

## COMMISSION DIRECTIVE 2005/26/EC

of 21 March 2005

establishing a list of food ingredients or substances provisionally excluded from Annex IIIa of Directive 2000/13/EC of the European Parliament and of the Council

(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 foodstuffs<sup>(1)</sup>, and in particular second subparagraph of Article 6(11) thereof,

Whereas:

- (1) Annex IIIa of Directive 2000/13/EC establishes a list of food ingredients to be indicated on the label as they are likely to cause adverse reactions in susceptible individuals.
- (2) In accordance with Directive 2000/13/EC the Commission may provisionally exclude certain ingredients or products of those ingredients from Annex IIIa to that Directive, while food manufacturers or their associations conduct scientific studies to establish that those ingredients or products comply with the conditions for definite exclusion from that Annex.
- (3) The Commission received 27 applications regarding 34 ingredients or products thereof, of which 32 fall within the scope of this Directive, and have been submitted to the European Food Safety Authority (EFSA) for a scientific opinion.
- (4) Based on the information provided by the applicant, and other information available, the EFSA has considered that certain products of ingredients are not likely, or not very likely, to cause adverse reactions in susceptible individuals. In certain cases, EFSA has concluded that it cannot draw a firm conclusion, though no reported cases were mentioned.
- (5) Those products or ingredients complying with these conditions should therefore provisionally be excluded from Annex IIIa of Directive 2000/13/EC,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

The ingredients or substances listed in the Annex to this Directive shall be excluded from Annex IIIa of Directive 2000/13/EC until 25 November 2007.

*Article 2*

1. Member States shall adopt and publish, by 21 September 2005 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from 25 November 2005.

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*

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

*Article 4*

This Directive is addressed to the Member States.

Done at Brussels, 21 March 2005.

For the Commission  
Markos KYPRIANOU  
Member of the Commission

<sup>(1)</sup> OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15).

## ANNEX

**List of food ingredients and substances provisionally excluded from Annex IIIa of Directive 2000/13/EC**

Ingredients	Products thereof provisionally excluded
Cereals containing gluten	<ul style="list-style-type: none"> <li>— Wheat based glucose syrups including dextrose<sup>(1)</sup></li> <li>— Wheat based maltodextrins<sup>(1)</sup></li> <li>— Glucose syrups based on barley</li> <li>— Cereals used in distillates for spirits</li> </ul>
Eggs	<ul style="list-style-type: none"> <li>— Lysozym (produced from egg) used in wine</li> <li>— Albumin (produced from egg) used as fining agent in wine and cider</li> </ul>
Fish	<ul style="list-style-type: none"> <li>— Fish gelatine used as carrier for vitamins and flavours</li> <li>— Fish gelatine or Isinglass used as fining agent in beer, cider and wine</li> </ul>
Soybean	<ul style="list-style-type: none"> <li>— Fully refined soybean oil and fat<sup>(1)</sup></li> <li>— Natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources</li> <li>— Vegetable oils derived phytosterols and phytosterol esters from soybean sources</li> <li>— Plant stanol ester produced from vegetable oil sterols from soybean sources</li> </ul>
Milk	<ul style="list-style-type: none"> <li>— Whey used in distillates for spirits</li> <li>— Lactitol</li> <li>— Milk (casein) products used as fining agents in cider and wines</li> </ul>
Nuts	<ul style="list-style-type: none"> <li>— Nuts used in distillates for spirits</li> <li>— Nuts (almonds, walnuts) used (as flavour) in spirits</li> </ul>
Celery	<ul style="list-style-type: none"> <li>— Celery leaf and seed oil</li> <li>— Celery seed oleoresin</li> </ul>
Mustard	<ul style="list-style-type: none"> <li>— Mustard oil</li> <li>— Mustard seed oil</li> <li>— Mustard seed oleoresin</li> </ul>

<sup>(1)</sup> 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.