

DIRECTIVE 2003/89/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 10 November 2003
amending Directive 2000/13/EC as regards indication of the ingredients present in foodstuffs
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission ⁽¹⁾,

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

Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁽³⁾,

Whereas:

- (1) In order to achieve a high level of health protection for consumers and to guarantee their right to information, it must be ensured that consumers are appropriately informed as regards foodstuffs, *inter alia*, through the listing of all ingredients on labels.
- (2) By virtue of Article 6 of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs ⁽⁴⁾, certain substances need not appear in the list of ingredients.
- (3) When used in the production of foodstuffs and still present, certain ingredients or other substances are the cause of allergies or intolerances in consumers, and some of those allergies or intolerances constitute a danger to the health of those concerned.
- (4) The Scientific Committee on Food set up by Article 1 of Commission Decision 97/579/EC ⁽⁵⁾ has stated that the incidence of food allergies is such as to affect the lives of many people, causing conditions ranging from very mild to potentially fatal.

(5) The said Committee has acknowledged that common food allergens include cow's milk, fruits, legumes (especially peanuts and soybeans), eggs, crustaceans, tree nuts, fish, vegetables (celery and other foods of the Umbelliferae family), wheat and other cereals.

(6) The most common food allergens are found in a wide variety of processed foods.

(7) The said Committee has also noted that adverse reactions to food additives may occur and that the avoidance of food additives is often difficult since not all of them are invariably included on the labelling.

(8) It is necessary to provide that additives, processing aids and other substances with allergenic effect covered by Article 6(4)(a) of Directive 2000/13/EC are subject to labelling rules, to give appropriate information to consumers suffering from food allergy.

(9) Even if labelling, which is intended for consumers in general, is not to be regarded as the only medium of information acting as substitute for the medical establishment, it is nevertheless advisable to assist consumers who have allergies or intolerances as much as possible by providing them with more comprehensive information on the composition of foodstuffs.

(10) The list of allergenic substances should include those foodstuffs, ingredients and other substances recognised as causing hypersensitivity.

(11) In order to provide all consumers with better information and to protect the health of certain consumers, it should be made obligatory to include in the list of ingredients all ingredients and other substances present in the foodstuff. In the case of alcoholic beverages, it should be mandatory to include in the labelling all ingredients with allergenic effect present in the beverage concerned.

(12) In order to take account of the technical constraints involved in the manufacture of foodstuffs, it is necessary to authorise greater flexibility with regard to the listing of ingredients and other substances used in very small quantities.

⁽¹⁾ OJ C 332 E, 27.11.2001, p. 257 and OJ C 331 E, 31.12.2002, p. 188.

⁽²⁾ OJ C 80, 3.4.2002, p. 35.

⁽³⁾ Opinion of the European Parliament of 11 June 2002 (not yet published in the Official Journal), Council Common Position of 20 February 2003 (OJ C 102 E, 29.4.2003, p. 16) and Position of the European Parliament of 2 July 2003 (not yet published in the Official Journal), Council Decision of 22 September 2003.

⁽⁴⁾ OJ L 109, 6.5.2000, p. 29. Directive as amended by Commission Directive 2001/101/EC (OJ L 310, 28.11.2001, p. 19).

⁽⁵⁾ OJ L 237, 28.8.1997, p. 18. Decision as amended by Decision 2000/443/EC (OJ L 179, 18.7.2000, p. 13).

- (13) In order to keep up with the development of scientific knowledge and progress as regards technological means of removing the allergenicity in ingredients and other substances and in order to protect consumers against new food allergens and avoid unnecessary obligations on labelling, it is important to be able to revise the list of ingredients rapidly, when necessary by including or deleting certain ingredients or substances. The revision should be based on scientific criteria determined by the European Food Safety Authority set up by Regulation (EC) No 178/2002⁽¹⁾ and take the form of implementing measures of a technical nature, the adoption of which should be entrusted to the Commission in the interest of simplifying and accelerating the procedure. Furthermore, the Commission should, if necessary, draw up technical guidelines for the interpretation of Annex IIIa.
- (14) Directive 2000/13/EC should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 2000/13/EC is amended as follows:

1. Article 6 shall be amended as follows:

(a) paragraph 1 shall be replaced by the following:

'1. Ingredients shall be listed in accordance with this Article and Annexes I, II, III and IIIa.'

