

Food Safety, Risk Assessment & Risk Management of GMOs for Food and Field Release EU Laws Regulating this Area

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EU Response to the Need to Guarantee High Level of Food Safety

- Food scares (BSE, dioxins, birdspest) have led to a decrease in public trust
- Concerns about the release of GMOs and market introduction of GM food/feed
- Regulation 178/2002: General principles and requirements of food law, establishing the EFSA and procedures in food safety matters

Regulation EC 178/2002 Laying down the general principles and requirements of food law

- Common European framework of concepts, principles and procedures for food and feed production and risk analysis
- Entire food and feed chain is taken as a continuum
- High level of health protection through appropriate and harmonised risk analysis procedures
- Include societal, economic, ethical factors in risk management
- Regain public trust in the European food supply

EU Legislation GM Organisms

- **‘Genetically Modified Organism’** : Organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination
- **Directive 90/219**: contained use of GMOs,
- **Directive 2001/18 (replaces 90/220)**: field testing, environmental- and market release, import/processing viable GMOs, animal feed applications
- **Novel Food Regulation 258/97**
market release of novel foods, including GMOs

Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (1)

- Case by case environmental risk assessment prior to any release
- Assessment of potential cumulative long-term effects
- Establish common methodology to carry out the environmental risk assessment (e.r.a.)
- Precautionary principle must be taken into account
- Introduction of GMOs in the environment follows a 'step by step' procedure: scale of release is gradually increased
- No GMOs will be placed on the market without first satisfactory field testing in the research and development stage

Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (2)

- Use of those antibiotic marker genes phased out which may have adverse effects on human health and the environment (by Dec. 2004)
- Public consultation *mandatory*, and a requirement for public registration of releases
- Ethical considerations may be taken into account by Member States

New Elements Directive 2001/18/EC

- 10 Year limit on the length of market consents
- Defined time periods when considering consent applications
- Monitoring plan required:
 - to confirm assumptions about occurrence of adverse effects made in risk assessment
 - to identify the occurrence of adverse effects which were not anticipated
- New traceability requirements
- Consultation of Scientific Committees is *mandatory*
- Existing consents under 90/220 have to be renewed after a transition period

New Elements Directive 2001/18/EC

- Requirement for the Commission to report on the socio-economic advantages and disadvantages of GMOs which have been authorised for placing on the market
- European Group on Ethics in Science and New Technologies should be consulted on issues of general nature

Principles for Environmental Risk Assessment of GMOs (Annex II and III 2001/18)

- Comparative e.r.a. for GMOs
- Characteristics of GMOs
 - parent organism
 - genetic modification
 - intended release and scaling
 - selective advantage
 - receiving environment
- Identification adverse effects (immediate/delayed) on humans, animals and the environment
- Effects on dynamics of populations and genetic diversity

Monitoring Plan (Annex VII)

- Objective:
 - confirm environmental risk assessment
 - identify not anticipated adverse effects
- Further assessment of environmental changes
- Detailed monitoring plan, incorporating general surveillance
- Identify who is responsible and will carry out the monitoring

Guidance document



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

GUIDANCE DOCUMENT

FOR THE RISK ASSESSMENT OF GENETICALLY MODIFIED PLANTS
AND DERIVED FOOD AND FEED

6-7 MARCH 2003

Prepared for the Scientific Steering Committee by

The Joint Working Group on Novel Foods and GMOs

Composed of members of the Scientific Committees on
Plants, Food and Animal Nutrition

EC Scientific Committee on Plants

Mandate: 1997 - 2000; 2000 - 2003:

Scientific and technical questions relating to plants intended for human or animal consumption, production or processing of non-food products as regards characteristics liable to affect human or animal health or in the environment, including the use of pesticides.

