



EU Framework Legislation for GMOs & Future Challenges

Niall Gerlitz SANCO E1





Part I: EU Framework Legislation for GMOs





Need for European Legislation

- Managing possible risk
- Protect consumers' right to know and choose
- Avoid trade barriers
 - First wave of directives – 90s
 - New legislative framework – following food crisis





The “new” regulatory framework

Directive 2001/18/EC on the deliberate release of
GMOs into the environment

Regulation (EC) No 1829/2003
on GM food and feed

Regulation (EC) No 1830/2003
on traceability and labelling of GMOs



Scope of Directive 2001/18/EC and Regulation (EC) No. 1829/2003

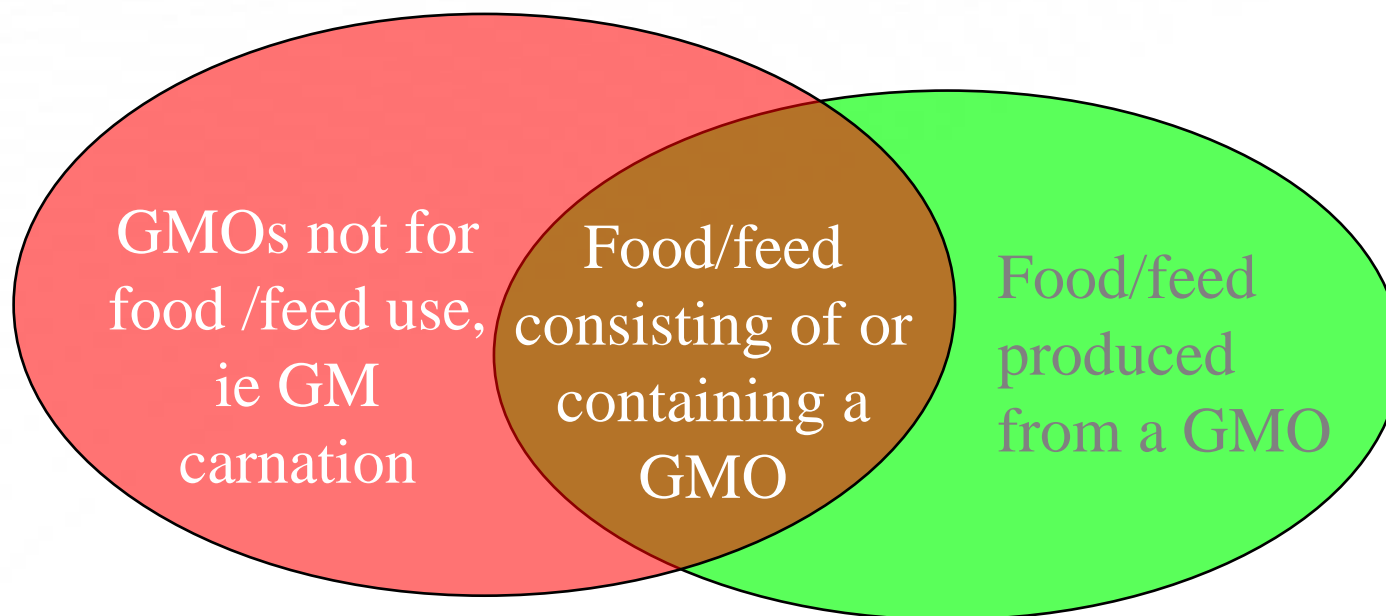
Directive
2001/18/EC
“living” GMOs

Reg (EC) No. 1829/2003
Food/feed consisting, containing
or produced from a GMO





Interaction between Directive 2001/18/EC and Regulation (EC) No. 1829/2003





Regulation (EC) NO. 1829/2003 - overview

- Integrated approach: Food, Feed & cultivation
- Centralised, transparent authorisation procedure
- Rules on traceability and labelling (⇒ Reg. 1830/2003)