(b) the following paragraph shall be inserted:

'3a. Without prejudice to the rules for labelling to be established pursuant to paragraph 3, any ingredient, as defined in paragraph 4(a) and listed in Annex IIIa, shall be indicated on the labelling where it is present in beverages referred to in paragraph 3. This indication shall comprise the word "contains" followed by the name of the ingredient(s) concerned. However, an indication is not necessary when the ingredient is already included under its specific name in the list of ingredients or in the name under which the beverage is sold.

Where necessary, detailed rules for the presentation of the indication referred to in the first subparagraph may be adopted in accordance with the following procedures:

- (a) as regards the products referred to in Article 1(2) of Council Regulation (EC) No 1493/99 of 17 May 1999 on the common organisation of the market in wine^(*), under the procedure laid down in Article 75 of that Regulation;

- (b) as regards the products referred to in Article 2(1) of Council Regulation (EEC) No 1601/91 of 10 June 1991 laying down general rules on the definition, description and presentation of aromatised wines, aromatised wine-based drinks and aromatised wine-product cocktails^(**), under the procedure laid down in Article 13 of that Regulation;

- (c) as regards the products referred to in Article 1(2) of Council Regulation (EEC) No 1576/89 of 29 May 1989 laying down general rules on the definition, description and presentation of spirit drinks^(***), under the procedure laid down in Article 14 of that Regulation;

- (d) as regards other products, under the procedure laid down in Article 20(2) of this Directive.

(*) OJ L 179, 14.7.1999, p. 1. Regulation as last amended by Commission Regulation (EC) No 1795/2003 (OJ L 262, 14.10.2003, p. 13).

(**) OJ L 149, 14.6.1991, p. 1. Regulation as last amended by Regulation (EC) No 2061/96 of the European Parliament and of the Council (OJ L 277, 30.10.1996, p. 1).

(***) OJ L 160, 12.6.1989, p. 1. Regulation as last amended by Regulation (EC) No 3378/94 of the European Parliament and of the Council (OJ L 366, 31.12.1994, p. 1).;

- (c) the following point shall be added to paragraph 4(c):

'(iv) substances which are not additives but are used in the same way and with the same purpose as processing aids and are still present in the finished product, even if in altered form.'

- (d) the second subparagraph of paragraph 5 shall be amended as follows:

- (i) the fourth indent shall be replaced by the following:

'— where fruit, vegetables or mushrooms, none of which significantly predominates in terms of weight and which are used in proportions that are likely to vary, are used in a mixture as ingredients of a foodstuff, they may be grouped together in the list of ingredients under the designation "fruit", "vegetables" or "mushrooms" followed by the phrase "in varying proportions", immediately followed by a list of the fruit, vegetables or mushrooms present; in such cases, the mixture shall be included in the list of ingredients in accordance with the first subparagraph, on the basis of the total weight of the fruit, vegetables or mushrooms present;'

- (ii) the following indents shall be added:

'— ingredients constituting less than 2 % of the finished product may be listed in a different order after the other ingredients,

(¹) OJ L 31, 1.2.2002, p. 1. Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

- where ingredients which are similar or mutually substitutable are likely to be used in the manufacture or preparation of a foodstuff without altering its composition, its nature or its perceived value, and in so far as they constitute less than 2 % of the finished product, they may be referred to in the list of ingredients by means of the phrase "contains ... and/or ...", where at least one of no more than two ingredients is present in the finished product. This provision shall not apply to additives or to ingredients listed in Annex IIIa.;
- (e) the second subparagraph of paragraph 8 shall be replaced by the following:
- 'The list referred to in the first subparagraph shall not be compulsory:
- (a) where the composition of the compound ingredient is defined in current Community legislation, and in so far as the compound ingredient constitutes less than 2 % of the finished product; however, this provision shall not apply to additives, subject to paragraph 4(c),
 - (b) for compound ingredients consisting of mixtures of spices and/or herbs that constitute less than 2 % of the finished product, with the exception of additives, subject to paragraph 4(c),
 - (c) where the compound ingredient is a foodstuff for which a list of ingredients is not required under Community legislation.;
- (f) the following paragraphs shall be added:

'10. Notwithstanding paragraph 2, the second subparagraph of paragraph 6 and the second subparagraph of paragraph 8, any ingredient used in production of a foodstuff and still present in the finished product, even if in altered form, and listed in Annex IIIa or originating from an ingredient listed in Annex IIIa shall be indicated on the label with a clear reference to the name of this ingredient.

