

The Application of Risk
Assessment –
**Using science to establish
effective food safety control
for the European Union**

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Outline

- European Food Safety Authority (EFSA)
 - Reasons for creation
 - Legal basis and structure
 - Role in enhancing food safety
- Use of risk assessment as a food safety tool
- Implications for external countries/businesses

1995 - The WTO SPS Agreement

- **Article 3(3):** Members may introduce or maintain sanitary or phytosanitary measures ... if there is a **scientific justification**, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate
- **Article 5(1):** 1. Members shall ensure that their sanitary or phytosanitary measures are based on an assessment ... of the risks to human ... life or health, taking into account **risk assessment** techniques developed by ... international organizations.

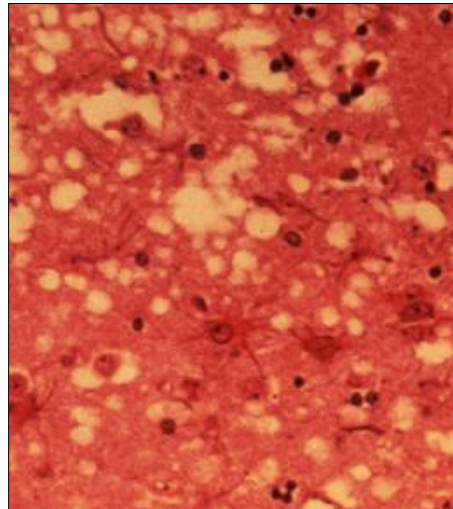
WORLD TRADE
ORGANIZATION



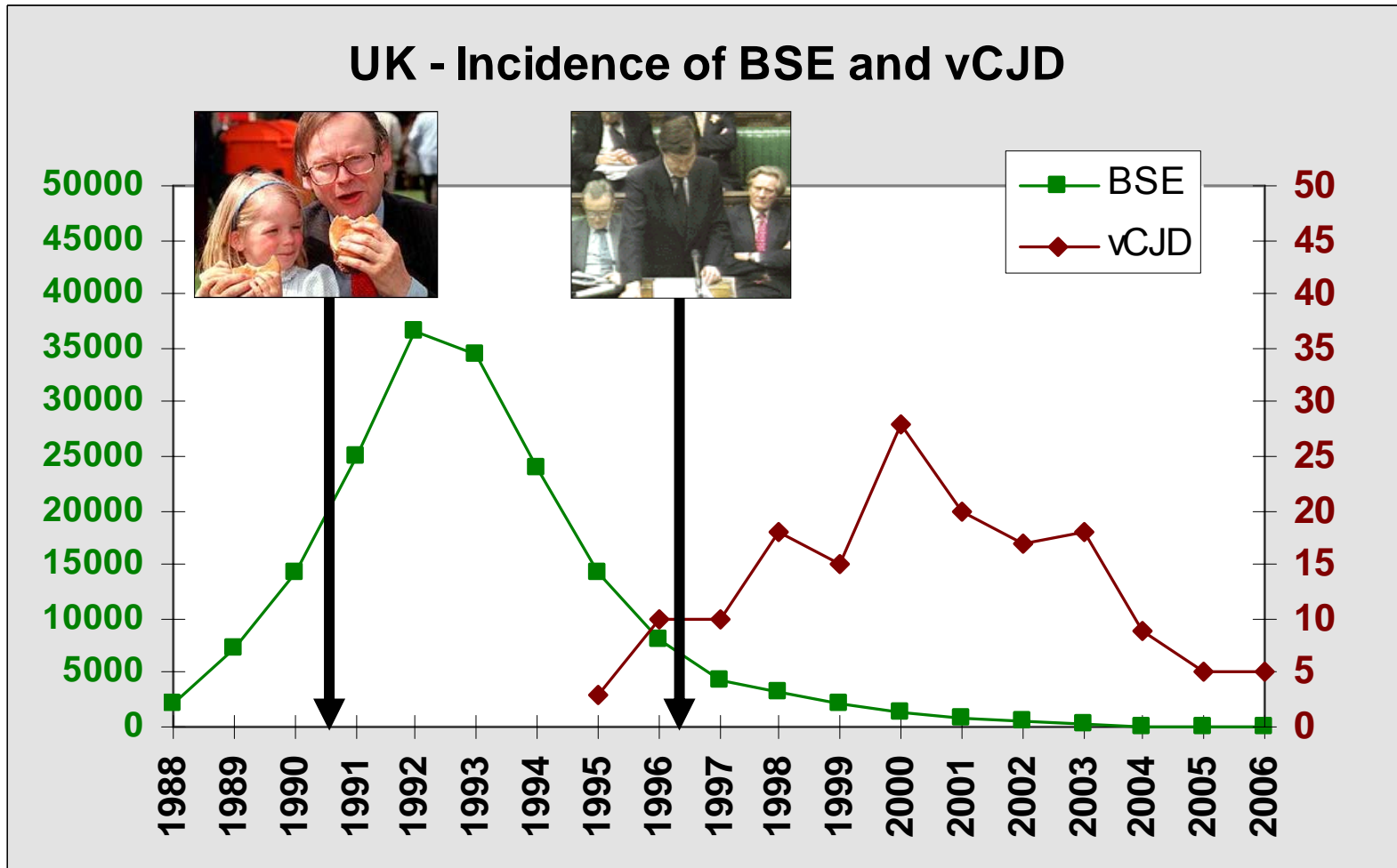
European food safety crises

(1) BSE

- Bovine Spongiform Encephalopathy (BSE)
- First appearance: UK 1985



UK data: BSE in cattle and vCJD in people



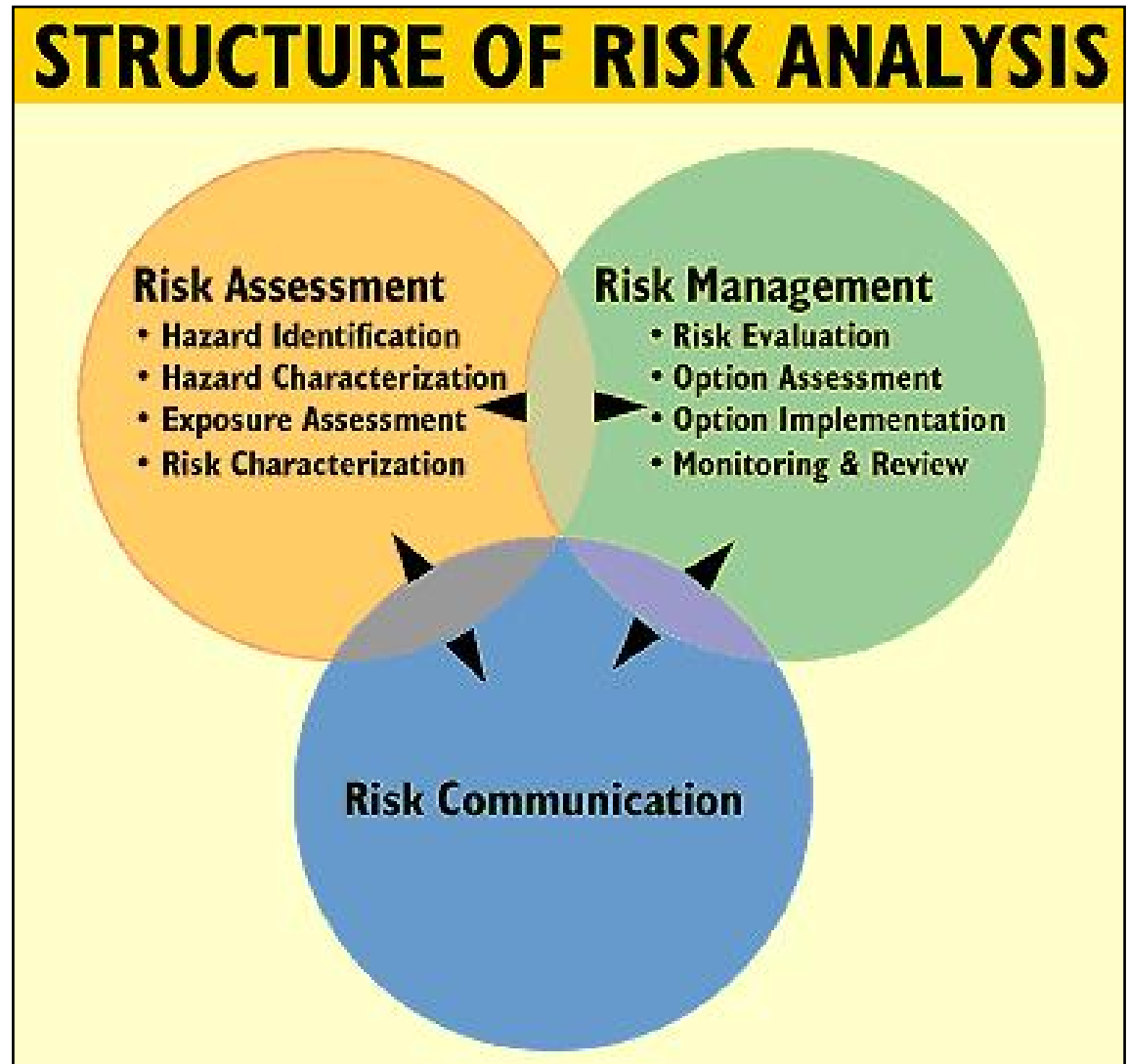
Dioxin crisis

- **January 1999:** Fat mixture contaminated with dioxin at a fat and oil processing plant. Fat used in manufacture of animal feed
- **February 1999:** Initial problems with chickens
- **March 1999:** Investigations lead to suspicion of problem with fat
- **April 1999:** Dioxin suspected as source of problem
- **May 1999:** High levels of dioxin found in various foods. Recalls initiated in Belgium, The Netherlands, France, Germany, Luxembourg *and elsewhere*

