EU regulatory framework on GMOs

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History

- 1990:
  Adoption of Directives 90/219/EEC on contained use of GMOs and 90/220/EEC on the deliberate release of GMOs into the environment
- 1992 – 1998:
  18 GMOs authorised under Directive 90/220/EEC for placing on the market in the EU
- 1999: The Council requested the Commission to:
  - *adopt more stringent and transparent rules for the placing on the market of GMOs*
  - *to put in place rules on labelling and traceability*
- 2000:
  Signature of the Cartagena Protocol on Biosafety
- 2001 – 2003:
  Revision of the EU legal framework on biotechnology

The revised regulatory framework

- Directive 2001/18/EC on the deliberate release of GMOs into the environment (ENV)
- Regulation 1830/2003 on labelling and traceability of GMOs (ENV)
- Regulation 1829/2003 on GM food and feed (SANCO)
- Regulation 1946/2003 on the transboundary movements of GMOs (ENV)

- These rules are complemented by a large number of technical guidelines

Overview

- Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms
- Directive 90/219/EEC on the contained use of genetically modified micro-organisms
- Regulation 1830/2003 on the traceability and labelling of GMOs and GM food and feed products
- Regulation 1946/2003 on the implementation of the Cartagena Protocol

Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC

Directive 2001/18/EC Structure

- PART A: General provisions
- PART B: Release for research purposes
- PART C: Release for placing on the market
- PART D: Final provisions
- 8 Annexes

Directive 2001/18/EC: Objectives

- To protect human health and the environment when:

  a. releasing GMOs into the environment for any purposes, such as experimental uses

  b. placing on the market GMOs as or in products

(Art. 1)

Directive 2001/18/EC: General obligations

- Environmental risk assessment to be carried out before the submission of any notification (notifiers);
- Case-by-case assessment of the potential adverse effects on human health and the environment (Member States and the Commission);
- Designation of competent authorities in order to examine the notifications (Member States);
- Inspections and control measures (Competent Authorities of Member States);
- Measures to ensure traceability of marketed products (Member States)

(Art. 4)

Directive 2001/18/EC: Definition of a GMO

- Genetically Modified Organism (GMO) means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination
- Following techniques are **not** considered to result in genetic modification:
  - in vitro fertilisation;
  - natural processes such as conjugation, transduction and transformation;
  - polyploidy induction

(Art. 2(2))

Directive 2001/18/EC: Deliberate release into the environment

- Deliberate release into the environment means any intentional introduction into the environment of a GMO or a combination of GMOs for which no specific containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment

(Art. 2(3))

Directive 2001/18/EC, Part B: Deliberate release of GMOs for any other purpose than for placing on the market

Directive 2001/18/EC, Part B: Standard authorisation procedure (1)

- Any person must submit a notification to a competent authority of a Member State within whose territory the release is to take place.

(Article 6)

Directive 2001/18/EC, Part B: Standard authorisation procedure (2)

- The competent authority shall respond in writing to the notifier within 90 days of receipt of the notification
- Summary of notifications accessible to all Member States

(Article 6)

Directive 2001/18/EC, Part C: Notification procedure

- The notification shall be submitted to the competent authority of the Member State where such a GMO is to be placed on the market for the first time

(Article 13)

Directive 2001/18/EC, Part C:
Timeframes for placing on the market

- The Member State which receives the notification has 90 days to prepare an assessment report
- Other Member States and the Commission have 60 days to comment on the assessment report
- The “clock” stops if the competent authority of the Member State requests further information
- The “clock” restarts when further information is provided and circulated
- If the Commission or other Member States raise and maintain objections against the authorisation of the product: “Community procedure”

(Art. 14 – 18)

Directive 2001/18/EC, Part C: Community procedure

- The Commission consults with EFSA on the raised objections. EFSA issues an opinion within 90 days
- The Commission submits its draft decision to the Regulatory Committee
- If the Regulatory Committee issues no decision or a decision against the draft proposal, the Commission submits the proposal to the Council
- If the Council fails to decide within three months, the Decision shall be adopted by the Commission
- The Commission has in total 120 days to adopt/publish a Decision, not counting the time of EFSA consultation or if awaiting further information from the notifier

