

EU and GMOs

Role of EFSA

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Chair EFSA GMO Panel

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European Food Safety Authority (EFSA) Established in 2003

EFSA

- Structure:
 - Executive director
 - Management Board
 - Advisory forum
 - Scientific committee and panels
 - 10 Scientific Panels
- Independent, e.g. from European Commission (EC)
- Advice to EC and Member States
- Risk Assessment, not Risk Management



Parma

Illustration: The best of Parma

<http://www.efsa.europa.eu>

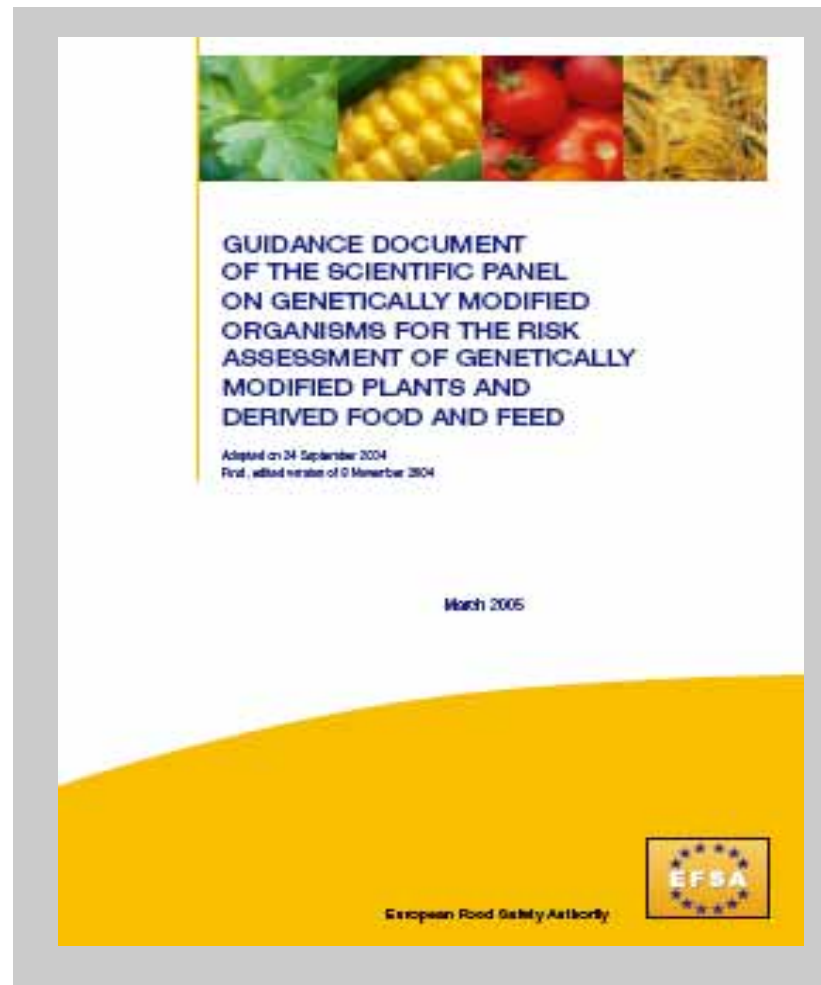
EFSA Scientific Panel on GMOs

- Structure
 - Chair, 21 permanent (3 years) members
 - Working Groups (mix of permanent and *ad-hoc* members)
- Tasks
 - Scientific opinions on dossier applications
 - **under Regulation 1829/2003**
 - **under Directive 2001/18/EC**
 - Guidance for the legal framework
 - Response to questions
 - European Commission
 - Member States, other authorities
 - Members Europarlament
 - Self-tasking

Guidance Documents Designed by the GMO Panel

- **Guidance for the risk assessment of GM plants and derived food and feed**
 - **Transfer of EFSA guidance into EC Guidelines**
 - **Ownership Member States**
- **Guidance on Post Market Environmental Monitoring**
- **Guidance for the risk assessment of GM microorganisms for food and feed use**
- **Guidance for the renewal of existing products**
- **Guidance for stacked events**
- **Guidance for the risk assessment of GM plants used for non-food/ feed purposes**
- **Guidance for GM animals (ongoing)**

