

COMMISSION REGULATION (EC) No 50/2000

of 10 January 2000

on the labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 99/112/EEC of 18 December 1998 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 the Council ⁽²⁾, and in particular Article 4(2) thereof,

Whereas:

(1) Regulation (EC) No 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients ⁽³⁾ does not apply to additives and flavourings intended to be used in foodstuffs as, for the purpose of testing these substances for their safety evaluation, they come under other Community provisions, namely Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption ⁽⁴⁾, as amended by Directive 94/34/EEC of the European Parliament and of the Council ⁽⁵⁾, and Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production ⁽⁶⁾, as amended by Commission Directive 91/71/EEC ⁽⁷⁾;

(2) these additives and flavourings are also excluded from the scope of Council Regulation (EC) No 1139/98 of 26 May 1998 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 ⁽⁸⁾;

(3) a consequence of this exclusion is that additives and flavourings that have been genetically modified or have been produced from genetically modified organisms and are used as ingredients in foodstuffs are not subject to the specific labelling provisions laid down in Article 8 of Regulation (EC) No 258/97 and the labelling provisions laid down in Article 2 of Regulation (EC) No 1139/98;

(4) it is important that consumers should also be informed of the use of additives or flavourings that have been genetically modified or have been produced through genetic engineering as they are already informed of the presence of other ingredients containing or produced from genetically modified organisms;

(5) some Member States have served notice of their intention to impose at national level indications on labelling informing consumers of the use of additives and/or flavourings produced from genetically modified organisms;

(6) such provisions are likely to create new obstacles to infra-Community trade;

(7) the Commission, in its Decision 98/613/EC of 21 October 1998 concerning a draft decree of the Republic of Austria concerning the identification of genetically modified additives and flavourings ⁽⁹⁾, took the view, with the agreement of the Member States, that the most satisfactory solution would be to draw up Community provisions on labelling;

(8) accordingly, it would be useful to make it obligatory to indicate on the labelling of the foodstuffs concerned that the additives or flavourings used are or contain genetically modified organisms or have been produced from such organisms, in accordance with the same principles as those laid down for the labelling of ingredients that are, contain, or are produced from genetically modified organisms;

(9) the provisions of this Regulation do not apply to additives and flavourings sold as such to the final consumer. Separate measures imposing similar obligatory labelling for additives and flavourings should be introduced;

(10) in particular, in accordance with the approach adopted in Article 8 of Regulation (EC) No 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 this food or food ingredient no longer equivalent to an existing food or food ingredient. To this end additives and flavourings that have been genetically modified or have been produced from genetically modified organisms that are not equivalent to their traditional counterparts must be subject to labelling requirements;

⁽¹⁾ OJ L 33, 8.2.1979, p. 1.

⁽²⁾ OJ L 43, 14.2.1997, p. 21.

⁽³⁾ OJ L 43, 14.2.1997, p. 1.

⁽⁴⁾ OJ L 40, 11.2.1989, p. 27.

⁽⁵⁾ OJ L 237, 10.9.1994, p. 1.

⁽⁶⁾ OJ L 184, 15.7.1988, p. 61.

⁽⁷⁾ OJ L 42, 15.2.1991, p. 25.

⁽⁸⁾ OJ L 159, 3.6.1998, p. 4.

⁽⁹⁾ OJ L 291, 30.10.1998, p. 35.