The EU model approach

1. Risk assessment: European Food Safety Authority
2. Risk management: European Commission through a regulatory committee procedure





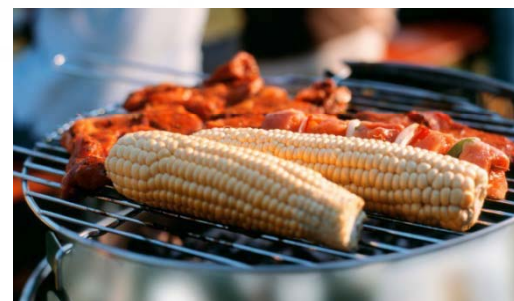
Risk Assessment





Step 1: Application - Art. 5/17 (Reg 1829/2003)

- Scope of applications
 - Food
- GMO for food use
 - Food containing or consisting of GMOs
 - Food produced from or containing ingredients produced from GMO (e.g. oil, lecithin)





- Feed
 - GMO for feed use
 - Feed containing or consisting of GMOs
 - Feed from GMOs (e.g. soya meal)

- Deliberate release into the environment
 - Import and processing (shipping, making silage)
 - Seeds and plant propagation material for cultivation





Step 2: Opinion - European Food Safety Authority - Art. 6/18 (Reg 1829/2003)

- GMO panel consists of 21 independent experts who deliver opinions on applications.





GMO Panel

- Covering the necessary expertises
 - For molecular characterisation: biochemistry, food and environmental microbiology, genetics
 - For food and feed safety: toxicology, immunology, biotechnology, food chemistry..
 - For the environment: ecology, plant biology, agronomy, entomology, biometrics...
 - Assisted by 50 ad hoc working groups covering pesticides, natural toxins, food sciences, and animal pathology





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

Adopted on 24 September 2004
First, revised version of 9 November 2004

March 2005



Applications have
to comply with
the guidance for
RA and GM
plants.





- EFSA publishes overall opinion with the following annexes:
 - Scientific opinion of GMO
 - Cartagena Protocol
 - Labelling
 - Validation report (CRL)
 - Validated detection method (CRL)
 - Certified reference materials
 - Monitoring plan
 - Member State comments