EFSA Guidance document for GM Plants and derived Food and Feed



<http://www.efsa.europa.eu>

Self Tasking Activities

- Use of antibiotic marker genes in GM plants (2004, 2007, 2009)
- Guidance for post-market environmental monitoring (2005)
- New approaches for the allergenicity assessment (ongoing)
- Safety and nutritional assessment of GM plant derived food/feed – the role of animal feeding trials (report March 2008 Food & Chemical Toxicology)
- Statistical approaches in comparative assessment of GMOs (ongoing)
- Environmental Risk Assessment (Non-target organisms)

Comparative Safety Assessment Approach for GMOs

Underlying assumption:

- Traditionally cultivated crops have a history of safe use for the environment/ consumer/animals
- These crops can therefore serve as a *baseline* for the environmental and food/ feed safety assessment of GM crops

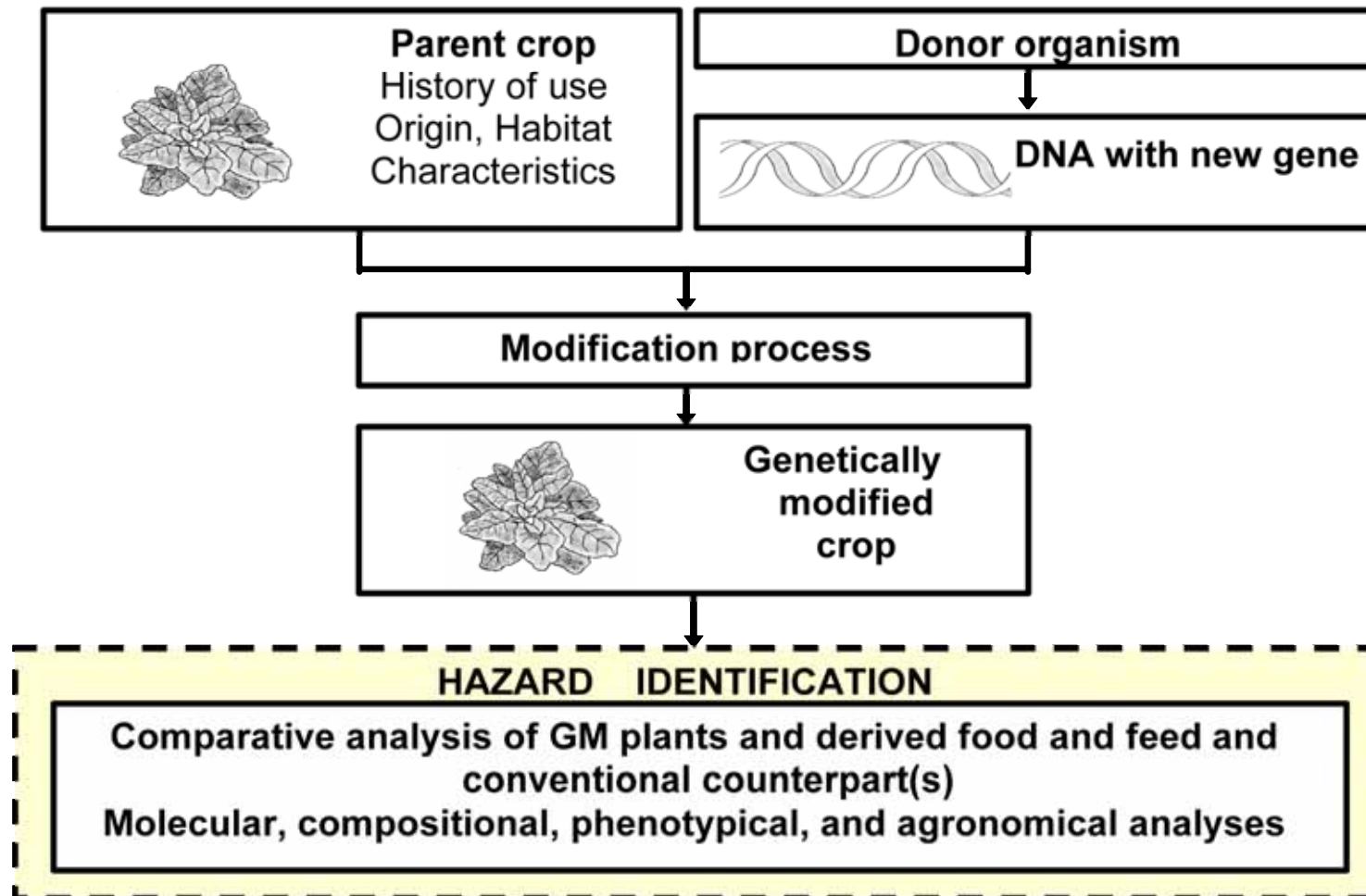
Safety Assessment Strategy for GM Crops: Two-step Procedure