- (11) in accordance with the approach adopted in Article 8 of Regulation (EC) No 258/97, labelling requirements must be based on scientific assessment;
- (12) clear labelling rules should be formulated for the abovementioned products so as to ensure that official inspections can be carried out on the basis of reliable, reproducible and practicable data;
- (13) care should also be taken to ensure that the labelling requirements are not excessively complex but nevertheless sufficiently detailed to provide consumers with the information they need;
- (14) Regulation (EC) No 1139/98 specifies the criterion according to which the labelling obligations become operative for food produced from genetically modified maize or soya;
- (15) the presence in additives and, flavourings used as ingredients in a foodstuff of protein or DNA resulting from genetic modification is, as matters stand, also the criterion that best meets the abovementioned requirements. Such an approach could be re-examined in the light of new scientific evidence;
- (16) in view of the scope and consequences of the proposed action, the Community measures introduced by this Regulation are not only necessary but indeed essential to achieve the objectives;
- (17) adventitious contamination of additives and flavourings with DNA or protein resulting from genetic modification cannot be excluded; it is useful to examine the possibility of setting up a threshold in order to avoid labelling as a result of such contamination;
- (18) 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 provides for specific additional labelling requirements for food and food ingredients intended for final consumers and mass caterers hereinafter referred to as 'specified foodstuffs' containing additives and/or flavourings as described in paragraph 2 (hereinafter referred to as 'specified additives and flavourings').
2. The following are specified additives and flavourings:
 - additives falling within the scope of Directive 89/107/EEC and/or
 - flavourings for use in foodstuffs falling within the scope of Directive 88/388/EEC

which are, contain or are produced from genetically modified organisms within the meaning of Council Directive 90/220/EEC⁽¹⁾.

Article 2

Without prejudice to the other requirements of Community legislation on food labelling, the labelling of the specified foodstuffs must inform final consumers and mass caterers of:

- (a) in accordance with Article 4(1), any characteristic or food property such as:
 - composition
 - nutritional value or nutritional effects
 - intended use of the additives, or flavourings
 as a result of which the specified additives or flavourings are no longer equivalent to existing additives or flavourings;
- (b) the presence in the specified additives or flavourings of material which is not present in existing equivalent additives or flavourings and which may affect the health of certain sections of the population;
- (c) the presence in the specified additives or flavourings of material which is not present in existing equivalent additives or flavourings and which gives rise to ethical concerns;
- (d) in accordance with Article 4(2), the presence of an additive or flavouring that is or contains an organism genetically modified by techniques of genetic modification, the non-exhaustive list of which is laid down in Annex I A, Part 1, of Directive 90/220/EEC.

Article 3

The specified additives or flavourings shall be deemed to be no longer equivalent within the meaning of Article 2(a) if scientific assessment, based upon an appropriate analysis of existing data, can demonstrate that the characteristics assessed are different in comparison with traditional additives or flavourings, having regard to the accepted limits of natural variations of such characteristics. This is the case where the specified additives or flavourings contain protein and/or DNA resulting from genetic modification.

Article 4

1. The additional specific labelling requirements with regard to the information referred to in Article 2(a) are as follows:

The words 'produced from genetically modified ...' shall appear in the list of ingredients provided for in Article 6 of Directive 791/112/EEC, in parentheses, immediately after the indication of the additive or flavouring in question.

Alternatively, this wording may appear in a prominently displayed footnote to the list of ingredients, linked to the additive or the flavouring concerned by an asterisk (*). It shall be printed in a font that is at least of the same size as that used for the list of ingredients itself.

⁽¹⁾ OJ L 117, 8.5.1990, p. 15.

For specified foodstuffs for which there is no list of ingredients, this wording shall appear clearly on the product's label.

2. The additional specific labelling requirements with regard to the information referred to in Article 2(d) are as follows:

The words 'genetically modified' shall appear in the list of ingredients immediately after the indication of the additive or flavouring in question.

Alternatively, this wording may appear in a prominently displayed footnote to the list of ingredients, linked to the additive or the flavouring concerned by an asterisk (*). It shall be printed in a font that is at least of the same size as that used for the list of ingredients itself.

For specified foodstuffs for which there is no list of ingredients, this wording shall appear clearly on the product's label.

Article 5

This Regulation shall not apply to specified foodstuffs lawfully manufactured and labelled in the Community or lawfully imported into the Community and put into free circulation before the entry into force of this Regulation.

Article 6

This Regulation shall enter into force 90 days following its publication in the *Official Journal of the European Communities*.

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

Done at Brussels, 10 January 2000.

For the Commission

Erkki LIIKANEN

Member of the Commission
