COMMISSION REGULATION (EC) No 1813/97

of 19 September 1997

concerning the compulsory indication on the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs [1], as last amended by Directive 97/4/EC of the European Parliament and of the Council [2], and in particular Article 4 (2) thereof,

Whereas in accordance with the provisions of Part C of Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms [3] consents have been given for the placing on the market of certain genetically modified products by Commission Decision 96/281/EC of 3 April 1996 concerning the placing on the market of genetically modified soya beans (*Glycine max* L.) with increased tolerance to the herbicide glyphosate pursuant to Council Directive 90/220/EEC [4], and by Commission Decision 97/98/EC of 23 January 1997 concerning the placing on the market of genetically modified maize (*Zea mays* L.) with the combined modification for insecticidal properties conferred by the Bt-endotoxin gene and increased tolerance to the herbicide glufosinate ammonium pursuant to Council Directive 90/220/EEC [5];

Whereas in accordance with Directive 90/220/EEC there have been no safety grounds for mentioning on the label of genetically modified soya beans (*Glycine max* L.) or of genetically modified maize (*Zea mays* L.) that they have been obtained by genetic modification techniques;

Whereas Directive 90/220/EEC does not cover non-viable products derived from genetically modified organisms;

Whereas certain Member States have taken measures in respect of the labelling of foods and food ingredients produced from the products concerned; whereas differences between those measures are liable to impede the free movement of those foods and food ingredients and thereby adversely affect the functioning of the internal market; whereas it is therefore necessary to adopt detailed uniform Community labelling rules for the products concerned;

Whereas Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients [6], lays down, in Article 8, additional specific labelling requirements in order to ensure proper information for the final consumer;

Whereas, in order to prevent distortions of competition, the same labelling rules for the information of the final consumer should apply to foods and food ingredients consisting of or derived from GMOs which have been placed on the market before the entry into force of Regulation (EC) No 258/97 in accordance with a consent given pursuant to Directive 90/220/EEC, and to foods and food ingredients which are placed on the market thereafter;

Whereas, therefore, as a first step, it is appropriate to require that the same provisions as those laid down in Article 8 of Regulation (EC) No 258/97 should apply to the labelling of the specific foodstuffs covered by this Regulation;

Whereas further measures should be adopted as soon as possible to lay down detailed uniform Community rules for the labelling of the foodstuffs covered by this Regulation;

Whereas, having regard to the scope and effects of the proposed action, the Community measures introduced by this Regulation are not only necessary but essential if the objectives set are to be attained; whereas those objectives cannot be attained by the Member States acting individually;

Whereas the measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS REGULATION:

Article 1

1. This Regulation shall apply to the labelling of foods and food ingredients produced from:

[1] OJ L 33, 8. 2. 1979, p. 1.
[2] OJ L 43, 14. 2. 1997, p. 21.
[3] OJ L 117, 8. 5. 1990, p. 15.
[4] OJ L 107, 30. 4. 1996, p. 10.
[5] OJ L 31, 1. 2. 1997, p. 69.
[6] OJ L 43, 14. 2. 1997, p. 1.

— genetically modified soya beans covered by Decision 96/281/EC,

— genetically modified maize covered by Decision 97/98/EC.

2. This Regulation shall not apply to food additives, flavourings for use in foodstuffs or extraction solvents used in the production of foodstuffs as referred to in Article 2 (1) of Regulation (EC) No 258/97.

Article 2

Without prejudice to the other requirements of Community law concerning the labelling of foodstuffs, the following additonal specific labelling requirements shall apply in order to ensure that the final consumer is informed of:

(a) any characteristic or food property such as:

— composition,

— nutritional value or nutritional effects,

— intended use of the food,

which renders the food or food ingredient no longer equivalent to an existing food or food ingredient.

The food or food ingredient shall be deemed to be no longer equivalent for the purpose of this Article if scientific assessment, based upon an appropriate analysis of existing data, can demonstrate that the characteristics assessed are different in comparison with a conventional food or food ingredient, having regard to the accepted limits of natural variations for such characteristics.

In this case, the labelling must indicate the characteristics or properties modified, together with the method by which that characteristic or property was obtained;

(b) the presence in the food or food ingredient of material which is not present in an existing equivalent foodstuff and which may have implications for the health of certain sections of the population;

(c) the presence in the food or food ingredient of material which is not present in an existing equivalent foodstuff and which gives rise to ethical concerns;

(d) the presence of an organism genetically modified by techniques of genetic modification, the non-exhaustive list of which is laid down in Annex I A, Part 1 to Directive 90/220/EEC.

Article 3

This Regulation shall enter into force on 1 November 1997. Detailed uniform Community rules for the labelling of the foodstuffs referred to in Article 1 shall be adopted as soon as possible.

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

Done at Brussels, 19 September 1997.

For the Commission

Martin BANGEMANN

Member of the Commission