Directive 2001/18/EC, Part C: Issuance of consent

- When a favourable decision has been taken, the competent authority which initially prepared the assessment report shall give its final consent within 30 days following the publication of the decision

(Article 18)

Directive 2001/18/EC, Part C: Content of the consent

- A GMO (as or in a product) can be marketed only upon a written consent of the competent authority
- The consent explicitly specifies:
  - its scope, including the identity of the GMO and its unique identifier;
  - the period of validity;
  - the conditions for the placing on the market, including handling and packaging;
  - eventual control sampling;
  - labelling requirements;
  - monitoring requirements

(Article 19)

Directive 2001/18/EC, Part C: Products on the market or pending

- 18 products approved under Directive 90/220/EEC – e.g. soybean, maize, chicory, carnations and vaccines against rabies and other diseases
- 4 products approved under Directive 2001/18/EC (NK603, MON863 and 1507 maize, and GT73 oilseed rape)
- As of today 7 products are pending under Directive 2001/18/EC (e.g. maize, potato with altered starch composition, oilseed rape and carnation)

Directive 2001/18/EC, Part C: Labelling

- Member States shall take all measures to ensure the labelling of GMOs at all stages of the placing of the market.
- For products where adventitious or technically unavoidable traces of authorised GMOs cannot be excluded, a minimum threshold may be established below which these those products shall not have to be labelled.
- The threshold levels shall be established according to the product concerned.
- The general threshold set through Regulation 1830/2003/EC for products of direct processing is 0,9%.

(Art. 21)

Directive 2001/18/EC, Part C: Free circulation clause

- Member States may not prohibit, restrict or impede the placing on the market of GMOs which are authorised according to the Directive.
- This prohibition covers general bans on GMOs in a particular region or/and for a particular period, or additional requirements raised by Member States

(Article 22)

Directive 2001/18/EC, Part C: Safeguard clause (1)

- A Member State can provisionally restrict or prohibit an authorised GMO as or in product on following cumulative conditions:
  - reception of new or additional information since the date of the consent, based on new or additional scientific knowledge;
  - the information affects the environmental risk assessment that was carried out by the notifier;
  - there are detailed grounds that the GMO constitutes a risk to human health or the environment

(Article 23)

Directive 2001/18/EC, Part C: Safeguard clause (2)

- The Member State which raises the safeguard measure shall immediately inform the Commission and the other Member States.
- A decision on the notified safeguard measure shall be made within 60 days according to the Committee Procedure (Regulatory Committee)
- The period needed for EFSA and the Council to decide, or for the notifier to eventually submit additional requested information, is not taken into account

(Article 23)

Directive 2001/18/EC, Part D: National “co-existence” measures

- Member States may take appropriate measures to avoid the unintended presence of GMOs in other products
- These measures concern so far the co-existence of GM crops with conventional and organic crops.
- Up to date 10 Member States have notified to the Commission more than 20 legislative acts regulating the co-existence of GM and other types of crops

(Article 26a)

Directive 2001/18/EC, Part D: The Scientific Committee (EFSA)

- Directive 2001/18/EC was adopted before the establishment of EFSA (European Food Safety Authority).
- Since its establishment, and according to the provisions of Regulation 178/2002/EC, EFSA has replaced the Scientific Committee mentioned in the Directive.

(Art. 62, Regulation 178/2002/EC)

Directive 2001/18/EC, Part D: Consultation of Scientific Committee (EFSA)

- During the authorisation procedure, EFSA shall be consulted by the Commission:
  - in case where a competent authority or the Commission raises an objection regarding the risks of the GMO to human health or the environment;
  - in case the assessment report of the competent authority that received the notification indicates that the GMO should not be placed on the market
- EFSA may also be consulted by the Commission on any other matter that may have an adverse affect on human health and the environment

(Article 28)

