27+ countries
490+ million consumers
  - Educated, informed
    - with ATTITUDE
  - With high expectations
    - safety, quality, choice, availability, price, convenience, taste

Worlds’ largest importer of food
  Cannot afford to be protectionist
Outline

- Legal Framework
- Compare systems
- Problems
- WTO case
- R&D
Legal Framework

- WTO
- SPS
- Codex alimentarius Commission
- Biosafety protocol
- Internal EU
  - General
  - Specific
EU General Food Law

Regulation (EC) N° 178/2002

- General principles
- Liability
- Risk analysis
- Traceability
- Rapid Alert System
- EFSA
TRACEABILITY

NOT A FOOD SAFETY MEASURE PER SE, BUT A RISK MANAGEMENT TOOL

Food & feed business operators shall be able to:

- Identify from whom and to whom a product has been supplied and

- Have systems and procedures in place that allow for this information to be made available to the authorities (art. 18).

- Can have more detailed requirements for specific sectors to protect brands/areas
EU regulatory framework for GMOs

- GMO Deliberate Release Directive (Dir. 2001/18/EC)
- Traceability and labelling of GMOs and GM Food and Feed (Reg. (EC) No. 1830/2003)
- Reg. (EC) No. 1946/2003 on the transboundary movements of GMOs
... on the deliberate release into the environment of GMOs

- Clear definition of GMO and relative technology
- Scope: product containing GMOs or consisting of such organisms
- The experimental release of GMOs into the environment e.g. field trials
- The placing on the market of GMOs e.g. cultivation, importation or transformation
One door, one key

For products containing/consisting of GMOs:

- One application under Reg. 1829/2003 for the authorisation both of food/feed use and the deliberate release of GMOs into the environment - in accordance with the criteria of Dir. 2001/18

- Or the application — or part of the application — is split and submitted both under Dir. 2001/18 and Reg. 1829/2003

GMOs likely to be used as food and feed can only be authorised for both uses ⇒ after Starlink case
The authorisation procedure (1)

Basic approach:

- **Risk assessment:** European Food Safety Authority

- **Risk management:** European Commission through a regulatory committee procedure
The authorisation procedure (2)

First step - Application

- Submitted to MS competent authority
- Applicant has to include:
  - definition of the scope
  - indication of confidential parts
  - post-market monitoring plan if appropriate
  - detection method, samples and identification
- Receipt in 14 days and inform EFSA
The authorisation procedure (3)

EFSA – risk assessment

- GMO Panel – independent scientists
- Both environmental risk and human and animal health risks assessed
- Timeframe: 6 months unless further information needed
- Opinion opened for public comment (30 days)
The authorisation procedure (4)

Commission – risk management

- Draft decision granting/refusing authorisation (3 months)
- Justification if diverging from EFSA opinion
- Proposal to be approved by a qualified majority in the SCOFCAH (Member States representatives)

- If no QM ⇒ Council of Ministers
- If Council ⇒ no action or no QM ⇒ Commission adopts the decision (3 months)
The authorisation procedure (5)

- Authorisation
  - Granted for 10 years
  - Renewable for 10-year periods
  - Subject to a post-market monitoring

- Authorised products shall be entered in the public register of GM food and feed
Labelling rules and thresholds

Fundamental principle

GM products have to be labelled
LABELLING: OBJECTIVES

- Freedom to choose
- Avoid misleading the consumer
- Build confidence
- 94.6% want to have free choice on GM food (Source: Eurobarometer)
Presence of authorised GMOs:

Labelling and traceability requirements do NOT apply in case of adventitious or technically unavoidable presence if:

- Traces of authorised GMOs below the limit of 0.9%
- Operators have to prove that they have taken adequate measures to avoid the presence
Presence of unauthorised GMOs

Adventitious presence (burden of proof to the operators) of an unauthorised GMO:

- Positive assessment by an EU Scientific Committee is necessary
- The threshold is fixed at 0.5%

**Below:** labelling/traceability not enforced  
**Above:** prohibition to put the product on the market

Canice Nolan, 16-17 January 2008
Co-existence

- Farmers should be able to choose between conventional, organic and GM crop production
- Consumers should be able to make informed decisions
- Traders and retailers need orientation to organise markets
- Consequently, suitable measures during cultivation, harvest, transport, storage, and processing are necessary to ensure co-existence
- In addition, EU labelling rules provide orientation. Labelling is required for both, organic production and GMO use – not for safety reasons, but for transparency

Canice Nolan, 16-17 January 2008
GMO situation on the market

- Are there labelled products on the market? Question to MS
- November 2004: 77 GM-labelled products on the markets of 10 EU countries, mostly in France, Germany, the Netherlands, Czech and Slovak Republics
- Strong resistance from consumers
The EU, like the USA, does not assume that GMO products are safe.