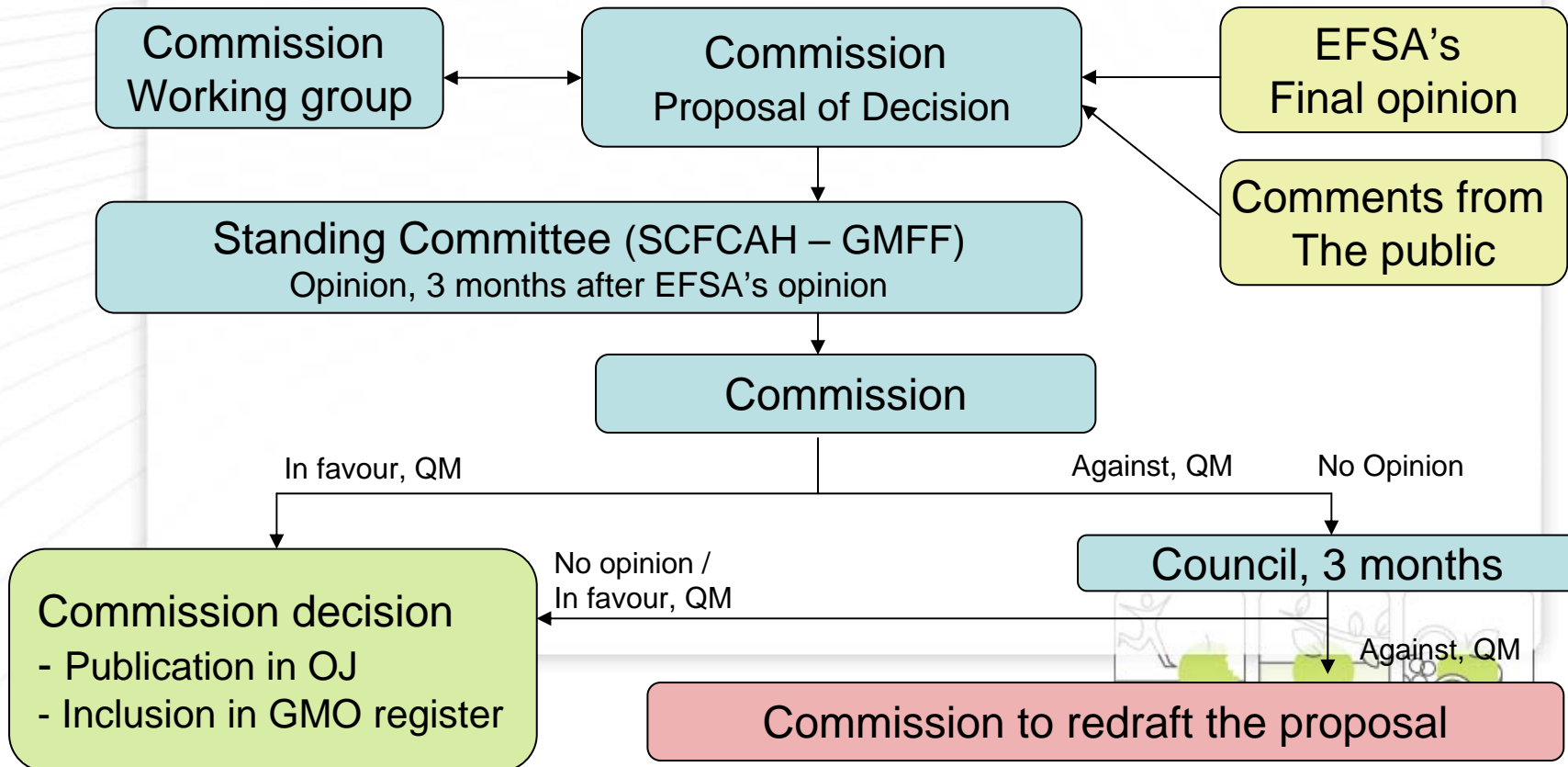


Risk Management





Step 3. Authorization procedure – Art. 7/19&35 (Reg. 1829/2003)





Authorisation

- Authorisation
 - Granted for 10 years
 - Renewable for 10-year periods
 - Decision to be published in the Official Journal
- Authorization holder responsible for safety, post market monitoring etc.
- Authorised products are entered in the Community register

http://ec.europa.eu/food/dyna/gm_register/index_en.cfm





Consumer information - labelling

- Compulsory for food/feed containing, consisting of, or produced from GMOs regardless of the presence of modified DNA or proteins
 - In the list of ingredients if pre-packaged
 - Otherwise visible if non pre-packed
- 0,9% threshold for adventitious presence of authorised GMOs (operators responsible to take measures)
- Lower levels may be adopted via comitology





Consumer information - labelling

- National provision for GM-free labels and for menus
- NOT for products obtained from animals fed with GM feed or treated with GM medicines (eggs, milk, meat) but the issue is becoming more and more important and often addressed at private level





Current status of authorisations

- 14 applications approved under current framework legislation
 - 9 maize
 - 2 soyabean
 - 1 sugarbeet
 - 1 oilseed rape
 - 1 cotton
- 13 applications with EFSA positive opinion awaiting final authorisation
- 44 applications still under EFSA assessment
- 14 applications are for cultivation





Part II: the Challenges ahead





Major challenges for the future

1. Consumers' resistance
2. Debate on labelling requirements
3. Asynchronous and asymmetric authorization
4. Contamination with unauthorized GMOs