Directive 2001/18/EC Annexes

- The Annexes constitute a very significant part of the Directive, since they provide for the technical elements of its implementation.
- They lay down provisions on issues such as:
  - The techniques in order to determine genetic modification
  - Principles for the environmental risk assessment;
  - Information required in the notifications;
  - Guidelines for the assessment reports;
  - Guidelines for the monitoring plans

(Annexes I A – VII)

Directive 2001/18/EC, Part C: Implementing measures (1)

- Commission Decision 2002/623/EC:

  Guidance notes for environmental risk assessment

- Council Decision 2002/811/EC:

  Guidance notes for monitoring

- Council Decision 2002/812/EC:

  Summary notification Part C format

- Council Decision 2002/813/EC:

  SNIF Part B

Directive 2001/18/EC, Part C: Implementing measures (2)

- Commission Decision 2003/701/EC:
  Establishment of a format for presenting the results of deliberate release of higher plants for research purposes
- Council Decision 2004/204/EC:
  Detailed arrangements for the operation of the GM registers
- Commission Regulation (EC) 65/2004:
  System for the development and assignment of unique identifiers
- Commission Decision 2005/463/EC:
  Establishment of a network group for the exchange and co-ordination of information on co-existence

Directive 90/219/EEC on the contained use of genetically modified micro-organisms Objective

- To lay down measures for the contained use of genetically modified micro-organisms with a view to protecting human health and the environment

(Article 1)

Directive 90/219/EEC
Definition of the “contained use”

- Contained use shall mean any operation in which micro-organisms are genetically modified or in which such genetically modified micro-organisms are cultured, stored, used, transported, destroyed or disposed of and for which physical barriers (…) are used to limit their contact with the general population and the environment

(Art. 2(c))

Directive 90/219/EEC Classification of GMOs

- Group I: Those satisfying the criteria of Annex II (non-pathogenic and as safe in the reactor or fermentor as recipient or parental organism, but with limited survivability and/or replicability without adverse consequences in the environment)
- Group II: Those other than in Group I

(Art. 4)

Directive 1990/219/EEC Notifications

- Users of genetically modified micro-organisms are required to submit their notifications to the Member States competent authorities before commencing their contained use.
- In case of a genetically modified micro-organism under Group I, the contained use may proceed 90 days after the submission in case the competent authority does not indicate to the contrary
- In case of a genetically modified micro-organism under Group II, the contained use may proceed only upon the consent of the competent authority. The competent authority must issue the consent within 90 days from the submission

(Art. 11(4))

Directive 1990/219/EEC Obligations for MS

- Appropriate measures in order to avoid adverse effects on human health and the environment;
- Application of principles of good micro-biological practice;
- Designation of competent authorities;
- Existence of emergency plans;
- Availability of information on safety measures in the case of an accident;
- Inspections of installations
- Conduct and forward to the Commission of summary reports

(Art. 6, 7, 11, 14, 15, 17, 18)

Regulation (EC) No 1830/2003, concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC

Regulation 1830/2003/EC Objectives and scope

- Objective: to facilitate accurate labelling, monitoring the effects on the environment and, where appropriate, on health, and the implementation of the appropriate risk management measures
- Scope: authorised GMO products, food produced from authorised GMOs and feed produced from authorised GMOs

(Art. 1 and 2)

Regulation 1830/2003/EC Traceability

- Operators shall ensure that the following information is transmitted in writing to the operator receiving the product:
  - that it contains or consists of GMOs;
  - the unique identifier assigned to those GMOs (namely a simple numeric or alphanumeric code which serves to identify the GMO)

(Art. 4)

Regulation 1830/2003/EC Labelling

- The words “This product contains genetically modified organisms” or “This product contains genetically modified (name of organism(s)) appear on the label of a pre-packaged product or on the display of non-pre-packaged products

(Art. 6)

Regulation 1830/2003/EC General labelling threshold

- The general labelling obligation does not apply on products intended for direct processing with traces of authorised GMOs in a proportion lower than 0,9%
- These traces must be adventitious or technically unavoidable

(Art. 7, amending Art. 21 of Directive 2001/18/EC)

Thank you!