Both the EU and the US have taken measures to ensure that only safe products enter the market.
COM separates trade, agriculture, health and consumer protection

COM separate risk assessment and risk management

Provide comprehensive and orderly system of law with:

Clear rules, roles, penalties and redress
Problems

Challenges with the current system:

- Missing data for safety or validation of detection method ⇒ EFSA “clock” not started or stopped
- Lacking support from Member States for authorisation process ⇒ final decision is left to Commission
- Consumer resistance and companies’ poor communication strategy
Current EU debate

At a 2007 Stakeholder Conference in Vienna:

- A clear majority were in favour of further improvements to the scientific basis of the risk assessment to achieve more transparency and increased scientific dialogue.

- Many misgivings about the use of the comitology procedure for the authorisation of GMOs.

- Demand for rejection of applications by simple majority.
Regulatory authorities must address legitimate concerns of the citizens

- The European system of authorization is science-based and transparent.
- The authorisation system works and it delivers results within reasonable timelines.
- There is no EU moratorium.
- Asynchronous authorisations may pose trade problems.
- 2006 survey shows unchanged, strong concerns.
May 2003, the U.S., Argentina and Canada requested WTO consultations on the EU’s authorisation system for GMOs and GM food

After consultations which took place in June 2003, the three asked for the establishment of a Panel to settle the controversy

Three types of measures under challenge:
- an alleged *de facto* “moratorium” on the approval of agricultural biotechnology products since October 1998
- failure to consider for approval specific products, or the unjustified delays in the procedures
- national “safeguard measures” taken by six MS
WTO case

- Report made public 29 September 2006
- Adopted on 28 November 2006
- No appeal lodged
- “We are all winners”
- 19 December 2006 at DSB agreement to discuss timetable within 45 days
- The EU is currently discussing next steps with USA, CA, ARG
- 11 January 2008 is a key date
WTO case

- The Panel ruling does not affect the EU legislation and policy on GMOs (this was not even part of the dispute)

- Despite the claims of the complainants, the violation findings made by the report are mostly limited to procedural obligations; e.g. alleged **undue delays** in processing some applications for approval of GMOs in the past

- The Panel rejected the vast majority of the complainants' arguments

- Since the Panel was established in 2003, 13 authorisation decisions have been adopted and more than 30 applications are currently being examined

- This confirms that the EU system for GM approval authorisations is functioning in application of EU law
While US GM approval times lengthen and EU ones shorten, we look for a convergence one day.

Other examples in the USA:
- Flowers, plants in soil – ~30 years
- Vines for propagation – ~10 years
- Potatoes – 5 years
- BSE – >3 years

These are not times to a solution – they are unresolved issues and the clock is still running
Both, GM and organic agriculture grow strongly due to demands of the farming community and of the consumer.

Businesses must take customer demands seriously.

Market differentiation needs some organisation to function.

Authorities must take citizen’s concerns seriously – a regulatory system must reflect this respect.

The regulatory system must also respect WTO rules.

The EU rules for approval and labelling strike this balance.
Multi-annual and multinational Framework Research programs

Cooperation with third countries

Call for proposals currently open – deadline 26 February 2008 for agricultural biotech R&D projects

www.cordis.europa.eu/fp7

1st global conference on GMO analysis – Como 24-27 June 2008 (gmoglobalconference.jrc.it)
Scope for more discussion

- Adventitious presence
  - Authorised
  - Unauthorised
- Asynchronous approvals
- Analysis

- Cloning
On the Web

General Information
http://ec.europa.eu/food/index_en.htm

Food and Feed Law
http://ec.europa.eu/food/food/foodlaw/index_en.htm

Biotechnology
http://ec.europa.eu/comm/food/food/food/biotechnology/index_en.htm

European Food Safety Authority
http://efsaeuropa.eu/

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