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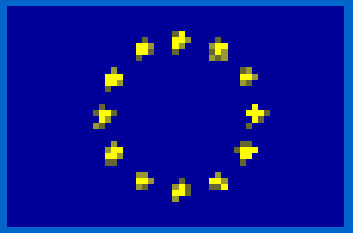
EU REGULATORY FRAMEWORK ON GM FOOD AND FEED

Historical evolution, legislation in vigour, state of play, steps forward

Structure of the presentation

- Part I – Historical background
- Part II – The new legislative framework: Regulation (EC) No 1829/2003
- Part III – State of play: approved products and pending applications



Part I

Introduction to the historical evolution of the EU legislative framework

The evolution of the biotech sector

- 70s: increasing academic research
- 80s: emerging DBF in the US
- 1985 first successful GM plant
- 1997 GM soy shipped to the EU

V1 vallemc; 18.10.2005

Need for European legislation

- Avoiding trade barriers in this emerging sector
- Fostering innovation via a clear legislative framework
- Managing possible risks connected with the new technology

"Old" legislative framework for GMO and GM Food

Directive 90/219/EC Contained use of GMO
Directive 90/220/EC Deliberate release of GMO
Regulation (EC) No 258/97 on Novel Food

Directive 90/220
Deliberate Release into the Environment

- ‘Organism' is any biological entity capable of replication or of transferring genetic material
- GMO definition

  «Genetically modified organism (GMO) means an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination»
- Annex IA ⇨ list of techniques which lead to a GM

Directive 90/220
Deliberate Release into the Environment

- Take into account different aspects related to
  - risks for the environment
  - risks for human health
  - use, labelling, packaging
  - continuous evaluation
- R & D purposes (part B) ⇨ notification to CA
- Placing on the market (part C) ⇨ EU procedure in case of objections
  - Requirements under part B + Annex III

Novel foods or novel food ingredients

Regulation 258/97

- No significant presence in the EU market ⇨ first shipment 1997
- 6 categories of novel foods and ingredients
  - containing GMOs
  - produced from GMO
  - Others
- Do not apply to additives and flavourings

Use as food or food ingredient
Regulation 258/97

- General conditions
  - not a danger for the consumer
  - not misleading
  - not differ from current foods or food ingredients
- Scientific assessment:
  Recommendation 97/618

Authorisation procedures
Regulation 258/97

- Full authorisation (art. 7)
- First assessment by the MS where first placing on the market
- Application should include proposed labelling
- If positive assessment⇨ Commission ⇨ other MS
- In case of objections consultation of the SCF and draft proposal to be approved by a QM
- Simple notification to the Comm. (art. 5)
- Substantial equivalence to existing foods or food ingredients (composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein).

Labelling
Regulation 258/97 (art. 8)

- Any property causing a non-substantial equivalence
- Possible effects on human health (ex. allergenicity)
- Ethical considerations
- Presence of a GMO (Ref. to Dir. 90/220)

Labelling
Regulation 1139/98

- Application of Regulation 258/97 (GM soy and maize already approved)
- Food with DNA and/or proteins from GMOs
- General approach ⇨ compulsory labelling
  - « produced from genetically modified ...»
  - « … genetically modified»

Labelling
Regulations 49/2000 and 50/2000

- Ingredients (Reg. 49/2000)
  - Keeps the DNA/protein based approach
  - 1% tolerance for adventitious presence

- Additives (Reg. 50/2000)
  - Additives/Flavourings no longer equivalent if they contain protein/DNA resulting from GM
  - Compulsory labelling

GM Feed: Situation before 2003

- No specific legislation
- Authorised under Directive 90/220/EC
- No labelling of derived products

Food Safety becomes an issue

- 1995: BSE crisis
- [*1997: First shipments of GM soy/corn]*
- 1999: Dioxin crisis
- 2000: UK F & M out-break

Food safety high on consumers'/citizens' agenda

EU citizens' view on GMOs

- 24% of EU citizens are concerned about the use of GMOs in agri (43% in some MS)
- 40% consider that they lack information
- Environmental NGOs remain the most trusty sources of information (42%) before scientists (32%)

Source: Eurobarometer 2004

Towards a new legislative framework: the White Book on food safety

- «From farm to fork» strategy
- Sound scientific risk analysis and precautionary principle
- Improvement of controls
- Inform and Involve the stakeholders
- Attention to existing/planned int'l standards
- Food and Feed integrated approach

«General Food law»
Regulation 178/2002/EC

- High level of protection of human health
- Protection of consumers' interests
- Common basis for measures governing food and feed ⇨ effective functioning of the internal market

