



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 25.02.1998
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Proposal for a

COUNCIL REGULATION (EC)

**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**

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. On 19 September 1997, the Commission adopted Regulation n° 1813/97 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.
2. This Commission Regulation applies to the labelling of foods and food ingredients produced from genetically modified soyabbeans and genetically modified maize which were granted consent under Directive 90/220/EEC before the entry into force of the Novel Foods Regulation. It was published in the Official Journal on 20.09.97, and entered into force on 1 November 1997.
3. Regulation (CE) n° 1813/97 was adopted on the basis of article 4(2) of Directive 79/112/EEC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs
4. In the interest of consumer protection, in order to ensure fair conditions of competition within the internal market, and in view of the need to ensure a coherent Community policy for foods produced from biotechnology, it was considered necessary to ensure that labelling rules for the information of the final consumer based on the same principles apply to foods and food ingredients produced from GMOs which have been placed on the market before the entry into force of Regulation (EC) n° 258/97 pursuant to a consent given under Directive 90/220/EEC, and to foods and food ingredients which are placed on the market thereafter.
5. In order to achieve this goal, the first step, implemented by the aforementioned Regulation (CE) n° 1813/97, consisted in requiring that the same provisions as those laid down in Article 8 of Regulation (CE) n° 258/97 apply to foods and food ingredients produced from genetically modified soyabbeans covered by Decision 96/281/EC and genetically modified maize covered by Decision 97/98/EC.
6. However, laying down general labelling rules for the aforementioned products is not sufficient in order to clarify which soya or maize products have to be labelled, and, when so, how. In order to achieve this result, it is also necessary, as a second step, drawing on the approach taken in Article 8 of Regulation (EC) N° 258/97, to lay down detailed uniform Community rules.

As a matter of fact, Article 3 of Regulation (CE) n° 1813/97 itself already laid down that "Detailed uniform Community rules for the labelling of the foodstuffs referred to in Article 1 shall be adopted as soon as possible."

7. The measures proposed in the attached proposal for a Regulation constitute the detailed uniform Community rules announced in Article 3 of Regulation (CE) n° 1813/97.

Proposal for

Council Regulation (EC) N°..../ 97 of....

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 COUNCIL OF THE EUROPEAN UNION,

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 foodstuffs¹, as last amended by Directive 97/4/EC of the European Parliament and of the Council², and in particular Article 4(2) thereof;

Having regard to the proposal from the Commission,

1. 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 organisms³, 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/EEC⁴, 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/EEC⁵;
2. 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;
3. Whereas Directive 90/220/EEC does not cover non-viable products derived from genetically modified organisms (hereinafter referred to as "GMOs");

¹ OJ n° L 33, 8.2.1979, p. 1.

² OJ n° L 43, 14.2.1997, p. 21

³ OJ n° L 117, 8.5.1990, p. 15

⁴ OJ n° L 107, 30.4.1996, p. 10

⁵ OJ n° L 31, 1.2.1997, p. 69

4. 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 uniform Community labelling rules for the products concerned;
5. Whereas European Parliament and Council Regulation (EC) N° 258/97 of 27 January 1997 concerning novel foods and novel food ingredients⁶, lays down, in Article 8, additional specific labelling requirements in order to ensure proper information for the final consumer; whereas these additional specific labelling requirements do not apply to foods and food ingredients which have been used for human consumption to a significant degree within the Community before the entry into force of Regulation (EC) N° 258/97 and are not for this reason considered to be novel;
6. Whereas, in order to prevent distortions of competition, labelling rules for the information of the final consumer based on the same principles 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) N° 258/97 pursuant to a consent given under Directive 90/220/EEC, and to foods and food ingredients which are placed on the market thereafter;
7. Whereas, therefore, Commission Regulation (EC) N° 1813/97 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/EEC⁷ has laid down general labelling rules for the above-mentioned products;
8. Whereas it is now urgent to lay down detailed uniform Community rules for the labelling of the foodstuffs covered by Regulation (EC) N° 1813/97;
9. Whereas, in particular, drawing on the approach taken in Article 8 of Regulation (EC) N° 258/97, it is necessary to ensure that the final consumer is informed of any characteristic or food property, such as composition, nutritional value or nutritional effects or the intended use of the food, which renders a food or food ingredient no longer equivalent to an existing food or food ingredient; whereas, for this purpose, foods and food ingredients produced from genetically modified soya beans or from genetically modified maize which are not equivalent to conventional counterparts should be subject to labelling requirements;
10. Whereas, drawing on the approach taken in Article 8 of Regulation (EC) N° 258/97, it is necessary that labelling requirements are based on scientific evaluation;
11. Whereas it is necessary to establish clear labelling rules for the above-mentioned products, allowing official control on a reliable, readily repeatable and practicable basis; whereas common scientifically validated testing methods should be developed.

