

**Proposal for a Regulation of the European Parliament and of the Council concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC**

(2001/C 304 E/22)

(Text with EEA relevance)

COM(2001) 182 final — 2001/0180(COD)

(Submitted by the Commission on 20 August 2001)

THE EUROPEAN PARLIAMENT AND THE COUNCIL  
OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95(1) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

- (1) Directive 2001/18/EC of the European Parliament and the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Directive 90/220/EEC of the Council <sup>(1)</sup>, as amended by Regulation (EC) No .../2002 [on genetically modified food and feed], requires Member States to take measures to ensure traceability and labelling of authorised genetically modified organisms (GMOs) at all stages of their placing on the market.
- (2) Differences between national laws, regulations and administrative provisions concerning traceability and labelling of GMOs as products or in products as well as traceability of food and feed produced from GMOs may hinder their free movement, creating conditions of unequal and unfair competition. A harmonised Community framework for traceability and labelling of GMOs should contribute to the effective functioning of the internal market. Directive 2001/18/EC should be amended accordingly.
- (3) Traceability requirements for GMOs should facilitate both the withdrawal of products where unforeseen adverse effects to human health, animal health or the environment are established, and the targeting of monitoring to examine potential effects on, in particular, the environment.

(4) Traceability requirements for food and feed produced from GMOs should be established to facilitate accurate labelling of such products, in accordance with the requirements of Regulation (EC) No .../2002 [on genetically modified food and feed], so as to enable operators and consumers to exercise their freedom of choice in an effective manner as well as control and verification of labelling claims. Requirements for food and feed produced from GMOs should be similar in order to avoid discontinuity of information in cases of change in end use.

(5) Transmission and retention of information that products contain or consist of GMOs, and the unique codes for those GMOs, at each stage of their placing on the market provides the basis for appropriate traceability and labelling for GMOs. The codes may be used to access specific information on GMOs from a register, and to facilitate their identification, detection and monitoring in accordance with Directive 2001/18/EC.

(6) Transmission and retention of information that food and feed have been produced from GMOs also provides the basis for appropriate traceability of products produced from GMOs.

(7) Guidance on sampling and detection should be developed in order to facilitate a coordinated approach for control and inspection, and provide legal certainty for operators.

(8) Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation.

(9) Certain traces of GMOs in products may be adventitious or technically unavoidable. Such presence of GMOs should therefore not trigger labelling and traceability requirements.

(10) Since the measures necessary for the implementation of this Regulation are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission <sup>(2)</sup>, they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision.

<sup>(1)</sup> OJ L 106, 17.4.2001, p. 1.

<sup>(2)</sup> OJ L 184, 17.7.1999, p. 23.

- (11) Systems for the development and assignment of unique codes for GMOs should be established before the measures relating to traceability and labelling can be applied.
- (12) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union,

HAVE ADOPTED THIS REGULATION:

#### Article 1

##### Subject matter

This Regulation provides a framework for the traceability of genetically modified organisms (GMOs), and food and feed produced from GMOs, with the objective of facilitating accurate labelling, environmental monitoring and withdrawals of products.

#### Article 2

##### Scope

1. This Regulation shall apply, at all stages of the placing on the market, to:
- (a) products consisting of, or containing GMOs, placed on the market in accordance with Community legislation;
- (b) foods and food ingredients, including food additives and flavourings, produced from GMOs, placed on the market in accordance with Community legislation;
- (c) feed materials, compound feedingstuffs and feed additives, produced from GMOs, placed on the market in accordance with Community legislation.
2. This Regulation shall not apply to medicinal products for human and veterinary use authorised under the provisions of Council Regulation (EEC) No 2309/93 <sup>(1)</sup>.

#### Article 3

##### Definitions

For the purpose of this Regulation:

1. 'genetically modified organism' means genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC;

2. 'produced from GMOs' means derived, in whole or in part, from GMOs, but not containing or consisting of GMOs;
3. 'traceability' means the ability to trace GMOs and products produced from GMOs at all stages of their placing on the market through the production and distribution chains;
4. 'unique code' means a simple numeric or alphanumeric code which serves to identify a GMO on the basis of the authorised transformation event from which it was developed and providing the means to retrieve specific information pertinent to that GMO;
5. 'operator' means a person who places a product on the market and also a person who receives a product that has been placed on the market in the Community, at any stage of the production and distribution chain, but does not include the ultimate consumer;
6. 'food' means food as defined in [Article 2 of the Proposal for a Regulation of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food];
7. 'food additive' means food additive as defined in Article 1(2) of Council Directive 89/107/EEC <sup>(2)</sup>;
8. 'flavouring' means flavouring as defined in Article 1(2) of Council Directive 88/388/EEC <sup>(3)</sup>;
9. 'feed' or 'feedingstuff' means feed or feedingstuff as defined in [Article 3(4) of the Proposal for a Regulation laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food];
10. 'compound feedingstuffs' means compound feedingstuffs as defined in Article 2(b) of Council Directive 79/373/EEC <sup>(4)</sup>;
11. 'feed materials' means feed materials as defined in Article 2(a) of Council Directive 96/25/EC <sup>(5)</sup>;
12. 'feed additives' means additives as defined in Article 2(a) of Council Directive 70/524/EEC <sup>(6)</sup>;
13. 'placing on the market' means making available to third parties, whether in return for payment or free of charge;

<sup>(2)</sup> OJ L 40, 11.2.1989, p. 27.

