



EUROPEAN COMMISSION  
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL  
Directorate D - Food Safety: production and distribution chain  
**D4 - Food law and biotechnology**

Brussels, 18 December 2003  
D(2003)

**Guidelines from the Commission' services for  
the contents of the notifications requested by new  
paragraph 11 of Directive 2000/13/EC, as  
amended by Directive 2003/89/EC**

(These guidelines constitute an opinion from the Commission 'services and shall not be considered as binding)

**BACKGROUND**

Directive 2000/13/EC, as amended by Directive 2003/89/EC does not allow any labelling exemptions for a list of ingredients, specified in Annex IIIa, that are known to trigger allergies or intolerances. Whenever the listed ingredients are used in the production of foodstuffs, they must be labelled.

However, according to experts, some of the substances included in Annex IIIa, especially some "products thereof" that are derived from major food allergens, may never pose a threat for consumers with allergies. In addition, other substances that may trigger allergies are used in such a way that the finished product would not be a risk for people with allergies. Foodstuffs including such ingredients, or manufactured with the use of such substances as processing aids, are consumed safely by allergic people.

Up until now, these arguments have not been scientifically demonstrated. Nonetheless, the Legislator has accepted that they are founded on a serious basis, and the new paragraph 11 of Directive 2000/13/EC establishes a procedure allowing for a temporary labelling exemption of relevant derivatives, thus giving the time to provide the necessary scientific evidence.

Paragraph 11 reads as follow:

*“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.”*

The following ingredients are listed in Annex IIIa:

*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 illinoiesis (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*

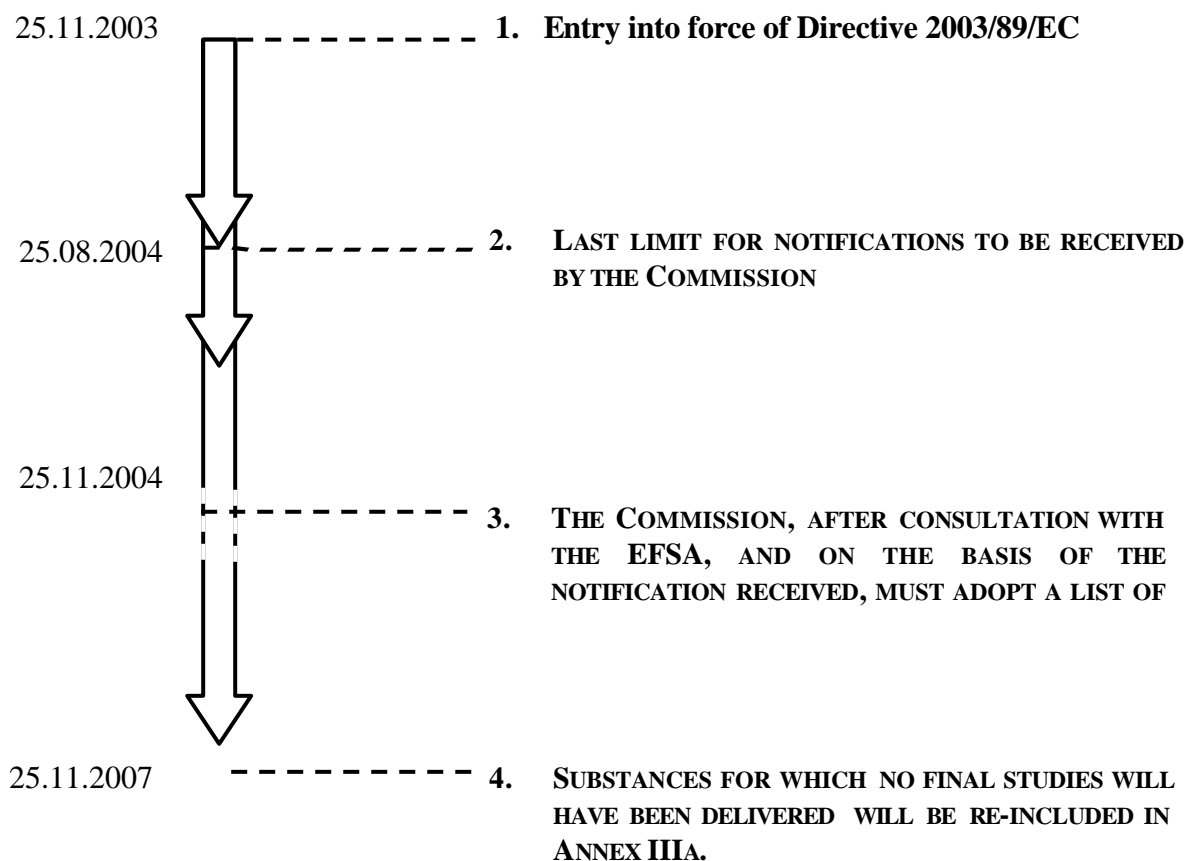
*Sesame seeds and products thereof*

***Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO<sub>2</sub>.***

The Commission services first draws attention to the timetable which will have to be observed, as emphasized in the figure below.