Regulation 178/2002

- Definition of ‘food’ and other terms
- Establish general principles and requirements of food law
- Established the ‘**European Food Safety Authority**’ (EFSA)
- Provided a legal basis for the Rapid Alert System, for crisis management and emergencies

Risk Analysis



Definitions

- **‘risk analysis’** means a process consisting of three interconnected components: risk assessment, risk management and risk communication;
- **‘risk assessment’** means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation;

Definitions

- **‘risk management’** means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options;

Definitions

- **‘risk communication’** means the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions;

General principles of food law

- **Article 6**
- 1. In order to achieve the general objective of a high level of protection of human health and life, food law shall be based on **risk analysis** except where this is not appropriate to the circumstances or the nature of the measure.
- 2. **Risk assessment** shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.

EFSA – Article 22

- 2. The Authority shall provide **scientific advice** and **scientific and technical support** for the Community's legislation and policies in all fields which have a direct or indirect impact on **food and feed safety**. It shall provide **independent information** on all matters within these fields and communicate on risks.
- 3. The Authority shall contribute to a high level of protection of human life and health, and in this respect take account of **animal health and welfare, plant health and the environment**, in the context of the operation of the internal market.

EFSA – Article 24

- **Bodies of the Authority**
- (a) a Management Board;
 - Independent people appointed on basis of expertise, knowledge and experience
- (b) an Executive Director and his staff;
- (c) an Advisory Forum;
 - Representatives of risk assessment bodies in Member States
- (d) a Scientific Committee and Scientific Panels.

Scientific Committee and Panels

- Food additives, flavourings, processing aids and materials in contact with food (AFC)
- Animal health and welfare (AHAW)
- Biological hazards (BIOHAZ), including BSE-TSE-related risks
- Contaminants in the food chain (CONTAM)
- Additives and products or substances used in animal feed (FEEDAP)
- Genetically modified organisms (GMO)
- Dietetic products, nutrition and allergies (NDA)
- Plant protection products and their residues (PPR)
- Plant health (PLH)

EFSA - Chronology

- **January 28 2002:** EFSA legally established by Regulation 178/2002
- **May 2003:** Scientific Expert panels established
- **July 2003:** First scientific risk assessment adopted
- **July 2005:** Inauguration of EFSA's official seat in Parma
- **October 2005:** EFSA completes its transfer to Parma, Italy and closes headquarters in Brussels

- **December 2005:** Evaluation report

Evaluation – Key Recommendations

- Develop active networking and stronger cooperation with Member States
- Strengthen EFSA's relationship with its institutional partners (EU and international) and stakeholders
- Enhance EFSA's organisation
- Enhance the impact and effectiveness of EFSA communications
- Develop EFSA's role in nutrition
- Define EFSA's medium and longterm vision