Plant protection products (91/414/EEC)

Genetically Modified Organisms (90/220/EEC, 2001/18/EC)

SCP Achievements

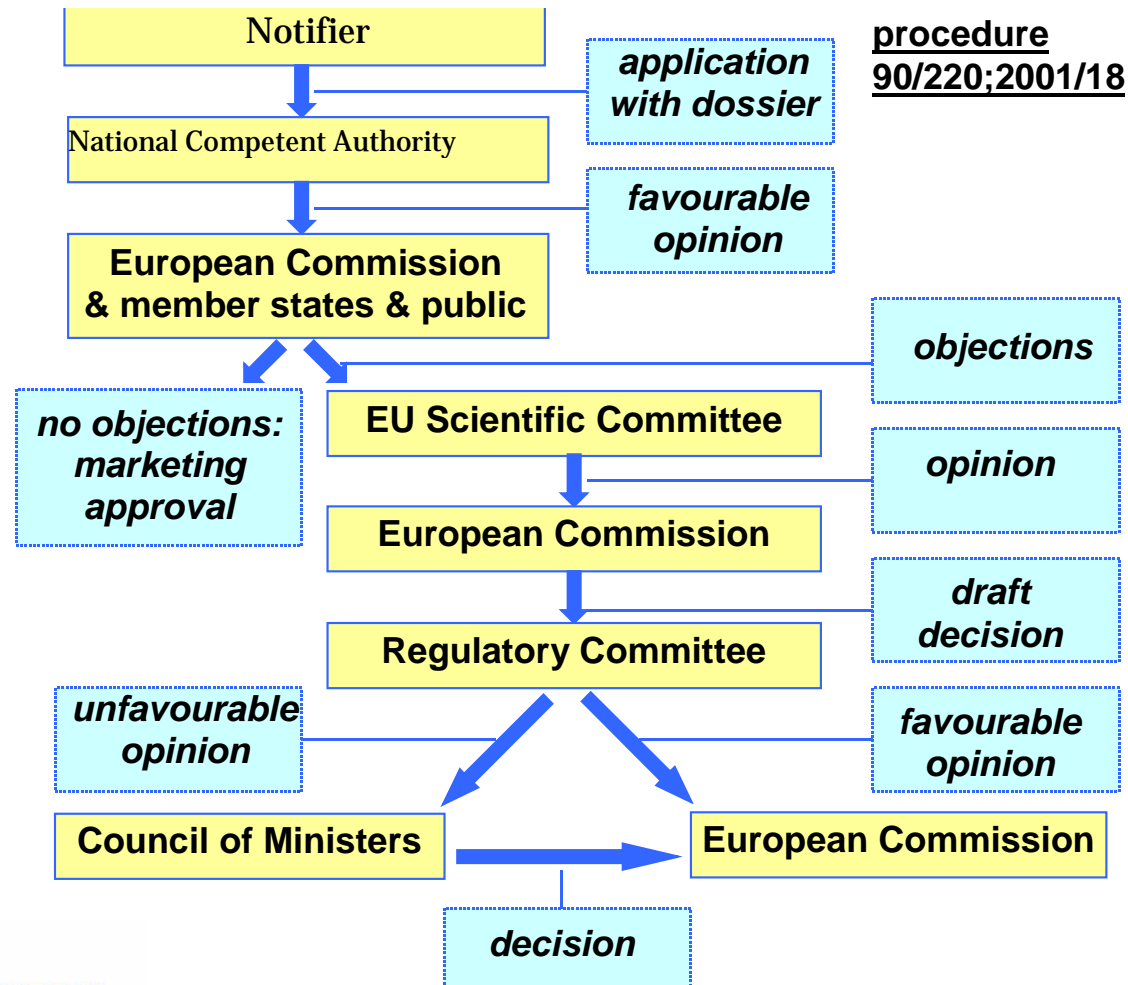
Total 90 opinions adopted

27 GMO opinions - 7 crops: maize, oilseed rape, sugarbeet, potato, tomato, cotton, chicory

- 17 specific gm dossiers
- 3 gm micro-organisms
- 4 guidance documents
- 6 'Article 16' opinions

Common Joint SCP/SCF/SCAN GM Working Group

Community Authorisation Procedure



New Guidance Document on GM Plants and Derived Food and Feed

The EFSA Journal (2004) 99, 1-93

GUIDANCE DOCUMENT OF THE SCIENTIFIC PANEL
ON GENETICALLY MODIFIED ORGANISMS FOR THE
RISK ASSESSMENT OF GENETICALLY MODIFIED
PLANTS AND DERIVED FOOD AND FEED