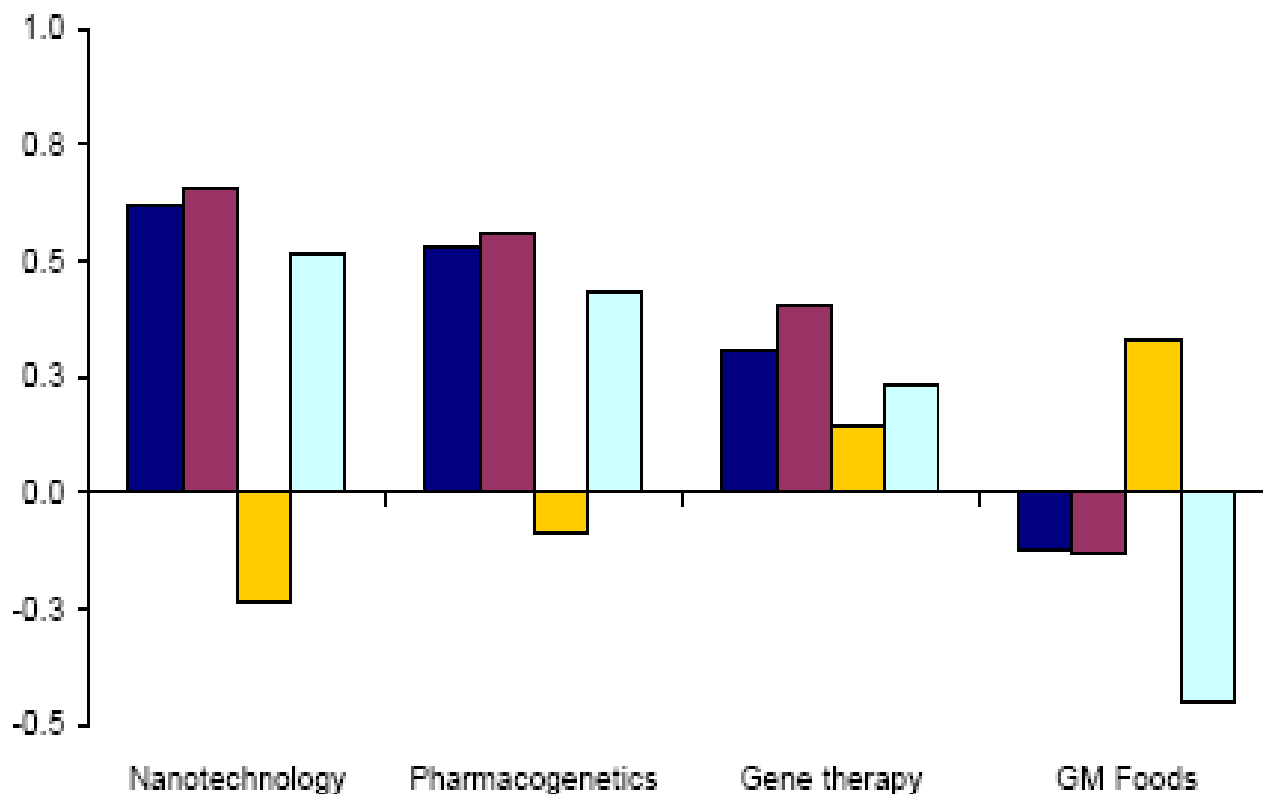




1 – Challenge : consumer resistance

Figure 4: Evaluations of four technologies

■ Morally acceptable
 ■ Useful
 ■ Risky
 ■ Should be encouraged





2 – Challenge: debate on labelling

- Greenpeace petition – February 2007: (1mln signatures for labelling of animal products)
- EFSA concluded: no scientific basis
- Impact on the legislative philosophy and on the market
- Demand for GM free products / evolving national legislation and production practises





3 – Challenge: asynchronous and asymmetric authorisations

- GM products authorised in other countries and not in EU.
- Contaminated Imports.
- Important for feed import (soybean and maize products).
- Commission reflecting on possible solutions but in the respect of the current legal framework.
- Submission to the EU for authorisation is important to prevent asynchronous authorisations.