⇩⇩⇩⇩

↳ Creation of EFSA for sound scientific opinions

↳ Traceability ⇨ business operators liability

European Food Safety authority

- Key EU institution for food and feed safety
- Best possible independent scientific opinions
- Uniform R.A. methodologies
- Scientific and technical support for the Commission
- Internationally recognised safety assessments
- Collaboration of national scientific assessment bodies and link between Commission and MS in the RASFF

Traceability: definition

- Definition "The ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution"
- It applies at all stages of production, processing and distribution
- Business operators have to apply appropriate procedures and are liable for infringements

The EU GM legislative framework of the 90's in question

- Directive 90/220/EC had to be reviewed (1998)

- Need for a regulatory approach taking into account the evolution of the market and integrating food and feed in accordance with Reg. 178/2002

New legislative framework

Directive 2001/18 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

Part II

The new legislative framework: Regulation (EC) No 1829/2003 on GM food and feed and its interaction with the other legislative texts

Overview

A - Scope of the legal acts and their interaction

B - The authorisation procedure

C - Labelling rules

D - Thresholds

E - Conclusions

18 April 2004 – New legislative framework

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

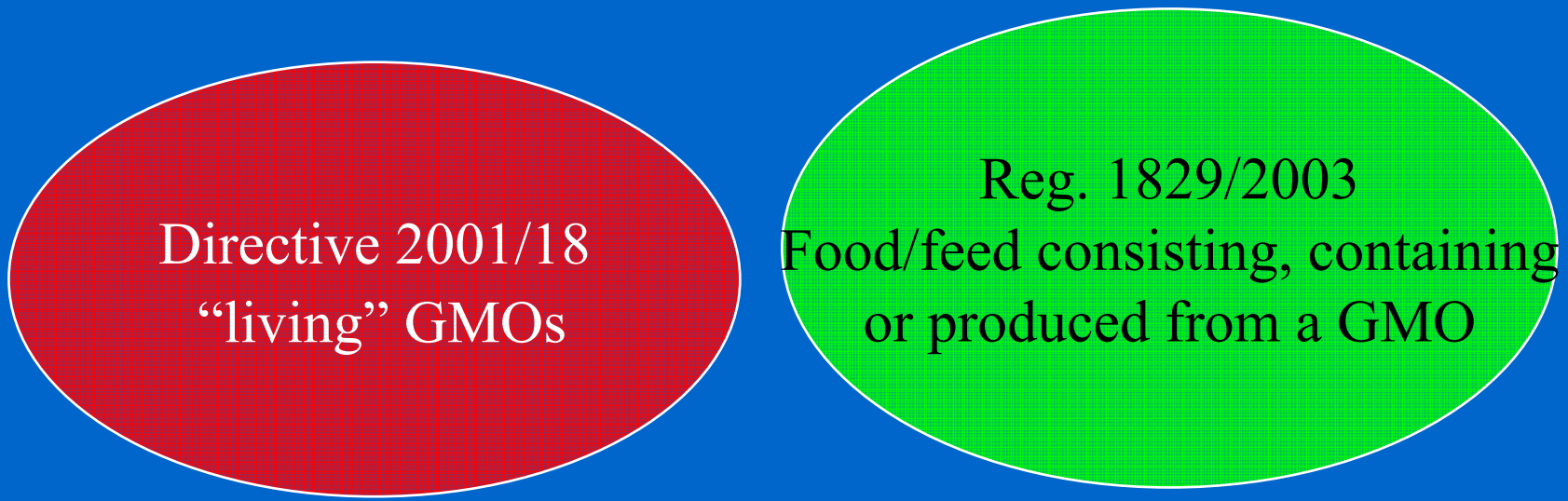
Regulation (EC) No 1829/2003 on GM food and feed