September 2004

CONTENT OF THE DOCUMENT

- I. *Introduction*
- II. *The Risk Assessment Strategy*
- III. *Information Required in Applications for GM Plant and/or Derived Food and Feed*
 - A. *General Information*
 - B. *Information relating to (A) the Recipient or (B) (where appropriate) Parental Plants*
 - C. *Information Relating to the Genetic Modification*
 - D. *Information Relating to the GM Plant*
- IV. *Risk Characterisation of Genetically Modified Plants Regarding Food/Feed Safety and Environmental Impact*

EU Regulation on Novel Foods and Novel Food Ingredients (EC/258/97)

- Containing or consisting of gmo's
- Produced from gmo's
- New or modified primary molecular structure
- Consisting of or isolated from micro-organisms, fungi or algae
- Products with no history of safe use
- Products processed with new methods

Novel Foods and Novel Food Ingredients approved in the EU

- rape seed oil
- rape seed oil
- rape seed oil
- rape seed oil
- maize products
- maize products
- maize products
- maize products
- rape seed oil
- rape seed oil
- rape seed oil
- riboflavin
- cottonseed oil
- cottonseed oil

AgrEvo
Plant Genetic Systems
Plant Genetic Systems
Monsanto
Monsanto
AgrEvo
Novartis
Pioneer
Hoechst/AgrEvo
Hoechst/AgrEvo
Plant Genetic Systems
Hoffman - La Roche
Monsanto
Monsanto

New Regulations GM food/feed and Labelling and Traceability

- Regulation (EC) 1829/2003 on Genetically Modified Food and Feed
- Regulation (EC) 1830/2003 concerning the Traceability and Labelling of GMOs and the Traceability of Food and Feed Products produced from GMOs and Amending Directive

Regulation (EC) 1829/2003 on Genetically Modified Food and Feed

- Risk assessment under responsibility of EFSA (2001/18)
- Notification procedure abandoned
- Covers food and feed produced from a GMO, no single authorisation
- Criterium: GM source material is present (no processing aids)
- Includes GM additives, flavourings
- 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

Regulation (EC) 1829/2003 on Genetically Modified Food and Feed

- Clear labelling irrespective presence of DNA or protein
- No labelling in case of adventitious or technically unavoidable presence of minute traces of GMOs:
 - 0,9% for GM material authorised in the EU
 - 0,5% for GM material not authorised in the EU, but favourably evaluated (transitional measure)
- When combined level of GM traces is higher than the threshold level, the presence should be indicated
- Unintended presence of GMOs in other products should be avoided and guidelines for co-existence of GM, conventional and organic crops should be developed

Regulation (EC) 1829/2003 on Genetically Modified Food and Feed

- Register of authorised GM food and feed should be established, including product specifications, evidence for safety, methods for sampling and detection.
- *The Food Safety Authority shall publish detailed guidance to assist the applicant in the preparation and presentation of the dossier, before the date of application of the Regulation (April 18 2004).*
- A time limit of six months is respected by the Authority for giving its opinion; this limit may be extended when supplementary information is requested.

Authorization : Scope

Within scope :

- food and feed consisting of or containing a GMO (or GMM);
- food and feed produced **from** a GMO (or GMM).

Out of scope :

- food and feed produced **with** a GMO (or GMM).

Scope : Micro-organisms

Substrate

+

Micro-organism

At production site

Micro-organism

+

Other food ingredients

Purified substance

Fermented food
(containing the MO)

Fermented food
(MO removed)

Used as such
(vitamin, sweetener)

Used in food as ingredient
or processing aid
(additive, flavouring,
vitamin for fortication of food)

Placed on the
market as food or
food ingredient

Status of Food Produced by Fermentation Using a GM Micro-Organism

Joint Council / Commission statement to the minutes

« The Council and the Commission agree that the status of food produced by fermentation using genetically modified micro-organisms not present in the final product needs to be clarified, at the latest in the context of the report to be presented by the Commission as foreseen in Article 48 of the Regulation. »

GMO EFSA Regulation (EC) 1829/2003

EFSA shall:

- inform the Member States and the European Commission when a new application has been submitted to EFSA;
- make the summary of the application available to the public;
- carry out the risk assessment (+/- networking);
- forward its opinion to the European Commission, the Member States and the applicant, and
- make its opinion public.

