

Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 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 (EC) No 1830/2003 OF THE
EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 22 September 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

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⁽¹⁾,

Having regard to the opinion of the European Economic and Social Committee⁽²⁾,

Having regard to the opinion of the Committee of the Regions⁽³⁾,

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁽⁴⁾,

Whereas:

- (1) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms⁽⁵⁾ 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 therefore be amended accordingly.
- (3) Traceability requirements for GMOs should facilitate both the withdrawal of products where unforeseen adverse effects on human health, animal health or the environment, including ecosystems, are established, and the targeting of monitoring to examine potential effects on, in particular, the environment. Traceability should also facilitate the implementation of risk management measures in accordance with the precautionary principle.

Status: Point in time view as at 11/12/2008.

Changes to legislation: There are outstanding changes not yet made to Regulation (EC) No 1830/2003 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

- (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 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed⁽⁶⁾, so as to ensure that accurate information is available to operators and consumers to enable them to exercise their freedom of choice in an effective manner as well as to enable 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) The transmission and holding 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 provide 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) The transmission and holding of information that food and feed have been produced from GMOs also provide the basis for the appropriate traceability of products produced from GMOs.
- (7) The Community legislation concerning GMOs as or in feed should also apply to feed intended for animals which are not destined for food production.
- (8) 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. Account should be taken of registers containing information on genetic modifications in GMOs established by the Commission in accordance with Article 31(2) of Directive 2001/18/EC and Article 29 of Regulation (EC) No 1829/2003.
- (9) Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation.
- (10) Certain traces of GMOs in products may be adventitious or technically unavoidable. Such presence of GMOs should therefore not trigger labelling and traceability requirements. It is therefore necessary to fix thresholds for the adventitious or technically unavoidable presence of material consisting, containing or produced from GMOs both when the marketing of such GMOs is authorised in the Community and when their adventitious or technically unavoidable presence is tolerated by virtue of Article 47 of Regulation (EC) No 1829/2003. It is also appropriate to provide that, when the combined level of adventitious or technically unavoidable presence of the above material in a food or feed or in one of its components is higher than the aforesaid labelling thresholds, such presence should be indicated in accordance with the provisions of this Regulation and detailed provisions to be adopted for its implementation.
- (11) It is necessary to ensure that consumers are fully and reliably informed about GMOs and the products, foods and feed produced therefrom, so as to allow them to make an informed choice of product.

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- (12) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission⁽⁷⁾.
- (13) Systems for the development and assignment of unique identifiers for GMOs should be established before the measures relating to traceability and labelling can be applied.
- (14) The Commission should submit a report to the European Parliament and the Council on the implementation of this Regulation and, more specifically, on the effectiveness of the rules on traceability and labelling.
- (15) 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:

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- (1) [OJ C 304 E, 30.10.2001, p. 327](#) and [OJ C 331 E, 31.12.2002, p. 308](#).
- (2) [OJ C 125, 27.5.2002, p. 69](#).
- (3) [OJ C 278, 14.11.2002, p. 31](#).
- (4) Opinion of the European Parliament of 3 July 2002 (not yet published in the Official Journal), Council Common Position of 17 March 2003 ([OJ C 113 E, 13.5.2003, p. 21](#)), Decision of the European Parliament of 2 July 2003 (not yet published in the Official Journal) and Council Decision of 22 July 2003.
- (5) [OJ L 106, 17.4.2001, p. 1](#). Directive as last amended by Council Decision 2002/811/EC ([OJ L 280, 18.10.2002, p. 27](#)).
- (6) See page 1 of this Official Journal.
- (7) [OJ L 184, 17.7.1999, p. 23](#).

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