4 – Challenge: unauthorised GMOs

- Bt 10 maize: US 2005, emergency measure
- LL Rice 601: US 2006, emergency measure
- Bt 63 Rice: China 2006, emergency measure
- LL Rice 604: US 2007, measures taken by US authorities





Better Training for Safer Food Training Activities





Background

The EC **Health and Consumers DG** organises training for:

- **Member State** competent authority staff
- Third, particularly **developing country** participants

Legal Basis: Article 51, Regulation 882/2004





Areas covered by the training:

- Food law
- Feed law
- Animal health rules
- Animal welfare rules
- Plant health rules





Aims

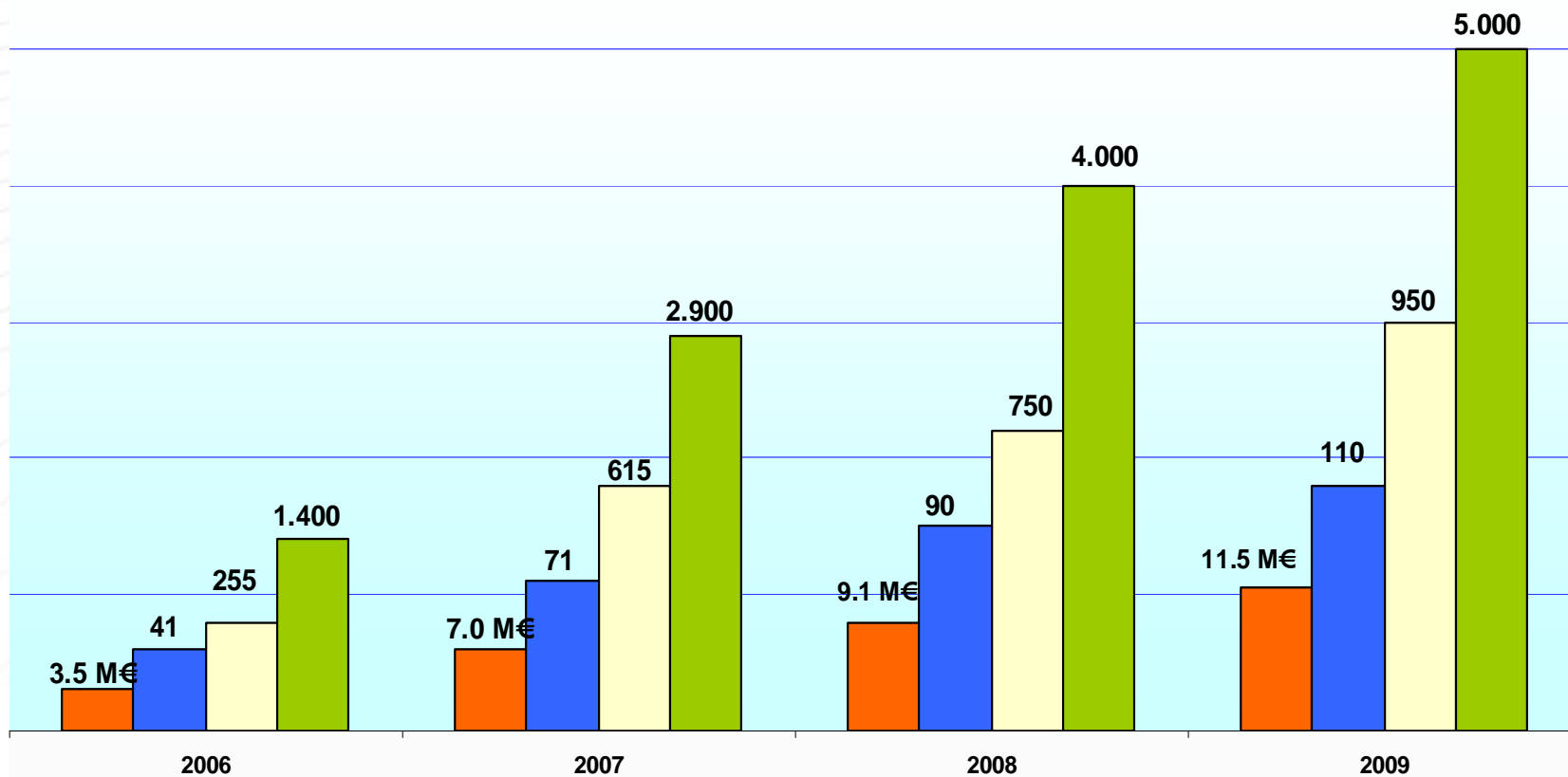
- High levels of food safety, animal health and welfare and plant health
- High levels of competence and awareness of EU rules
- Uniform and objective controls in all Member States
- A level playing field for business
- Increased access to the EU market for developing countries