GMO EFSAnet Regulation (EC) 1829/2003

EFSA has created an electronic system

(GMO EFSAnet)

- to have a secure data communication system where applications (including confidential information) are available to all Member States, the European Commission and the GMO Panel, and
- where competent national Authorities may be consulted to submit their comments.

- Step 0: EFSA receives a new application
- Step 1: EFSA check completeness application (EFSA, EC, JRC)
EFSA will request additional information if needed to the applicant
- Step 2: EFSA acknowledges valid application

Valid application



T= 0 ——— Risk assessment ———> T= 6 months

Step 0: EFSA/GMO secretariat receives a new application

- EFSA informs all members of GMO EFSAnet that an application has been submitted to EFSA and is under completeness check;
- EFSA informs public that an application has been submitted and is under completeness check and put the summary of the dossier available to the public.

Step 1: Completeness check of the application

- EFSA checks completeness of the application (ref. EFSA guidance doc)
- EC determines confidential data (Art. 30)
- JRC checks completeness information related to samples/methods (Art. 5(3)i, j)
- If application non valid, EFSA requests further information from the applicant
- If application non valid, EFSA informs all members of the EFSAnet and the public that the application is not valid and has returned to the applicant

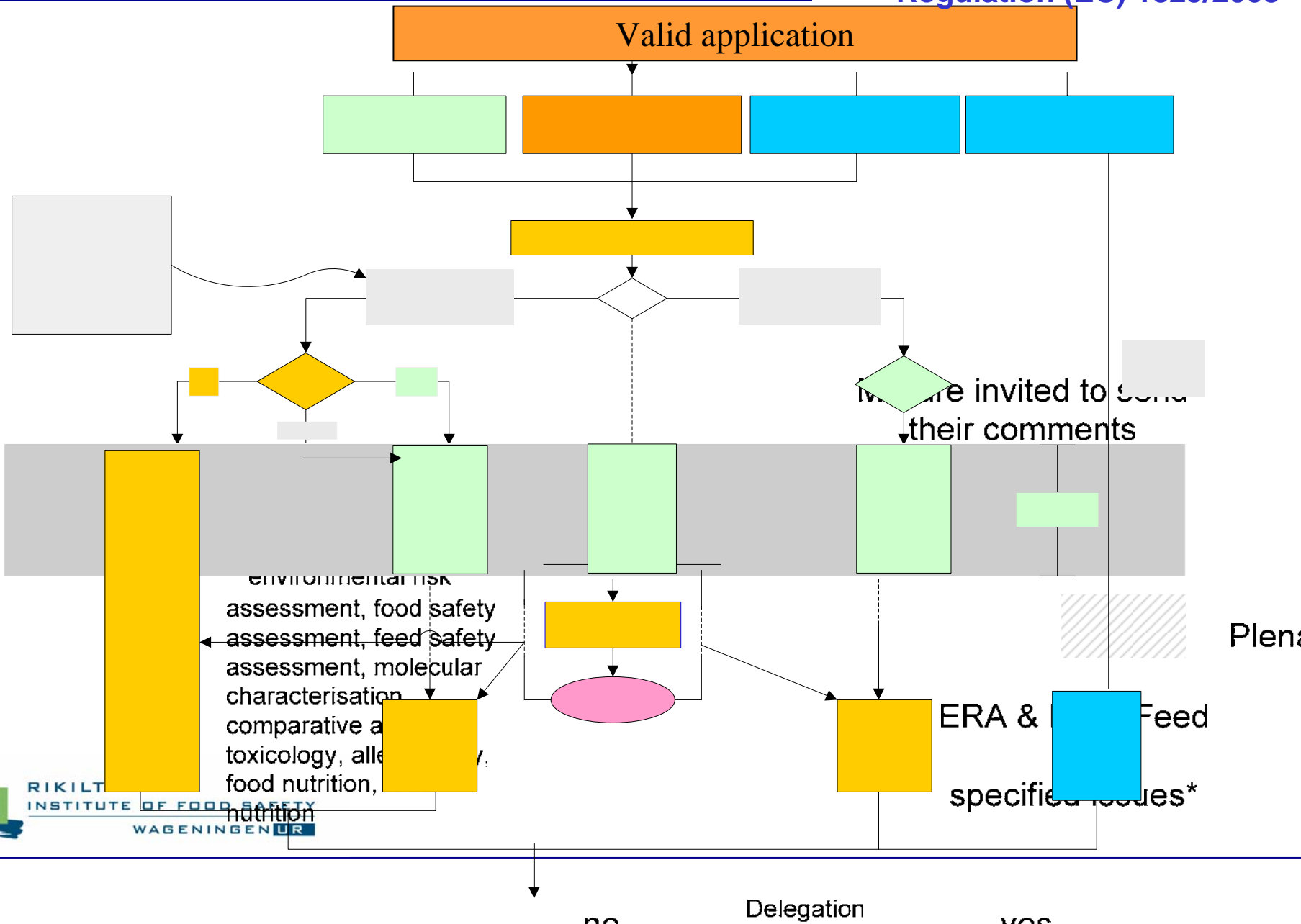
Step 2: EFSA acknowledges that the application is valid

