Principles of Risk Assessment in the EU Legislative Framework

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EFSA Consultative Workshop
Selection of comparators for the RA of GM plants
31 March 2011, Brussels
Directive 2001/18
Deliberate release of GMOs

CULTIVATION

Import & processing

ENVI
Risk
Regulation 1829/2003
Integrated approach of the Food/Feed chain
Environmental Risk Assessment
Annex II of Directive 2001/18
Decision 2002/623/EC
Environmental Risk Assessment
Objective

To identify & evaluate potential adverse effects [...] with a view to identifying if there is a need for risk management
Environmental Risk Assessment
General Principles

✔ Compare characteristics & use with non-GM
  => definition of a baseline

✔ Scientifically sound:
  ➢ Data based on Common methodology
  ➢ Associated uncertainty

✔ Case by case basis

✔ Take into account new information
# Environmental Risk Assessment Methodology

## Diagram 1: The six steps in the analysis of ERA

1. **Step 1:** Identification of characteristics which may cause adverse effects

2. **Step 2:** Evaluation of the potential consequences of each adverse effect, if it occurs

3. **Step 3:** Evaluation of the likelihood of the occurrence of each identified potential adverse effect

4. **Step 4:** Estimation of the risk posed by each identified characteristic of the GMO(s)

5. **Step 5:** Application of management strategies for risks from the deliberate release or marketing of GMO(s)

6. **Step 6:** Determination of the overall risk of the GMO(s)
Environmental risk assessment
Conclusions

✓ 9 points to be addressed

➢ Persistence/Invasiveness/gene transfer
➢ Target/Non-target organisms/Biogeochemical processes
➢ Human & Animal health
Food/Feed Safety Assessment
Regulation on GM food/feed

✅ Food/Feed must NOT
➢ have adverse effects
➢ mislead the consumer
➢ differ in a way that would be nutritionally disadvantageous
Conventional counterpart

Definition

A similar food or feed produced without the help of genetic modification and for which there is a well-established history of safe use.
Strategy of GM Food and Feed safety assessment

- Non GM

- GM

Modification(s):
- Intended
- Non intended

No modification
Strategy of safety assessment

Conventional counterpart
- History of safe use
- Known characteristics

Comparative analysis
- Phenotypic
- Composition

Molecular characterisation
- DNA
- Proteins

No modification

Unintended Modification(s)

Intended Modification(s)

Toxicity

Nutrition

Allergenicity

Exposure assessment

Risk characterization (Conclusion)

Tests with whole food/feed
Consumer information
Labelling

- In all cases: “genetically modified”
- In addition, when GM is different from conventional counterpart as regards:
  - Composition
  - Nutritional value or nutritional effects
  - Intended use of the food
  - Implications for the health of certain sections of the population
Adoption of additional rules through comitology

For Food/Feed (2011) & ERA (2012)

- More detailed requirements (e.g. inclusion of protocols)
- Increase the sense of ownership of Member States
- Improve the scientific and legal certainty
CCL: A comprehensive Risk Assessment Framework

- Council & Parliament
- Co-decision
- Comitology
- Public consultations
- EFSA
- Commission
Thank you!