Evolution 2006-2009

■ budget ■ Number of training activities ■ training days ■ Number of participants





Training programmes

- EU food import standards
- Avian Influenza
- RASFF/TRACES
- Food Testing on SPS issues
- GMO analysis





BTSF Training Activities 2009

5000 Participants

110 Training Activities

950 training days

Estimated Budget

11,5 M€



More information?

The screenshot shows a Microsoft Internet Explorer browser window displaying the website http://ec.europa.eu/food/training_strategy/index_en.htm. The page title is "Food Safety - From the Farm to the Fork". The main content area is titled "Training Strategy - Home" and contains the following text:

Better Training for Safer Food is a Commission training initiative covering food and feed law, animal health and welfare and plant health rules. It trains Member State and candidate country national authority staff involved in official controls in these areas.

This aims to keep participants up-to-date with Community law in these areas and should help to ensure more harmonised and efficient controls. Efficient controls are an essential factor in maintaining high levels of consumer protection, animal health and plant health. Harmonisation of controls should help to create a level playing field for food businesses.

Training is also organised specifically for third, particularly developing country participants so as to familiarise them with EU requirements. This should help to ease access to the EU market for products from developing countries.

Recent News

First BTSF training on GMO analysis

The first Better Training for Safer Food activity on analysis of genetically modified organisms (GMO) is to take place in Foz de Iguazu, Brazil on 4-5 December 2009. This event is being organised by DG Health and Consumers together with the European Commission Joint Research Centre.

The regional networking meeting will bring together around 40 participants from across Latin America and the Caribbean. It is aimed at strengthening Latin American and Caribbean countries' capacities in the area of testing for the presence of GMOs.

Upcoming workshops

23-27 November: Better Training for Safer Food in Africa - regional food hygiene workshop for South Africa
30 November-4 December: Feed law, Barcelona
1-3 December: Rapid Alert System for Food and Feed, Johannesburg
7-11 December: Better Training for Safer Food in Africa - regional food hygiene workshop for South-Eastern Africa, Zambia
15-17 December: EU meat hygiene and controls legislation, Bangkok

The right sidebar contains a "Topics" menu with items: Home, Overview, Training programmes 2009, Potential participants, Potential tenderers, News (2008-2009), General information, History, and Annual report 2008. Below this are sections for "Resources" (Speeches, Press Releases, Publications, Consultations, Committees, Events) and "International Affairs" (Organisations, Codex, OIE, Import Conditions, Pets and Animal Welfare, Enlargement, Agreements, EU - Russia: SPS issues). At the bottom of the sidebar are buttons for "FOOD AND FEED SAFETY", "ANIMAL HEALTH AND WELFARE", "PLANT HEALTH", and "FVO INSPECTIONS".

The browser's taskbar at the bottom shows several open applications, including "Inbox - Micro...", "BTSF general...", "FW: Internat...", "EUROPA - Fo...", "Desktop", "Marco disk", "Agenda_Brazi...", "presentation...", and "BTSF Brazil D...". The system clock shows 13:53.

http://ec.europa.eu/food/training_strategy/index_en.htm



THANK YOU

FOR YOUR ATTENTION