- All EFSAnet members are informed that the application is valid

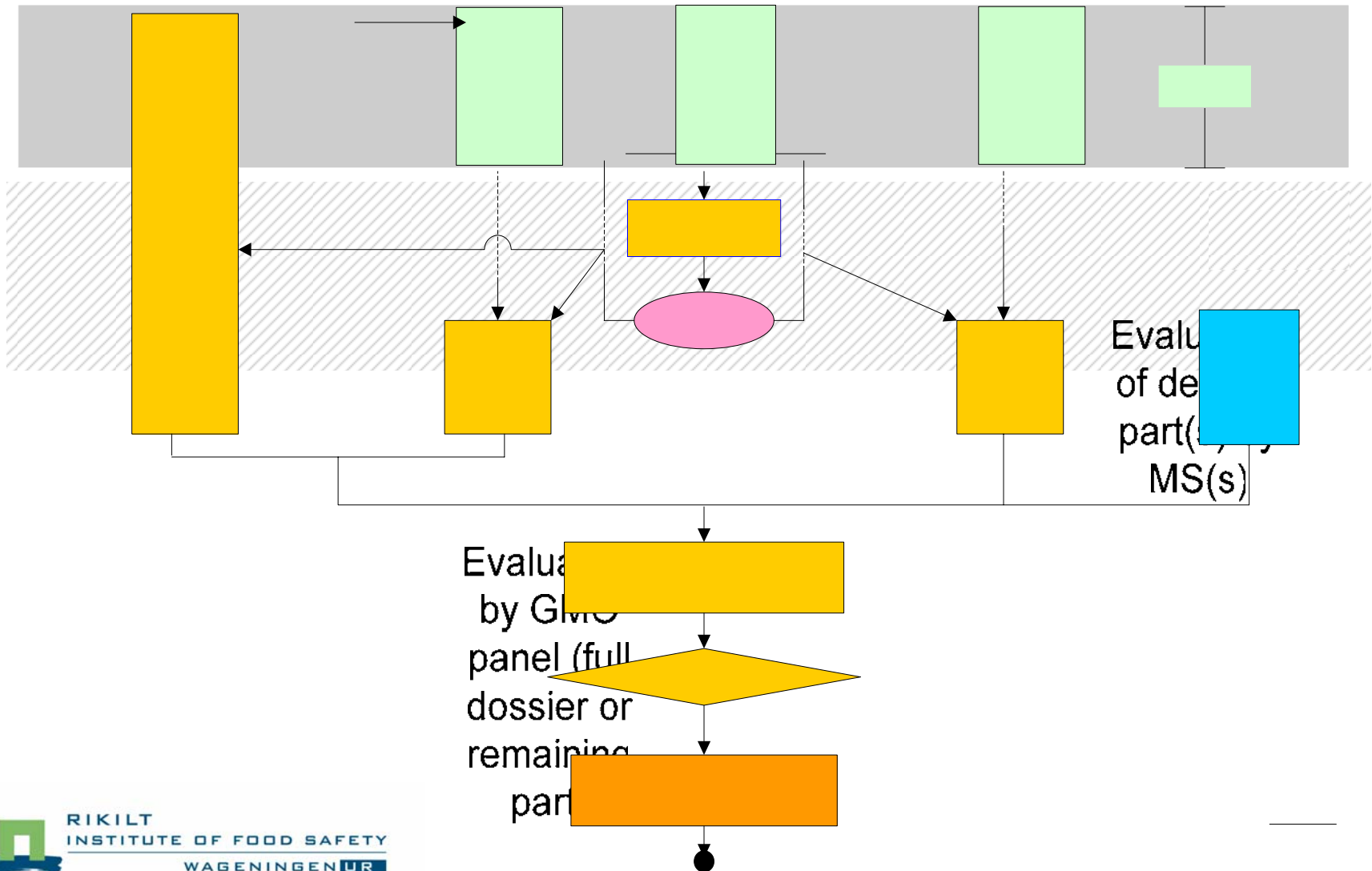


Preliminary flow chart (1)

GMO
Regulation (EC) 1829/2003



Preliminary flow chart (2)



Regulation (EC) 1830/2003 concerning the Traceability and Labelling of GMOs and the Traceability of Food and Feed Products produced from GMOs and Amending Directive 2001/18/EC

- Traceability should facilitate:
 - withdrawal of products in case of unforeseen adverse effects
 - targeting of monitoring of potential adverse effects
 - implementation of risk management measures
 - accurate labelling of products

Regulation (EC) 1830/2003 concerning the Traceability and Labelling of GMOs and the Traceability of Food and Feed Products produced from GMOs and Amending Directive 2001/18/EC

- Information must be transmitted by operators that products contain or consist of GMOs, and their unique codes at all stages of the production process and distribution
- Systems for the development and assignment of unique identifiers for GMOs should be established before the Regulation can effectively be applied.
- Central register will be put in place at Community level containing all available sequence information and reference material

Labelling of GM-Food and GM-Feed - Examples

GMO-type	EXAMPLE	Labelling Required at present	Labelling required in future
GM plant	Chicory ¹⁵	Yes	Yes
GM seed	Maize seeds	Yes	Yes
GM food	Maize, Soybean sprouts, Tomato	Yes	Yes
Food produced from GMOs	Maize flour ¹⁶	Yes	Yes
	Highly refined maize oil, soybean oil, rape seed oil ¹⁷	No	Yes
	Glucose syrup produced from maize starch ¹⁷	No	Yes
Food from animals fed on GM feed	Eggs, meat, milk	No	No