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

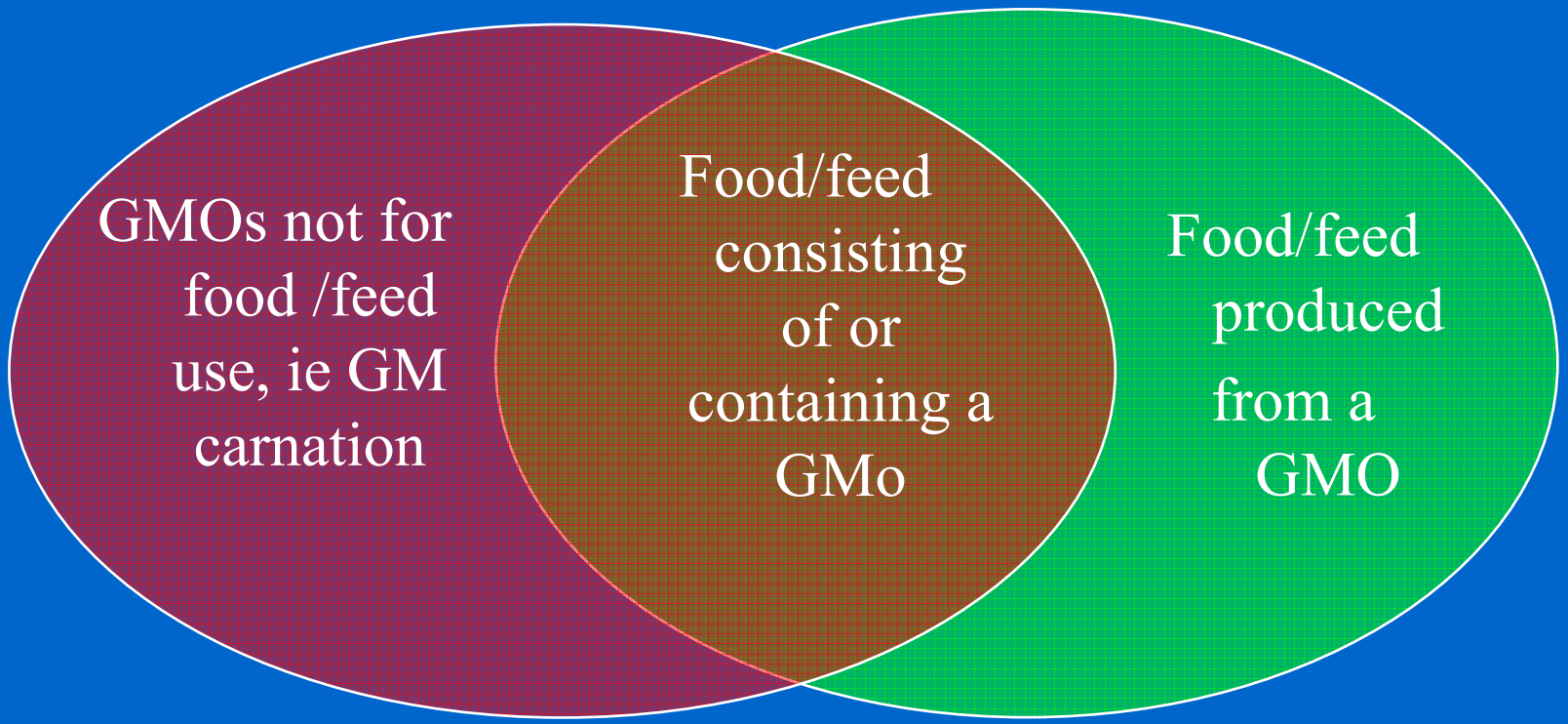
Directive 2001/18/EC

- Directive 2001/18/EC on the deliberate release into the environment of GMOs
  - Clear definition of GMO and relative techn.
  - Scope: product containing GMOs or consisting of such organisms
  - The experimental release of GMOs into the environment (for example field trials)
  - The placing on the market of GMOs (for ex. cultivation, importation or transformation)

A - Scope of Directive 2001/18 and Regulation 1829/2003



Interaction between Directive 2001/18 and Regulation 1829/2003



One door one key principle

- 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

B – Innovations of the new framework

- Principles
  - Centralised and transparent authorisation procedure with a clear time frame
  - New rules on traceability and labelling
  - Applies on newly authorised products and existing products
  - Clarifies what is currently on the market

The authorisation procedure (1)

- Fundamental 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 the competent authority of a MS
  - ❖ 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 envir. risk and human and animal health
  - Timeframe: 6 months unless further information needed
  - Opinion submitted to public comments (30 days)

Guidance documents: http://www.efsa.eu.int

The authorisation procedure (4)

- Commission role – 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 Minister
  - 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

C - Labelling rules and thresholds

Fundamental principle

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GM products have to be labelled

Labelling rules

- According to Reg. (EC) No. 1829/2003
  - Scope of labelling enlarged to include GM origin «derived from» or «produced from»
  - Labelling requirements apply to derived products regardless of the presence of modified DNA or proteins ⇨highly refined products (oil, lecithin...) and compound feed included
  - NOT for products obtained from animals fed with GM feed or treated with GM medicines (eggs, milk, meat)
  - NO negative labelling

How do we label? (1)

- List of ingredients
  - More than 1 ingredient ⇨ «genetically modified» or «produced from genetically modified [ingredient]» in parentheses following the ingredient concerned
  - Category ⇨ «contains genetically modified [organism]» or contains [ingredient] produced from genetically modified [organism]»
  - Within the list or in footnote of the list (font of the same size)
- No list of ingredients
  - "genetically modified" or "produced from genetically modified (name of the organism) clearly visible on the label
- No pre-packaging (NEW) ⇨ food display or next to it

How do we label? (2)

- In addition:

- Differences from the conventional counterpart

  a) composition

  b) nutritional value/effects

  c) intended use of the food

  d) implication for the health of certain sections of the population)