These guidelines are therefore issued to ensure that the submissions pursuant to Paragraph 11 will be properly introduced and will contain all the necessary information.

**Due to the time constraints, any incomplete dossier will not be taken into consideration.**



**NOTIFICATIONS**

The Commission services underline that the procedure laid down in Paragraph 11 will implement a temporary derogatory scheme in the context of allergens labelling. Therefore, the Commission services advise that it will have to be strictly interpreted, with respect to the following elements:

- Who may notify?
- What may be subject to notification?
- What shall be the content of the notification?

These points will be developed in these guidelines.

### **1) Who may notify?**

The objective of Paragraph 11 sub-paragraph 2 is to open the possibility of deleting ingredients or substances from the list of allergens, and, as a result, to exempt those ingredients or substances from mandatory labelling, first on a provisional basis, then, definitely, where scientific justifications have been provided.

This of course is an option, that may be used by the recipients of the legislation, who have to fulfil the labelling requirements, and will have to provide the justifications for a possible exemption.

**The notification procedure is therefore opened to the producers or manufacturers of the ingredients or substances for which the exemption is asked, or to the producers or manufacturers of foodstuffs including such ingredients or substances in their making process, or to representative associations of those producers or manufacturers.**

### **2) What may be the subject to notification?**

It is clear, from the wording of the provision mentioned above, that the notification procedure is not opened for the ingredients, listed in the annex, as such, or present as such in foodstuffs. **Only derived ingredients or substances are covered and likely to be the subject to notification.**

It is also specified that the notification concerns derivatives used “under specific circumstances”. This includes ingredients or substances obtained from processed allergens and present in a foodstuff, and also those used in the manufacture or the preparation of a foodstuff and removed, with only trace amounts in the final product.

**Finally, it is underlined that Annex IIIa only includes generic ingredients and that, therefore, the temporary list which might be established could only contain generic derivatives and/or derivatives used in generic, well defined conditions, such as, for example, the use as processing aid. No notification regarding an ingredient or**

**substance used in the manufacture of a specific foodstuff and/or of a particular brand will be accepted.**

### **3) Content of the notification**

It is to be understood that, if ingredients or substances are temporarily deleted from annex IIIa, the labelling exemptions could apply for two more years to them. The safety of consumers with allergies is at stake. It is then critical to restrict the deletion to ingredients or substances for which a substantial number of elements are available to suggest that serious doubt exists about their potential to trigger adverse reactions. All the more, this temporary deletion is not meant to be a free hand to the applicants: those who ask for it must be in the process of conducting appropriate studies that should be sufficient to draw conclusions about the threat for those with allergies or intolerances. Since the decision of the Commission after consultation with the EFSA will be based on those elements, they should be stressed in the notification provided by third parties. As a consequence, the Commission services advise that the notification should contain the following elements:

- **A clear characterisation of the ingredient or substance for which a temporary deletion from Annex IIIa is sought, and of the method, as well as conditions under which the consumers are exposed to it** (including, if applicable, the circumstances of usage for which the deletion would apply). It is obviously necessary to provide the proper details to identify without ambiguity the substance considered. It should of course include its scientific name(s) and its common name(s). Since the potential to trigger allergy of one substance may vary depending on its origin, or on the method used to obtain it, it is also necessary to provide details on all of those that are to be considered. If the deletion is meant to be restricted to specific circumstances, it is of course also necessary to detail those circumstances.
- **Arguments and data that support the claim that the ingredient or substance is not likely to trigger adverse reactions.** Those elements may include factual data such as origin and composition of the substance, production process, conditions of use, as well as dietary exposure estimates, and scientific data supporting the claim of absence of allergic reactions in sensitive individuals. In the case where a variability is possible in the production process or the conditions of use of the ingredient or substance, it should be clearly specified whether these arguments take it into account.

In the case where the ingredient or substance may be produced or used through different methods, it should be clearly specified whether these arguments apply in all cases.

- **An overall description of the studies that the applicant is conducting to determine the allergic potential of the substance considered.** It is important for the applicant to present an appropriate project that should be realistic to achieve the goal sought. Details can be given about the means that are planned to be implemented, and about the timetable that will allow providing the conclusion of the study before four years after the entry in force of the directive. Details about how the independence of the expertise will be guaranteed would also be appreciated. Again, the consistency with the description of the substance, and the conditions for which the deletion is sought, will be critical.

Finally, it is underlined that, according to the provision mentioned above, the notifications shall concern the “studies currently being conducted ...”.

**The Commission services consider that this condition can be met if it can be proved that the notified study has started at the latest on the last day of the possible notification period.**

Notifications should be sent to the following address:

**European Commission, Directorate General Health and consumer protection, Unit D4  
Rue Froissart 101, room 8/78. B.1049 BRUSSELS**