Example - Aspartame

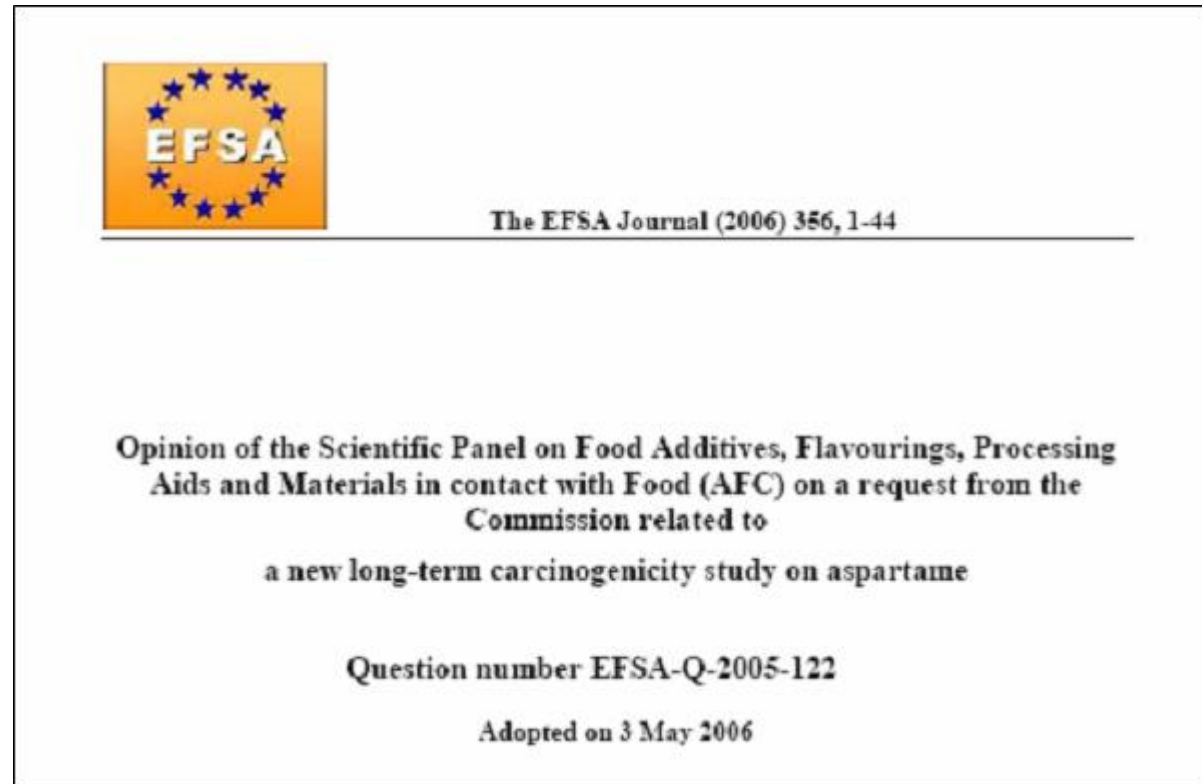
- First approved in some Member States in the 1980s
- **1984, 1987** and **1988**: Evaluation by the Scientific Committee for Food (SCF) established ADI of 40 mg/kg body wt.
- **1994**: EU sweetener legislation adopted and aspartame approved for use.
- **2002**: Further review by SCF. ADI retained.

- **June 2005:** EFSA informed of new Italian data from Italian Institute.
- **December 2005:** EFSA receives data from the Italians. EFSA scientific panel (AFC) starts priority review.



Risk in 6,000 food and drink products
**CANCER LINKED
TO SWEETENER**

- **May 2006:** AFC opinion – no change to ADI.



Example - Avian Flu

- **January 2004:** Initial assessment by Biological Hazards panel (BIOHAZ). No evidence that food chain would be a route to infection.
- **September 2005:** Further review. “No epidemiological information to date which suggests that the disease can be transmitted to humans through contaminated food. Normal cooking temperatures will inactivate the virus if present in foods.”



- **October 2005:** “As precautionary advice and in order to avoid known risks of food poisoning from Salmonella and other organisms, EFSA reconfirms longstanding recommendations that poultry meat and eggs be thoroughly cooked. Whilst it is unlikely that H5N1 could be passed onto humans by raw meat or eggs, cooking food properly would inactivate the virus and eliminate this potential risk.”