<sup>(3)</sup> OJ L 184, 15.7.1988, p. 61.

<sup>(4)</sup> OJ L 86, 6.4.1979, p. 30.

<sup>(5)</sup> OJ L 125, 23.5.1996, p. 35.

<sup>(6)</sup> OJ L 270, 14.12.1970, p. 1.

<sup>(1)</sup> OJ L 214, 24.8.1993, p. 1.

14. 'the first stage of the placing on the market of a product' means the initial transaction in the production and distribution chains, where a product is made available to a third party;
15. 'pre-packaged' means any single item for sale to the ultimate user, consisting of a product and the packaging into which it was put before being offered for sale, whether such packaging encloses the product completely or only partially, but in such a way that the contents cannot be altered without opening or changing the packaging.

#### Article 4

##### Traceability and labelling requirements for GMOs

1. When placing pre-packaged products consisting of, or containing GMOs on the market, operators shall ensure that the words 'This product contains genetically modified organisms' appear on a label.

2. At the first stage of the placing on the market of a product consisting of or containing GMOs, including bulk quantities, operators shall ensure that the following information is transmitted to the operator receiving the product:

- (a) that it contains or consists of GMOs;
- (b) the relevant unique code(s) assigned to those GMOs in accordance with Article 8.

However, the information referred to in point (b) may be replaced by a declaration by the operator that the product shall only be used as food or feed, or for processing, together with the unique codes for the GMOs that the product may contain.

3. At all subsequent stages of the placing on the market of products referred to in paragraph 2, operators shall ensure that the information received in accordance with paragraph 2 is transmitted to the operators receiving the products.

4. Without prejudice to Article 6, operators shall have in place systems and procedures to allow the identification, for a period of five years from each transaction, of the person from whom and to whom the products referred to in paragraph 2 have been made available.

5. Paragraphs 1 to 4 are without prejudice to other specific requirements in Community legislation.

#### Article 5

##### Traceability requirements for products produced from GMOs

1. When placing products produced from GMOs on the market, operators shall ensure that the following information is transmitted to operators receiving the product:

- (a) an indication of each of the food ingredients, including additives and flavouring(s), which is produced from GMOs;
- (b) an indication of each of the feed materials or additives which is produced from GMOs;
- (c) in the case of products for which no list of ingredients exists, an indication that the product is produced from GMOs.

2. Without prejudice to Article 6, operators shall have in place systems and procedures to allow the identification, for a period of five years from each transaction, as to the person from whom and to whom the products referred to in paragraph 1 have been made available.

3. Paragraphs 1 and 2 are without prejudice to other specific requirements in Community legislation.

#### Article 6

##### Exemptions

1. In cases where Community legislation provides for specific identification systems, such as lot or batch numbering for pre-packaged products, operators shall not be obliged to retain the information specified in Articles 4(2), 4(3) and 5(1), provided that this information and the lot or batch number is clearly marked on the package and that information about batch or lot numbers is retained for the period of time referred to in Articles 4(4) and 5(2).

2. By way of derogation from Articles 4(3), 4(4) and 5(2), operators delivering food to the ultimate consumer shall not be obliged to retain documentation detailing to whom products were sold.

3. Products intended for direct use as food, feed or processing which consist of or contain GMOs in respect of which the conditions set out in Article 12a of Directive 2001/18/EC<sup>(1)</sup> are met shall be exempt from the requirements of Article 4.

4. Food and feed produced from GMOs in respect of which the conditions set out in Articles 5 and 18 of Regulation (EC) No .../2002 [on genetically modified food and feed] are met shall be exempt from the requirements of Article 5.

#### Article 7

##### Amendment of Directive 2001/18/EC

Article 4(6) of Directive 2001/18/EC is deleted.

<sup>(1)</sup> [as amended by Regulation (EC) No .../2002 on genetically modified food and feed].

*Article 8***Unique codes**

In accordance with the procedure referred to in Article 10(2), the Commission shall:

- (a) prior to the application of Articles 1 to 7 and taking into account international developments, establish the system for development and assignment of unique codes to GMOs;
- (b) adapt the system provided for in point (a), as appropriate, taking into account further developments in international fora.

*Article 9***Inspection and control measures**

1. Member States shall ensure that inspections and other control measures, as appropriate, are carried out to ensure compliance with this Regulation.
2. Prior to the application of Articles 1 to 7, the Commission shall develop technical guidance on sampling and testing to facilitate a coordinated approach for the implementation of paragraph 1.

*Article 10***Committee**

1. The Commission shall be assisted by the committee instituted by Article 30 of Directive 2001/18/EC.

2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Articles 7 and 8 thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

*Article 11***Penalties**

Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission, by [180 days following the date of publication of this Regulation in the *Official Journal of the European Communities*] at the latest and shall notify it without delay of any subsequent amendment affecting them.

*Article 12***Entry into force**

1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

2. Articles 1 to 7 and Article 9(1) shall apply with effect from the ninetieth day following the date of publication in the *Official Journal of the European Communities* of the measure referred to in Article 8(a).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

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