Food produced with the help of a GM enzyme	bakery products produced with the help of amylase	No	No
Food additive/flavouring produced from GMOs	Highly filtered lecithin extracted from GM soybeans used in chocolate ¹⁷	No	Yes
GM Feed	Maize ¹⁸	Yes	Yes
Feed produced from a GMO	Corn gluten feed, Soybean meal	No	Yes
Feed additive produced from a GMO	Vitamin B2 (riboflavin)	No	Yes



Further Needs for Effectuation of the New Framework for GMO Introduction

- GMO DETECTION METHOD DEVELOPMENT
- TRACEABILITY SYSTEMS
- CO-EXISTENCE MEASURES

Commission Recommendation to ensure co-existence of GM crops with conventional and organic farming (C(2003))

- Co-existence: Ability of farmers to provide consumers with a choice between conventional, organic and GM products that comply with European labelling and purity standards
- Co-existence is not a *safety* issue
- Co-existence is concerned with potential *economic* loss through admixture of GM and non-GM crops

Commission Recommendation to ensure co-existence of GM crops with conventional and organic farming (C(2003))

- Co-existence measures should be taken by Member States and not by the EU:
 - efficient, cost-effective measures and best practice are specific to national and regional characteristics and farming practices, which vary greatly between member States and regions

Commission Recommendation to ensure co-existence of GM crops with conventional and organic farming (C(2003))

- Guidelines may include:
 - on-farm measures (isolation distances, buffer zones, pollen barriers such as hedge rows)
 - co-operation between neighbouring farms (information on sowing plans, crop varieties with different flowering time)
 - monitoring and notification schemes
 - training for farmers
 - advisory service