1. Identification of differences between the GM and non-GM crop
2. Assessment of the environmental and/or food/feed safety and nutritional impact of identified differences
 - *Concept of Familiarity*
 - *Concept of Substantial Equivalence*
 - *Comparative Safety Assessment*

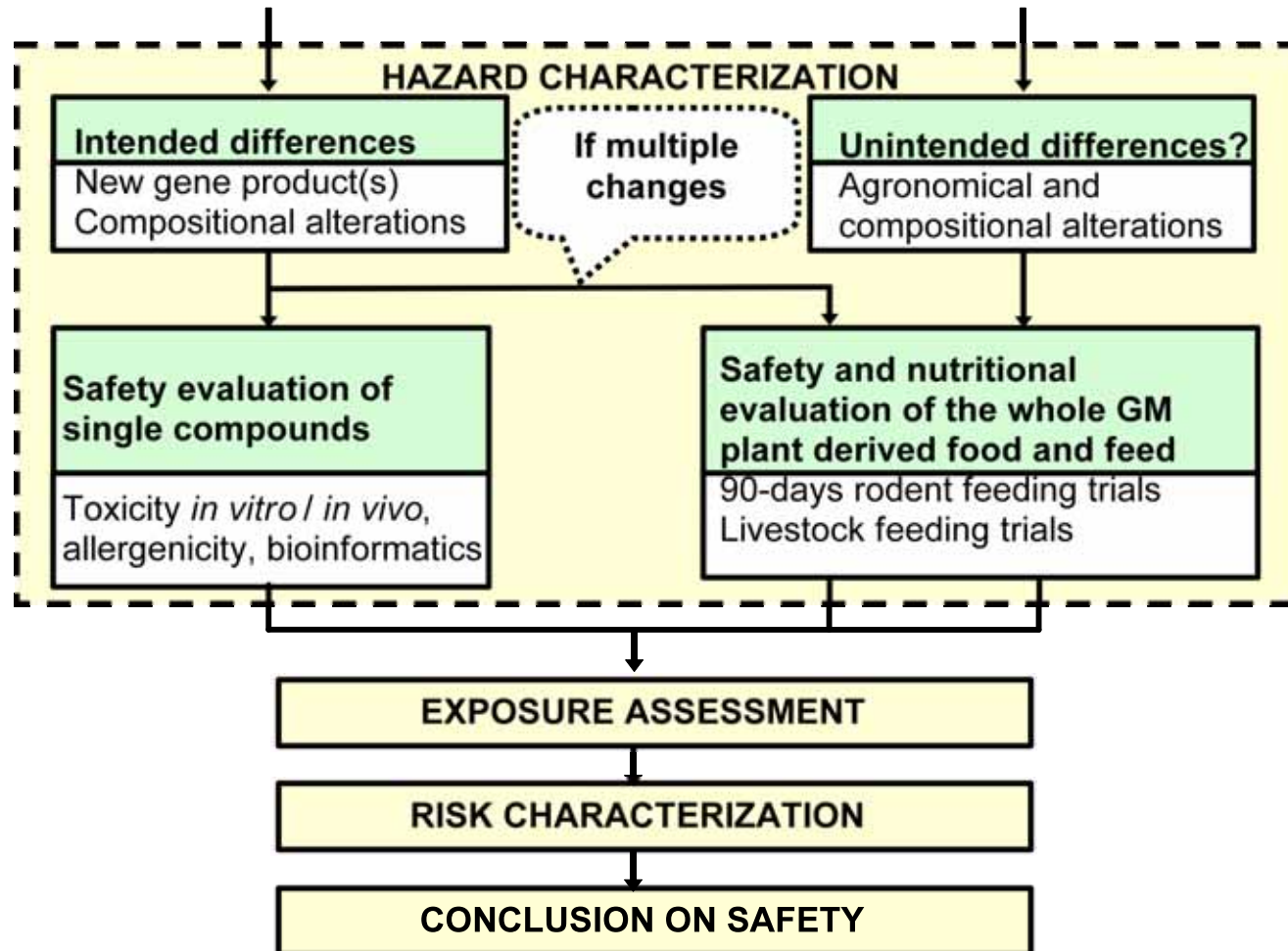
Principles for Environmental Risk Assessment of GMOs (Dir 2001/18)