- If the food may give rise to ethical or religious concerns

How do we label? (3)

- Specific discipline of Reg. 1830/2003
  - "This product contains GMOs" or
  - "This product contains GM [name of the organism]"

  Pre-packaged ⇨ on a label

  Non pre-packaged ⇨on the display or in connection with the product

D - Thresholds: presence of authorised GMOs

- Labelling and traceability requirements do NOT apply in case of adventitious or technically unavoidable presence IF
  - Traces of an authorised GMOs below the limit of 0.9%
  - Operators have to prove that they have taken adequate measures to avoid the presence

Thresholds: 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 and traceability not enforced

  Above prohibition to put the product on the market

E – Final considerations

- The framework is being successfully implemented
- Major challenges of 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
  - Consumers' resistance and companies' poor communication strategy
- Report on implementation is due by November 2005 ⇨ questionnaires to MS and stakeholders

More info

http://europa.eu.int/comm/food/food/biotechnology/index_en.htm

Part III

State of play for GM food and feed products: authorisations and applications

Categories of GM food and feed on the EU Market

1. Existing products already on the market
2. Newly authorised under Novel Food Regulation (transitory measures)
3. Newly authorised under Dir. 2001/18 (transitory measures)
4. New applications under Reg. (EC) No 1829/2003

1. Existing products: Notification until 18 October 2004

- Food and feed, that fall into the scope of the Regulation and are on the market needed to be notified to the Commission
- 26 existing products were notified
- Existing products are subject to the requirements of the new legislation
  - Data package
  - Labelling and traceability requirements
  - Validation of detection method

Notified existing products

- GMOs authorised under Directive 90/220
- GM food and ingredients notified under the Novel Food Regulation
- Not regulated food/feed already on the market without a specific authorisation (ex. food additives/feed materials produced from GMOs)

Notified products: Examination until 18 April 2005

- After examination of the dossier all the 26 notifications accepted ⇨ entry into the Register of GM food and feed (12 maize, 6 oils. r., 5 cotton, 1 soyb., biomass, yeast cr.)
- Can remain on the market between 3-9 years then renewal
- Some products were not notified ⇨ no longer allowed on the market
- Validation of detection methods to be completed

http://europa.eu.int/comm/food/food/biotechnology/authorisation/commun_register_en.htm

2. Newly authorised products under Novel Food Regulation

- Art. 46§1 of Reg. 1829/2003 – requests submitted under NFR for which safety assessment already forwarded to the Commission
- Application upgraded to the standards of Reg. 1829/2003 but dealt accordingly to NFR
- Bt11 and NK 603 maize authorised in 2004
- GA 21 & MON 863 maize authorised on 13/01/06

3. Newly authorised products under Dir. 2001/18

- Art. 46§3 of Reg. 1829/2003 – left over of the Directive assessment already forwarded to Com
- NK 603 maize authorised in Sept. 2004
- Mon 863 maize and GT 73 soybean adopted in August 2005

4 - New applications under Reg. (EC) No 1829/2003

- 33 applications received since the entry into force of the Regulation ⇨ 1507 just approved
- GM food and feed uses, import and processing + 8 cultivation
- Most of them maize (23), but also 4 cotton, 2 soybean, 1 rice, 1 sugar beet, 1 potato and 1 oilseed rape variety

1507 GM maize – 1st product to be authorised under Reg. 1829/2003

- EFSA opinion on 3 of March 2005
- Commission put authorisation proposal to vote after three months (03/06/2005)
- No QM in the SCOFCAH ⇨ Council
- No QM in Council
- Final adoption by the Commission 03/03/06

1507 GM maize – the interaction between different legal acts

- Application as food under Regulation (EC) No 1829/2003 on GM food and feed
- Application for import and processing under Directive 2001/18 – approved on 03/11/2005
- Application for cultivation under Directive 2001/18

Final remark: the situation on the market

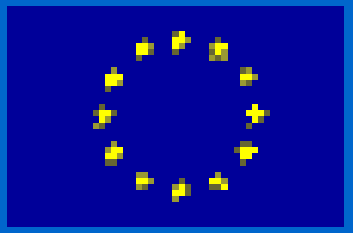
- Are there labelled products on the market? Question to Member States
- November 2004: only 77 GM labelled products on the markets of 10 EU countries, mostly in France, Germany, the Netherlands and Czech and Slovak Republics
- Strong resistance from the consumers' side

Conclusions

- GM food and feed are already on the EU market although still the object of public resistance
- Reg. 1829/2003 has clarified what is on the market via the notification procedure
- An increasing number of applications will be introduced through Reg. 1829/2003

The way ahead

- As stated in the meeting of 22 March 2005 the European Commission will work on the full implementation of the described legal framework



Thank you !!!