Commission Recommendation to ensure co-existence of GM crops with conventional and organic farming (C(2003))

- Question of liability should be addressed at the national level
- Existing insurance schemes may have to be adapted
- European Commission will report in 2005 on the experience gained in Member States

Tasks of EFSA

- **Risk assessment**
- **Risk communication**
- ***Not* risk management**

EFSA tasking

- **legal requirements**
- **by the Commission**
- **by the European Parliament**
- **by a Member State,**
- **on its own initiative: self tasking**

The 4 Components of EFSA

- **Management Board**
- **Advisory Forum**
- **Executive Director and staff**
- **Scientific Committee and 8 Panels**

The Management Board

- 14 members appointed on the basis of their individual expertise and competence + 1 member from the Commission (DG SANCO)
- broadest geographical distribution
- not representing any government ministry, organisation or sector
- 4 members with backgrounds in organisations representing consumers or other interests in the food chain
- 6 meetings in 2003 (webstreamed)

The Advisory Forum

- **15 Representatives of the Members States**
- **From national bodies with similar role to EFSA (e.g. AFSSA, FSA)**
- **Chaired by the Executive Director**

Tasks of the Advisory Forum

- Advise the Executive Director
- Advise on scientific matters, priorities and work programme
- Resolve contentious scientific matters through discussion
- Co-operation : ensure close collaboration between national bodies and EFSA, avoid duplication of effort
- Networking

Executive Director

- Geoffrey PODGER (UK) appointed by the Management Board, in post since 1/2/2003
 - *Legal representative of the Authority*
 - *Responsible for the day to day running of the EFSA*
 - *Drawing up and implementing work programme, budget priorities*
 - *All staff matters*

Staff

Should be 130 end of 2004, 250 after 3 years

- ***Support to the technical and scientific committees***
- ***Gathering scientific information***
- ***Early warning of risks***
- ***Communication***

EFSA Risk Assessments

- Taking forward the science of risk assessment of foods/feed
- Greater transparency of process including timeframes
- Authoritative views respected across Europe and beyond
- Increased stakeholder confidence in process
- Better liaison and coordination with national authorities

EFSA's Role in Risk Communication

- Independent of political process
- Open and transparent
- Coordination with national authorities
- Support to Commission over food 'scares'/emergencies

EFSA Risk Communication

- Europe-wide reference service largely via website
- Timely and accurate public announcements on key EU-wide issues
- Close coordination of communications with Member States to achieve more consistent culturally sensitive output

EFSA – The Main Changes

- Risk assessment divorced from risk management
- EFSA not part of the Commission nor answerable to it
- EFSA controlled by Board acting in independent capacity not national representatives
- EFSA works in close cooperation with national authorities
- Need to actively consider and meet stakeholder needs (including in particular consumers)
- Better support to and co-ordination of Panels

The 8 EFSA Panels

- Panel on contaminants in the food chain
- Panel on food additives, flavourings, processing aids and materials in contact with food
- Panel on dietetic products, nutrition and allergies
- Panel on biological hazards
- Panel on additives and products or substances used in animal feed
- Panel on genetically modified organisms
- Panel on animal health and welfare
- Panel on plant health, plant protection products and their residues

GMO Panel

- 21 members (info: www.efsa.eu.int)
- A reserve list is available (working groups!)
- Chairman: Harry Kuiper (NL)
- 13 different nationalities; ages 39-62
- Questions related to risk assessment of GMOs (humand health and the environment)/ not only food safety

Questions to GMO panel

- Authorisation dossiers
 - **Directive 2001/18/EC – deliberate release into environment:** questions from Commission in case MS have objections (19 dossiers since beginning of 2003) – no question to EFSA yet
 - **Regulation 258/97 – novel foods:** consultation of scientific panel on each GM application – no question to EFSA yet
 - **GM food & feed legislation:** centralised risk assessment by EFSA (information/consultation of MS)

Questions to GMO panel

- General questions from COM, EP or MS
 - E.g. Prohibition of GMOs in Upper Austria (Article 95(5)) of the Treaty – Question from Commission

- Legislative requirements
 - E.g. Guidance document (GM food & feed legislation)