Example - GM Food

- May 2000



STORM AS GM CROPS WRECK HONEY

Total ban urged as rape pollen from trial field is
carried 30 miles to contaminate farmer's bee hives

By Jane Worsfold
The Daily Express, London

Genetically modified crops have been planted in a field in Oxfordshire, and the rape pollen from the plants is being carried by the wind to contaminate a farmer's beehives. The farmer has asked the government to ban the crops. The government has said it will not do so.



EXCLUSIVE: Prince takes on the scientists

CHARLES: WHY I FEAR A GENETIC DISASTER



Prince Charles has launched a devastating attack on the "potential dangers" of GM food and cloning.

By Richard Kay and James Chapman
The prince's attack is a warning to the government to take action to protect the public from the dangers of GM food and cloning.

Prince Charles has launched a devastating attack on the "potential dangers" of GM food and cloning. The prince has said that he is "convinced" that GM crops are a "genetic disaster" and that they could lead to the "wrecking" of the food chain. He has also said that he is "convinced" that cloning is a "genetic disaster" and that it could lead to the "wrecking" of the human race. The prince has said that he is "convinced" that GM crops and cloning are a "genetic disaster" and that they could lead to the "wrecking" of the food chain and the human race.

More Charles: Personal attack against GM foods
Page 8, Col. 1

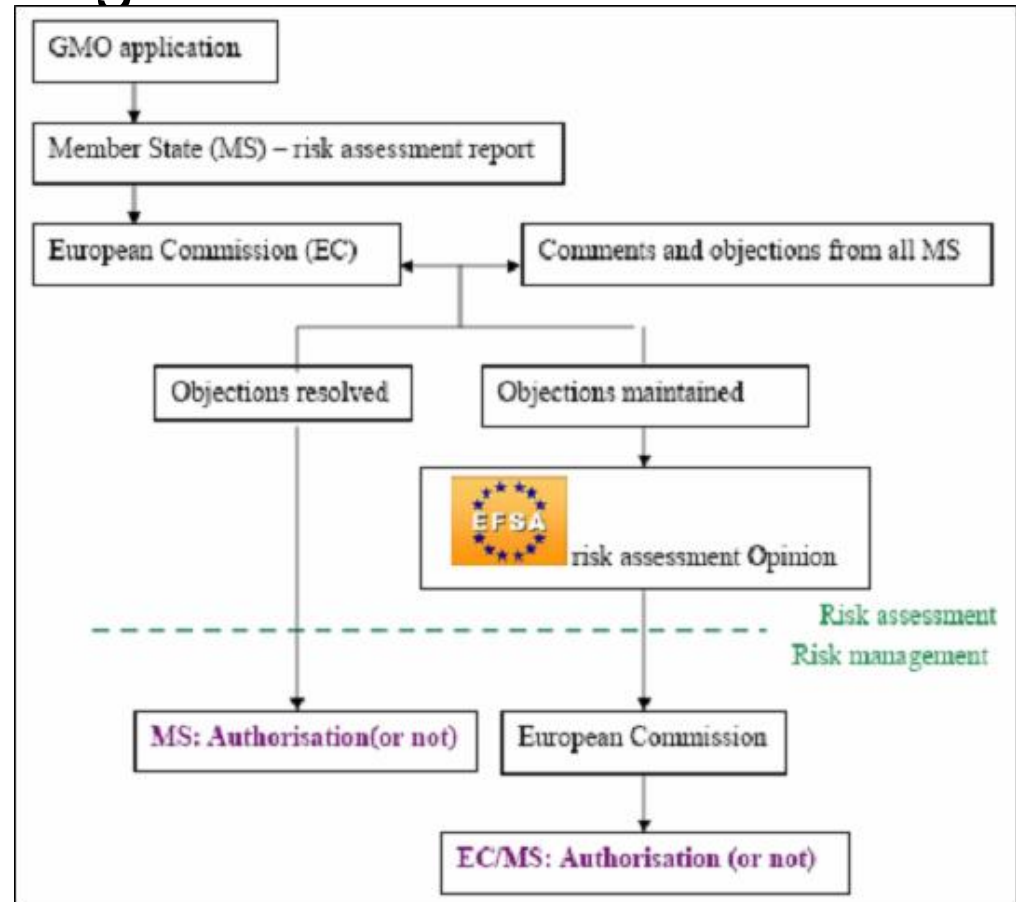
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EU consumers distrust GM food

