



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, [*insert date*]
COM(2007)

-

Draft

COMMISSION DIRECTIVE 2007/.../EC

of [...]

amending Annex IIIa to Directive 2000/13/EC of the European Parliament and of the Council as regards certain food ingredients

(Text with EEA relevance)

Draft

COMMISSION DIRECTIVE 2007/.../EC

of [...]

amending Annex IIIa to Directive 2000/13/EC of the European Parliament and of the Council as regards certain food ingredients

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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 foodstuffs¹, and in particular third subparagraph of Article 6(11) and Article 21 thereof

Whereas:

- (1) Annex IIIa to Directive 2000/13/EC establishes a list of food ingredients which must be indicated on the label of foodstuffs as they are likely to cause adverse reactions in susceptible individuals.
- (2) Directive 2000/13/EC provides for the possibility of excluding from the labelling requirement ingredients or substances derived from ingredients listed in Annex IIIa for which it has been scientifically established that they are not likely, under specific circumstances, to trigger adverse reactions.
- (3) Commission Directive 2005/26/EC² establishes the list of food ingredients or substances provisionally excluded from the labelling requirement until the 25 November 2007.
- (4) A number of applications for permanent exemption from the labelling requirement have been submitted to the European Food Safety Authority (EFSA). Those applications concern substances for which provisional exemptions were granted by Directive 2005/26/EC. On the basis of the EFSA opinions and other available information, it can be concluded that certain ingredients or substances derived from those ingredients listed in Annex IIIa to Directive 2000/13/EC are not likely, under specific circumstances, to cause adverse reactions in susceptible individuals.
- (5) Those ingredients or substances derived from those ingredients should therefore be permanently excluded from Annex IIIa to Directive 2000/13/EC.

¹ OJ L 109, 6.5.2000, p.29. Directive as last amended by Directive 2006/142/EC (OJ L 368, 23.12.2006, p.110)

² OJ L 75, 22.3.2005, p. 33. Directive as corrected by Directive 2005/63/EC (OJ L 258, 4.10.2005, p.3)

- (6) Annex IIIa of Directive 2000/13/EC should be amended accordingly.
- (7) Directive 2005/26/EC should be repealed on 26 November 2007 in view of the deadline set by Article 6(11), second subparagraph of Directive 2000/13/EC.
- (8) In order to avoid disruption of the market, it is necessary for this Directive to apply from the 26 November 2007.
- (9) It was expected that this Directive could be adopted and published well in advance of the date of 26 November 2007 in order to give time to the industry to adapt to the new rules. Since this has not been possible in practice, temporary measures appear therefore necessary to facilitate the application of the new rules. Indeed changes in labelling rules will affect industry, mainly small and medium enterprises, which need an adaptation period to smooth the transition towards new labelling requirements.
- (10) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex IIIa to Directive 2000/13/EC is replaced by the text in the Annex to this Directive as from 26 November 2007.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 May 2008 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, 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

Directive 2005/26/EC shall be repealed on 26 November 2007.

Member States shall allow foodstuffs placed on the market or labelled before 31 May 2009 that comply with the provisions of Directive 2005/26/EC to be marketed until stocks are exhausted.

Article 4

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

Article 5

This Directive is addressed to the Member States.

Done at Brussels, [...]

For the Commission

[...]

Member of the Commission

ANNEX IIIa

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

1. Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof, except:
 - (a) wheat based glucose syrups including dextrose³;
 - (b) wheat based maltodextrins¹;
 - (c) glucose syrups based on barley;
 - (d) cereals used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages.
2. Crustaceans and products thereof.
3. Eggs and products thereof.
4. Fish and products thereof, except:
 - (e) fish gelatine used as carrier for vitamin or carotenoid preparations
 - (f) fish gelatine or Isinglass used as fining agent in beer and wine
5. Peanuts and products thereof.
6. Soybeans and products thereof, except:
 - (a) fully refined soybean oil and fat; 1
 - (b) natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources;
 - (c) vegetable oils derived phytosterols and phytosterol esters from soybean sources;
 - (d) plant stanol ester produced from vegetable oil sterols from soybean sources.
7. Milk and products thereof (including lactose), except:
 - (a) whey used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages;
 - (b) lactitol.
8. Nuts, i.e. almonds (*Amygdalus communis L.*), hazelnuts (*Corylus avellana*), walnuts (*Juglans regia*), cashews (*Anacardium occidentale*), pecan nuts (*Carya illinoensis (Wangenh.) K. Koch*), Brazil nuts (*Bertholletia excelsa*), pistachio nuts (*Pistacia vera*), macadamia nuts and Queensland nuts (*Macadamia ternifolia*), and products thereof, except:

³ and products thereof, in so far as the process that they have undergone is not likely to increase the level of allergenicity assessed by the EFSA for the relevant product from which they originated.

- (a) nuts used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages.
- 9. Celery and products thereof.
- 10. Mustard and products thereof.
- 11. Sesame seeds and products thereof.
- 12. Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO₂.
- 13. Lupin and products thereof.
- 14. Molluscs and products thereof.