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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, [*insert date*]  
COM (2006)

Draft

**COMMISSION DIRECTIVE 2006/.../EC**

**of [...]**

**amending Annex IIIa of Directive 2000/13/EC of the European Parliament and of the Council listing the ingredients which must under all circumstances appear on the labelling of foodstuffs**

**(Text with EEA relevance)**

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**COMMISSION DIRECTIVE 2006/.../EC**

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**amending Annex IIIa of Directive 2000/13/EC of the European Parliament and of the Council listing the ingredients which must under all circumstances appear on the labelling of foodstuffs**

**(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 Article 6(11), third paragraph, thereof,

Having regard to the opinions of the European Food Safety Authority of 6 December 2005 and 15 February 2006,

Whereas:

- (1) Annex IIIa of Directive 2000/13/EC lists the ingredients which must under all circumstances appear on the labelling of foodstuffs, as they are likely to cause adverse reactions in susceptible individuals.
- (2) Article 6(11), first paragraph, of the aforementioned Directive stipulates that the list in Annex IIIa will be systematically re-examined and, where necessary, updated on the basis of the most recent scientific knowledge.
- (3) As part of this re-examination, the Commission asked the European Food Safety Authority (EFSA) to give its opinion on the possible inclusion in Annex IIIa of a number of other products.
- (4) As far as lupin is concerned, the EFSA states in its opinion of 6 December 2005 that this leguminous plant, of which there are 450 species, has long been consumed in its current state but that lupin flour is being added for a number of years in wheat flour for the production of bakery products. Cases of direct allergic reactions, some of them severe, have been documented and studies show that there is a relatively high risk of a cross-allergy to lupin in between 30% and 60% of persons who are allergic to peanuts.

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<sup>1</sup> OJ L 109 of 6.5.2000, p. 29. Directive as last amended by Directive 2003/89/EC – OJ L 308 of 25.11.2003, p. 15-18 .

- (5) In the case of molluscs (gastropods, bivalves or cephalopods), the EFSA states in its opinion of 15 February 2006 that they are most often consumed in their current state but are also used as ingredients, after any processing, in a number of preparations and in products such as surimi. Allergic reactions, which can be serious, affect up to 0.4% of the population, i.e. 20% of all cases of allergic reactions to seafood. The main allergenic protein in molluscs is tropomyosin, which is the same as that in crustaceans, and cases of cross-allergies between molluscs and crustaceans occur frequently.
- (6) It can be concluded from these observations that lupin and molluscs should be added to the list in Annex IIIa of Directive 2000/13/EC.
- (7) The measures provided for in this Directive comply with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

#### *Article 1*

The following ingredients shall be added to Annex IIIa of Directive 2000/13/EC:

“Lupin and products thereof

Molluscs and products thereof.”.

#### *Article 2*

1. The Member States shall, as from [12 months after publication], authorise the sale of foodstuffs which comply with this Directive.
2. The Member States shall, as from [24 months after publication], prohibit the sale of foodstuffs which fail to comply with this Directive. However, the sale of foodstuffs which fail to comply with this Directive and which have been labelled prior to this date shall be authorised until stocks run out.

#### *Article 3*

1. The Member States shall, by [12 months after publication] at the latest, adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive. They shall immediately communicate the text of those provisions to the Commission together with a correlation table of those provisions and this Directive.

When the Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by the Member States.

2. The Member States shall communicate to the Commission the texts of the main provisions of domestic law which they adopt in the field governed by this Directive.

*Article 4*

This Directive shall enter into force on the twentieth 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*