- Fear of the new
- Distinctive labelling made consumers aware of presence of GM material
- Previous food scares had made consumers distrustful of government and cautious of science
- First GM products conferred benefits for farming and industry

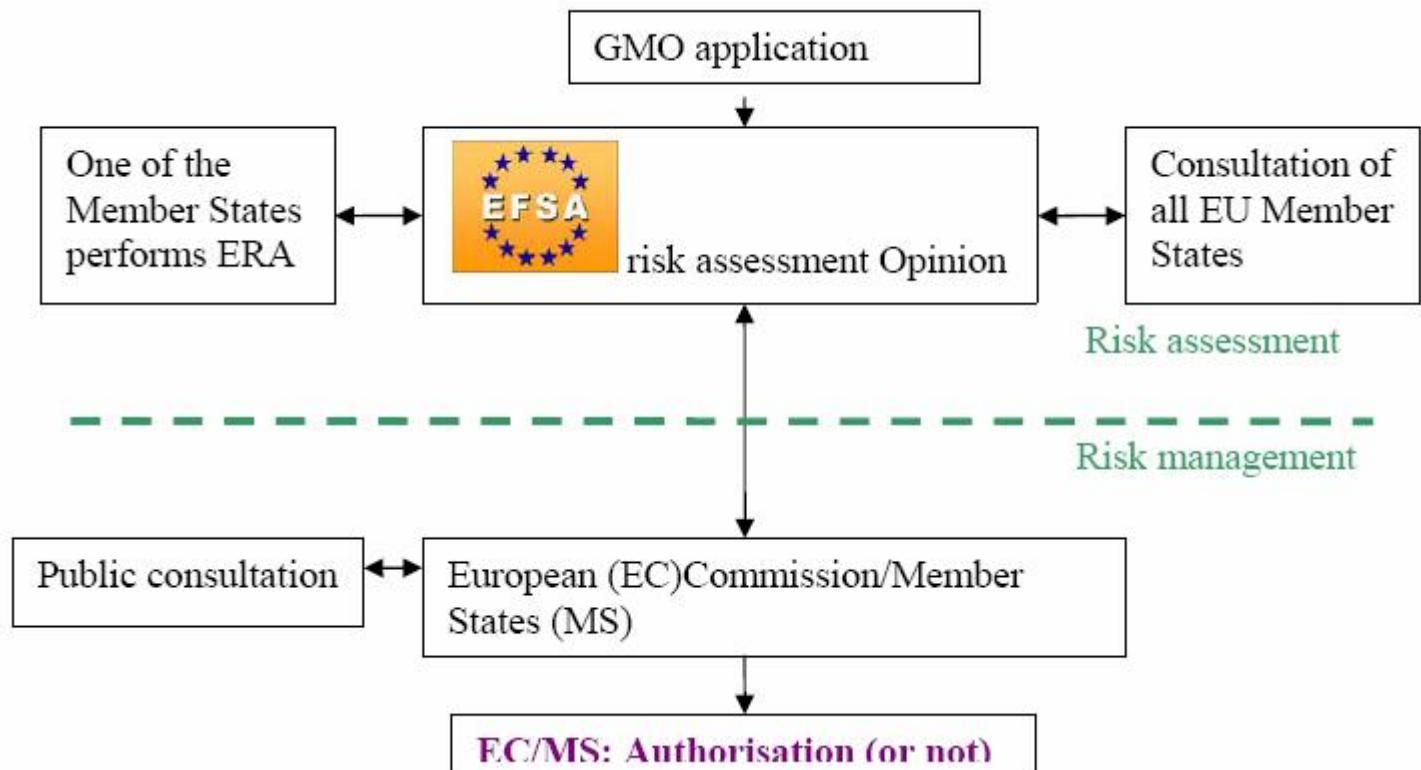
EFSA and GM food

- **Directive 2001/18/EC** on the deliberate release into the environment of genetically modified organisms.