- Characteristics of GMOs
 - parent organism
 - genetic modification
 - intended release and scaling
 - selective advantage
 - receiving environment
- Identification of adverse effects (immediate/delayed) on humans, animals and the environment
- Effects on dynamics of populations and genetic diversity
- Potential environmental impact:
 - Interactions between GM plant and (non)target organisms
 - Interactions of the GM plant with the biotic and abiotic environment
 - Potential for gene transfer

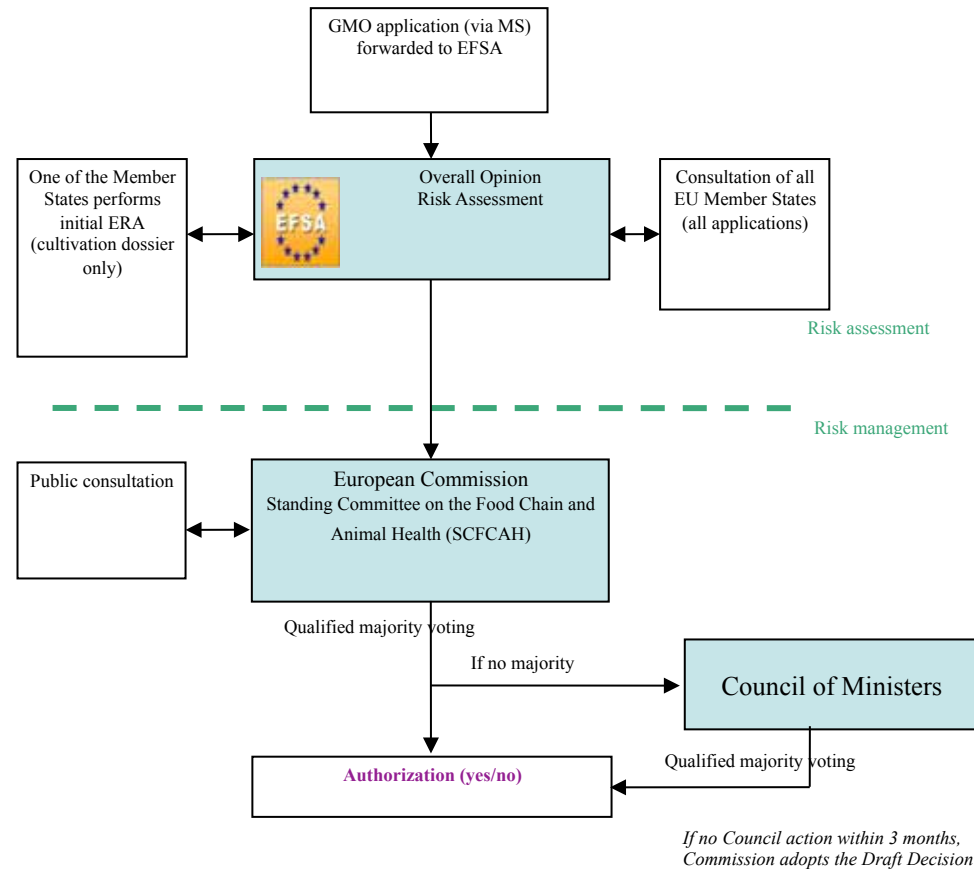
Safety and Nutritional Assessment of GM Plant Derived Food and Feed -1



Safety and Nutritional Assessment of GM Plant Derived Food and Feed - 2



EU Regulatory Framework for GMOs under EC 1829/2003



Conclusions/suggestions

- Robust framework designed by EFSA for risk assessment for GMOs in line with FAO/WHO, OECD
- EFSA GMO Opinions are detailed case-by-case risk assessments
- Overshoot in data requirements for risk assessment of GMOs compared with other novel foods
- Deadlock in market authorizations: never qualified majorities/minorities in voting by the Standing Committee/Council of Ministers
- Regulatory EU system is too complicated and not science driven, with Member States representing national (political) views

Conclusions

- EFSA Guidance transformed into EC Guidelines, the solution??
 - Legal basis
 - Ownership Member States
- Also other considerations like public attitudes, national politics considerations, labelling, co-existence etc. No weighing/prioritizing of the arguments
- Assessment and communication on risks and benefits
- Need for GMOs with positive functional/health claims (scientific evidence?)
- More balance in scientific approaches for the different novel food types, build up experience, and focus on product characteristics