The indication referred to in the first subparagraph shall not be required if the name under which the foodstuff is sold clearly refers to the ingredient concerned.

Notwithstanding paragraph 4(c)(ii), (iii) and (iv), any substance used in production of a foodstuff and still present in the finished product, even if in altered form, and originating from ingredients listed in Annex IIIa shall be considered as an ingredient and shall be indicated on the label with a clear reference to the name of the ingredient from which it originates.

11. The list in Annex IIIa shall be systematically re-examined and, where necessary, updated on the basis of the most recent scientific knowledge. The first re-examination shall take place at the latest on 25 November 2005.

Updating could also be effected by the deletion from Annex IIIa of ingredients for which it has been scientifically established that it is not possible for them to cause adverse reactions. To this end, the Commission may be notified until 25 August 2004 of the studies currently being conducted to establish whether ingredients or substances, derived from ingredients listed in Annex IIIa are not likely, under specific circumstances, to trigger adverse reactions. The Commission shall, not later than 25 November 2004, after consultation with the European Food Safety Authority, adopt a list of those ingredients or substances, which shall consequently be excluded from Annex IIIa, pending the final results of the notified studies, or at the latest until 25 November 2007.

Without prejudice to the second subparagraph, Annex IIIa may be amended, in compliance with the procedure referred to in Article 20(2), after an opinion has been obtained from the European Food Safety Authority issued on the basis of Article 29 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (*).

Where necessary, technical guidelines may be issued for the interpretation of the list in Annex IIIa, in compliance with the procedure referred to in Article 20(2).

(*) OJ L 31, 1.2.2002, p. 1. Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).;

2. in the second subparagraph of Article 19, 'Standing Committee on Foodstuffs set up by Council Decision 69/414/EEC (1)' shall be replaced by 'Standing Committee on the Food Chain and Animal Health set up by Regulation (EC) No 178/2002';
3. the footnote, 'OJ L 291, 29.11.1969, p. 9', shall be deleted;
4. in Article 20(1) 'Standing Committee on Foodstuffs' shall be replaced by 'Standing Committee on the Food Chain and Animal Health';
5. in Annex I, the designations 'crystallised fruit' and 'vegetables', and the corresponding definitions, shall be deleted;
6. Annex IIIa, the text of which is set out in the Annex to this Directive, shall be inserted.

Article 2

1. Member States shall bring into force, by 25 November 2004 the laws, regulations and administrative provisions necessary to:

- permit, as from 25 November 2004, the sale of products that comply with this Directive;

— prohibit, as from 25 November 2005, the sale of products that do not comply with this Directive; any products which do not comply with this Directive but which have been placed on the market or labelled prior to this date may, however, be sold while stocks last.

They shall forthwith inform the Commission thereof.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 10 November 2003.

For the European Parliament

The President

P. COX

For the Council

The President

A. MARZANO

ANNEX

ANNEX IIIa

Ingredients referred to in Article 6(3a), (10) and (11)

Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof

Crustaceans and products thereof

Eggs and products thereof

Fish and products thereof

Peanuts and products thereof

Soybeans and products thereof

Milk and products thereof (including lactose)

Nuts i. e. Almond (*Amygdalus communis* L.), Hazelnut (*Corylus avellana*), Walnut (*Juglans regia*), Cashew (*Anacardium occidentale*), Pecan nut (*Carya illinoensis* (Wangenh.) K. Koch), Brazil nut (*Bertholletia excelsa*), Pistachio nut (*Pistacia vera*), Macadamia nut and Queensland nut (*Macadamia ternifolia*) and products thereof

Celery and products thereof

Mustard and products thereof

Sesame seeds and products thereof

Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO₂.