present
- EU Scientific Committees, 1996-2003; Joint Working Group on Novel Foods and GMOs
- ENTRANSFOOD, the EU Thematic Network on the Safety Assessment of Genetically Modified Food Crops, 2000-2003
EFSA Guidance Documents for the risk assessment of GMO’s

- GD for risk assessment of GM plants containing stacked transformation events. May 2007;
- GD for the renewal of authorisations of existing GMO products. December 2006;
- GD for the risk assessment of GM microorganisms and their derived products intended for food and feed use. May 2006;
- GD for the risk assessment of GM plants and their derived products intended for food and feed use. April 2004
Requests for Scientific opinions

- General questions from the Commission
  - e.g., invocation of safeguard clause by MS, assessment of the impact of new data on earlier adopted opinions

- Self tasking
  - e.g., assessment of new scientific developments

- Legislative requirements
  - e.g., authorizations, guidance document for the application of Regulation 1829/2003 (preparation and presentation of dossiers)
Examples of Self Tasks

- Biosafety of antibiotic resistance marker genes;
- Post-market environmental and human/animal health monitoring of GM crops;
- Allergenicity assessment approaches: new scientific developments;
- Impact of GMOs on microbial biodiversity and function in the soil environment;
- Long-term environmental effects: new scientific developments;
- The use of animal feeding trials for the safety evaluation of whole GM foods/feed.
Requests for Scientific opinions

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EU GMO Regulations for Authorization

- **Directive 2001/18/EC**: deliberate release of GMOs in the environment (e.g. GM oilseed rape GT73 and GM maize NK603, MON 863, MON 863 x MON 810, 1507 and Bt11)

- **Regulation (EC) 1829/2003**: GMO’s in food & feed (e.g. GM maize NK603 x MON810, 1507, MON 863 x MON 810 and GM rice LLRICE62)
Applications under 2001/18/EC

- Applicant submits dossier in Member State of choice;
- Initial assessment by lead Member State;
- Subsequent evaluation by 26 Member States;
- If outstanding issues or objections of scientific nature, EFSA will develop an opinion;
- EFSA should provide its opinion within 90 days.
Community Authorisation Procedure

Notifier
National Competent Authority
European Commission & member states & public

application with dossier
favourable opinion

no objections: marketing approval

EFSA assessment
European Commission
Regulatory Committee

unfavourable opinion

Council of Ministers
European Commission

objections
opinion
draft decision
favourable opinion
decision

procedure 90/220;2001/18
Applications under Regulation (EC) 1829/2003

- Risk assessment under responsibility of EFSA;
- Covers food and feed produced from a GMO, GM additives, flavourings, enzymes;
- Not products from animals fed GM feed;
- Post-market monitoring may be required for GM foods and for GM feed where appropriate;
- Methods for sampling, identification and detection of GM food and feed should be provided by the applicant;
- Methods should be validated by the Community Reference Laboratory;
Applications under Regulation (EC) 1829/2003

- Register of authorised GM food and feed should be established by Commission, including product specifications, evidence for safety, methods for sampling and detection;
- The European Food Safety Authority shall publish detailed guidance to assist the applicant in the preparation and presentation of the dossier;
- A time limit of six months is respected by the Authority for providing its opinion; this limit may be extended when supplementary information is requested.
**Tasks for EFSA under 1829/2003**

- Informing all Member States and the European Commission when a new/transformed application has been submitted to EFSA;
- Making a summary of each application available to the public;
- Carrying out a completeness check of the dossier;
- make the valid application available to the MS’s, EC and GMO Panel;
Tasks for EFSA under 1829/2003

- carry out the risk assessment;
- delegation of (part of) risk assessment to a national body (90 days):
  - optional in case of food and feed products
  - obligatory in case of seeds or plant propagating material (environmental risk assessment).
- consult the competent authorities (for 2001/18/EC);
- forward its opinion, including a report, to the EC, the MS’s and the applicant;
- make its opinion available to the public.
Risk Assessment of GMO’s

- EU regulatory assessors have adopted a case-by-case approach, based on ‘comparative assessment’;

- Essential elements of the risk assessment are:
  - Compositional analysis;
  - Molecular characterisation (DNA sequence, genetic stability);
  - Substantial equivalence;
  - Toxicity, allergenicity, environmental assessment;
A fully integrated and iterative risk assessment approach of a new GM variety

- Parent Crop
  - Identity, Phenotypic & Agronomic Performance
  - Geographical Distribution
  - History of Safe Use
  - Compositional Analysis
- Donor, Transgene(s) and Delivery Process
  - Description of Donor
  - Description of Vector DNA
  - Transgene Delivery Process
  - Characterisation of Introduced DNA
  - Characterisation of Insertion Site
- Characterisation of Gene Product(s)
  - Structure, Identity and Characterisation
  - Mode of Action/Specificity
  - Toxicity
- Safety Assessment of New GM Crop/Food
  - Identity, Phenotypic & Agronomic Performance
  - Compositional Analysis
  - Nutritional Analysis
  - Safety Analysis: HH & E (Animal Studies)

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Risk Assessment of GMO’s

- Risk managers increasingly require the 90-day toxicity study being under political pressure from NGO’s;
- A 90-day study will only be sensible if the GMO can be fed at high concentrations;
- Testing the genetic insert (trait) is not appropriate;
- 90-day study requires at least 80 animals;
- Requiring such a study means buying time and postpone the decision-making.
Food Biotechnology: (GMO, transgenesis, cisgenesis)

• Human health concern?
• Environmental concern?
Food Biotechnology

• Genetic modification: a curse and a blessing
• Very much a political discussion: science and technology are ready to push applications!
• Consumer perception: science-oriented or a ‘religion’?
Environmental Risk Assessment of GMO’s

- Today it is still not fully clear what constitutes an environmental assessment;

- Essential elements of the environmental risk assessment currently include:
  - Toxicity to aquatic, terrestrial and sediment species including non-target species (e.g., sediment dwelling organisms, terrestrial insects);
  - Genetic stability of the trait/insert;
  - ‘Long-term’ environmental effects;
  - Environmental impact assessment (e.g. biodivergency, landscape diversity).
Food Biotechnology: Traceability

labelling

Trans-parency

Consumers choice

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Food Biotechnology: the future?

• Helping to secure our future food supply by investment in new (GM) plant varieties and micro-organisms:
  – growing on arid land;
  – growing on brackish soils;
  – growing on otherwise useless substrates;
  – producing more and different nutrients (in particular proteins);
  – assisting in biodegradation of waste;
  – but also....
Food Biotechnology: the future?

- Minimising the competition between crops for fuel and crops for food by developing new non-edible and fast-growing (GM) plant varieties and micro-organisms with:
  - a high biomass and/or high energy efficiency rate;
  - a high oil content (e.g., Sencio jacobaea)
  - a high lignin content.

- Investing in transparency: perception is the truth!
“Aim higher and wider”

Motto of the 11th World Scouts Jamboree, Marathon, Greece, 1963