EFSA and GM food

- **Regulation (EC) No 1829/2003** on genetically modified food and feed,



Austria and GMOs

- **1998:** Decision to permit sale of GM maize seed throughout the EU.
- **May 2000:** Austria informs EU Commission that it will ban sale of GM maize using 'safeguard' clause in legislation.
- **2001:** Data reviewed and not considered to raise any problem

- **July 2003:** EFSA review Austrian report and concluded: “no new scientific evidence in the report, in terms of risk to human health and the environment, to justify the ban. Neither did it find any new data that would justify changing the methods used, at present, to assess the environmental risk of GMOs that currently hold marketing consent in the EU”

- **February 2004:** New data submitted by Austria
- **July 2004:** EFSA opinion: “no new scientific evidence, in terms of risk to human health and the environment, that would ... justify a prohibition of these genetically modified crops authorised under ... Directive 2001/18/EC in Austria.”
- **September 2004:** Commission proposal to require Austria to permit GM maize
- **November 2004:** No decision in committee

- **April 2005:** Commission issues proposal for Council decision
- **June 2005:** Council decides that “there is still a degree of uncertainty in relation to the national safeguard measures” and Commission to “gather further evidence on the GMO in question and further assess, whether the measure ... [is] justified.”
- **November 2005:** EFSA again asked to review data

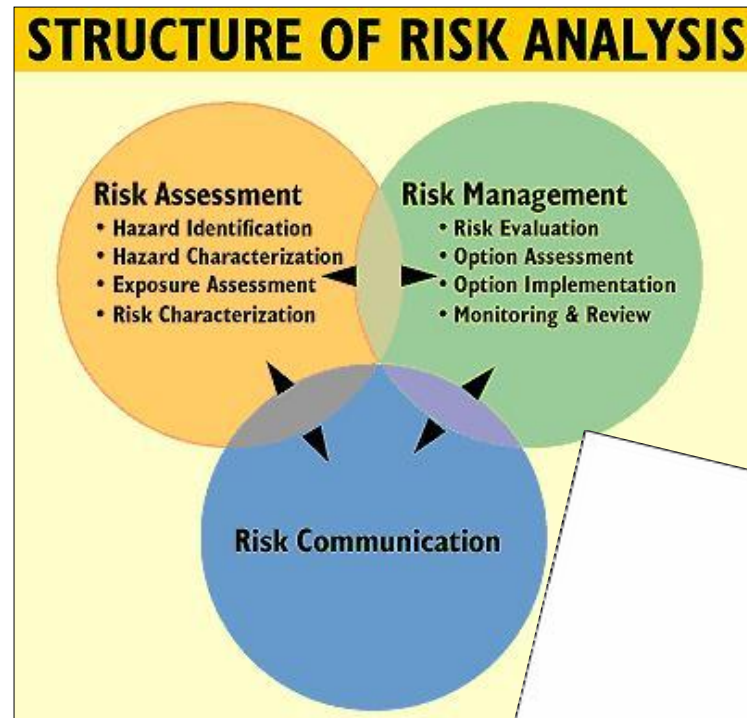
- **March 2006:** EFSA conclude “no reason to believe that the continued placing on the market of Zea mays L. line MON 810 is likely to cause any adverse effects for human and animal health or the environment under the conditions of its consents.”
- **October 2006:** Commission resubmits proposal for Council decision.
- **December 2006:** Council again rejects proposal

- Council justification:
- Maize had been approved according to an older Directive. The new Directive contains harmonized environmental risk assessment criteria which need to be used for the maize
- Where the conditions apply, a Member State may restrict by use of the safeguard clause
- The different agricultural structures and regional ecological characteristics in the European Union need to be taken into account in a more systematic manner in the environmental risk assessment of GMOs.

Overview

- Aspartame
- Avian flu
- GM food

- FoE: critical report on the work of EFSA with regard to GM food



International dimension

- WTO expects sound science to be at the basis of food safety controls
- EFSA provides the independent and transparent scientific evidence for use by decision makers (both EU and elsewhere)

EFSA – Five years old

- **January 2002:**
- Created to provide independent scientific advice
- **February 2007**
- Difficult initial period
- Slow development of policies
- Slow appointment of scientists to panel
- Established in city with poor access
- Relationship to national bodies uncertain

- **BUT**
- EFSA is here for the long term
- Reputation will depend upon sound science and independence in ‘risk assessment’
- It must leave politics (‘risk management’) to the politicians