⁶ OJ n° L 43, 14.2.1997, p. 1

⁷ OJ n° L 257, 20.9.97 p.7

12. Whereas it is also necessary to ensure that the labelling requirements are no more burdensome than necessary but sufficiently detailed to supply consumers with the information they require.
13. Whereas at this stage the presence in foods and food ingredients of DNA resulting from genetic modification constitutes the criterion best complying with the above-mentioned requirements ; whereas such an approach could be reconsidered in the light of future developments in scientific knowledge;
14. Whereas foods and food ingredients produced from genetically modified soya beans (*Glycine max L*) or from genetically modified maize (*Zea mays L.*), in which DNA resulting from genetic modification is present, are not equivalent and therefore are subject to labelling requirements ;
15. Whereas it is possible that DNA resulting from genetic modification has been destroyed by successive stages of processing ; whereas, in that case, foods and food ingredients should be considered equivalent for labelling purposes; whereas they are therefore not subject to labelling requirements;
16. Whereas nevertheless some processing methods may eliminate DNA but not proteins; whereas it cannot be excluded that such methods can be applied to food uses ; whereas foods and food ingredients in which DNA resulting from genetic modification is not present but in which there are proteins resulting from genetic modification present, cannot be considered to be equivalent ; whereas therefore, they are subject to labelling requirements.
17. Whereas the necessary information should be provided in the list of ingredients except in the case of products for which no such list exists, in which case it should appear clearly on the labelling of the product;
18. Whereas, with regard to foods and food ingredients which are intended to be placed on the market to be supplied to the final consumer, and which may contain both genetically modified and conventional produce, and without prejudice to the other labelling requirements of this Regulation, information for the consumer on the possibility that genetically modified produce may be present in the foods and food ingredients concerned is deemed -by way of exception, in particular as regards bulk consignments- to fulfil the requirements of this Regulation.
19. Whereas this Regulation is without prejudice to the operators' right to include voluntary claims in the labels of their products as to particulars other than those laid down in this Regulation (such as the absence of foods and food ingredients produced from genetically modified soyabeans and maize, or the presence of such foods and food ingredients in cases where it is not scientifically verifiable but evidence of it is available through other means), provided such claims are made in compliance with the provisions of Directive 79/112/EEC.
20. 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;

21. Whereas this Regulation replaces Regulation (EC) N° 1813/97 which should therefore be repealed;
22. Whereas in pursuance of the procedure laid down in Article 17 of directive 79/112/EEC, this text was submitted to the Standing Committee for Foodstuffs, which was unable to deliver an opinion, and whereas in accordance with that same procedure the Commission is required to address a proposal to the Council,

HAS ADOPTED THIS REGULATION

Article 1

1. This Regulation shall apply to foods and food ingredients which are to be delivered as such to the final consumer (hereinafter referred to as "the specified foodstuffs") produced, in whole or in part, from:
 - 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) N° 258/97.

Article 2

1. The specified foodstuffs shall be subject to the additional specific labelling requirements laid down in paragraph 3 of this article.
2. However, foods and food ingredients referred to in the first paragraph in which DNA resulting from genetic modification is not present shall not be subject to the specific labelling requirements, unless there are proteins resulting from genetic modification present.
3. The specific labelling requirements referred to in paragraph 1 are the following:
 - (a) Where the food consists of more than one ingredient, the words "produced from genetically modified soya" or "produced from genetically modified maize", as appropriate, shall appear in the list of ingredients provided for by Article 6 of Directive 79/112/EEC in parentheses immediately after the name of the ingredient concerned. Alternatively, these words may appear in a prominently displayed footnote to the list of ingredients which has a typeface of at least the same size as the list of ingredients itself.
 - (b) In the case of products for which no list of ingredients exists, the words "produced from genetically modified soya" or "produced from genetically modified maize", as appropriate, shall appear clearly on the labelling of the food.

- (c) Where in accordance with the provisions of the first indent of sub paragraph (b) of paragraph 5 of Article 6 of Directive 79/112/EEC an ingredient is designated by the name of a category, that designation shall be completed by the words "contains" or " may contain [ingredients] produced from genetically modified soya/genetically modified maize", as appropriate.
 - (d) Where an ingredient of a compound ingredient is derived from the specified foodstuffs, it shall be mentioned on the labelling of the final product, with the addition of the wording shown in point (b).
 - (e) By way of exception, where the presence in foods and food ingredients, of genetically modified produce subject to the labelling provisions of points (a) to (d), cannot be excluded but where no evidence of it is available, the use of the terms "may contain" or "may have been produced from" shall be considered to fulfil the requirements of those points.
4. The first, second and third paragraphs shall be without prejudice to the other requirements of Community law concerning the labelling of foodstuffs.

Article 3

Regulation (EC) 1813/97 is hereby repealed.

Article 4

The labelling requirements of this Regulation shall not apply to products which have been lawfully manufactured and labelled in the Community, or which have been lawfully imported into the Community and put into free circulation, before the entry into force of this Regulation.

Article 5

This Regulation shall enter into force 20 days after its publication in the Official Journal of the European Community.

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

Done at,

For the Council

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