2nd decade of agricultural biotechnology in the EU

EUROPEAN UNION
DELEGATION OF THE EUROPEAN COMMISSION TO THE USA

Canice Nolan - EC Delegation to the USA

The EU

- 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

EUROPEAN COMMISSION

Health & Consumer Protection
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Outline

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

Legal Framework

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

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)
- GM Food and Feed Regulation (Reg. (EC) No. 1829/2003)
- 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

Dir 2001/18/EC

... 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

⇩⇩⇩⇩

<u>GM products have to be labelled</u>

LABELLING: OBJECTIVES

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

Thresholds

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

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

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

Compare systems

- 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

Compare systems

- 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.

WTO case

- 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

Undue delay?

- 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

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Summary

- 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.

R&D

- 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/biotechnology/index_en.htm

European Food Safety Authority

http://efsa.europa.eu/

… and if all else fails, contact

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