- Self tasking

- ❖ **Note:** new are the *deadlines* put forward by Commission or legislation

Overview Adopted Opinions

GMO Panel (1)

1. Guidance document for the risk assessment of genetically modified plants and derived food and feed (Question No EFSA-Q-2003-005). Adopted 24 September 2004
2. Opinion for the placing on the market of insect-tolerant genetically modified maize 1507, for import and processing under Part C of Directive 2001/18/EC from Pioneer Hi-Bred International/ Mycogen Seeds (Question No EFSA-Q-2004-011). Adopted by GMO Panel on 24 September 2004

Adopted Opinions GMO Panel (2)

3. Opinion on a request from the Commission related to the Austrian invoke of Article 23 of Directive 2001/18/EC (Question No EFSA-Q-2004-062). Adopted on 8 July 2004
4. Opinion on a request from the Commission related to the Greek invoke of Article 23 of Directive 2001/18/EC (Question No EFSA-Q-2004-062. Adopted by GMO Panel on 8 July 2004
5. Opinion on the use of antibiotic resistance genes as marker genes in genetically modified plants. (Question No EFSA-Q-2003-109). Adopted on 2 April 2004

Adopted Opinions GMO Panel (3)

6. Opinion related to the safety of foods and food ingredients derived from insect-protected genetically modified maize MON 863 and MON 863 x MON 810, request submitted under Article 4 of the Novel Food Regulation (EC) No 258/97 by Monsanto (Question No EFSA-Q-2003-121). Adopted on 2 April 2004
7. Opinion on the placing on the market of insect-protected genetically modified maize MON 863 and MON 863 x MON 810, for import and processing under Part C of Directive 2001/18/EC, from Monsanto (Question No EFSA-Q-2003-089). Adopted on 2 April 2004

Adopted Opinions GMO Panel (4)

8. Opinion related to the placing on the market of herbicide-tolerant oilseed rape GT73, for import and processing, under Part C of Directive 2001/18/EC from Monsanto (Question No EFSA-Q-2003-078). Opinion adopted on 11 February 2004.
9. Opinion on Guidance notes supplementing Part B of Annex II to Council Directive 90/219/EEC, as amended by Directive 98/81/EC, on the contained use of genetically modified micro-organisms (Question No EFSA-Q-2003-004). Opinion adopted on 11 December 2003
10. Opinion related to the placing on the market of herbicide-tolerant genetically modified maize NK603, for import and processing, under Part C of Directive 2001/18/EC from Monsanto (Question No EFSA-Q-2003-003). Opinion adopted on 25 November 2003

Adopted Opinions GMO Panel (5)

11. Opinion related to the safety of foods and food ingredients derived from herbicide-tolerant genetically modified maize NK603, for which a request for placing on the market was submitted under Article 4 of the Novel Food Regulation (EC) No 258/97 by Monsanto (Question No EFSA-Q-2003-002). Opinion adopted on 25 November 2003
12. Opinion related to the Austrian notification of national legislation governing GMOs under Article 95(5) of the Treaty (Question No EFSA-Q-2003-001). Opinion adopted on 04 July 2003

Issues for Self Tasking GMO Panel

- Guidelines for GM microorganisms
- Guidelines for nutritionally enhanced GM crops
- Post-market monitoring and environmental monitoring of GMOs
- Animal toxicity testing of whole foods
- Strategies for assessment of allergenicity
- Co-existence of crops
- Use of profiling technologies in risk assessment
- Guidelines for non-food GMOs

Conclusions

- Regulatory Framework for GMO release in Europe is in place
- Safety of GMOs admitted to the European market is guaranteed by the rigorous and robust risk assessment procedure in the European Union
- Establishment of EFSA is an important step forwards for improved, harmonised and transparent risk assessment and risk communication
- Agreement on labelling and traceability

Conclusions (2)

- Detection methods for GMOs, sampling plans, availability of reference materials, access to information on the genetic modification etc must be further developed
- The practicability of traceability systems and inherent analytical controls must be further developed
- Co-existence measures in Member States must be further developed, tested and validated.
- Involvement of consumers in the decision making processes needs further attention

More information available at

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



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