

FINAL GUIDANCE DOCUMENT

**ON THE PRACTICAL APPLICATION
OF DIRECTIVE 2003/89/EC
ON INGREDIENT AND
ALLERGEN LABELLING**

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FINAL GUIDANCE DOCUMENT
on the practical application of Directive 2003/89/EC on ingredient and allergen labelling

These guidelines seek to establish EU wide guidance on the practical application of the new labelling rules with respect to ingredients and allergens that will serve as a reference for operators and enforcement authorities.

INTRODUCTION

Aim and scope

- Directive 2003/89/EC is an amendment of Directive 2000/13/EC as regards indication of the ingredients present in foodstuffs with the specific objective of improving consumer information on allergenic ingredients and products thereof, except where it has been demonstrated that products thereof are no longer able to trigger adverse reactions. It also provides for more detailed information to be given on the composition of food products by the deletion of the so-called 25% rule.
- **This directive applies only to ingredients and substances intentionally used in a foodstuff. The question of adventitious presence of allergenic substances in a food (so-called cross contact) is not addressed by these new rules.** It is the responsibility of manufacturers to apply appropriate controls (good manufacturing practices – HACCP) to their particular manufacturing operations and to advice consumers accordingly.
- The scope of application of this amending Directive (2003/89) is the same as that for the Labelling Directive i.e.:
 - “Foodstuffs to be delivered as such to the ultimate consumer”
 - “Foodstuffs intended for supply to restaurants, hospitals, canteens and other similar mass caterers”.

Entry into force

- **Publication in the Official Journal:** 25/11/03
- **Implementation in Member States’ legislation:** 25/11/04 (Complying products may be sold)
- **Prohibition on selling products that do not comply with the new rules:** 25/11/05
(Products that have been labelled or marketed prior to 25/11/05 may be sold while stocks last.)

1. INGREDIENT LISTING: GENERAL ISSUES

1.1 Specific flexibilities with respect to the “descending order of weight” rule

1.1.1 Mixtures of fruits and vegetables: Article 6.5, fourth indent

The allowance for mixtures of fruit or vegetables to be listed in another order, where no particular fruit or vegetable predominates, has now been replaced by the following provision:

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 a 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 first sub paragraph, on the basis of the total weight of the fruit, vegetables or mushrooms present;

- Three generic expressions are thus permitted, for ingredient labelling purposes only, and provided that the specific fruit, vegetables or mushrooms are listed. (This could be useful for purposes of QUID, provided that one or more of the fruits or vegetables is not subject to special emphasis.)

1.1.2 Ingredients constituting less than 2% of the finished product

The following indent is added to Article 6.5:

- ingredients **constituting less than 2%** of the finished product may be listed in a different order after the other ingredients.

- This refers to **each** ingredient, which constitutes less than 2% of the finished product and not to all the ingredients coming within the final 2% of the finished product.

1.1.3 Similar or mutually substitutable ingredients

The following indent has also been added to Article 6.5:

- 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.

- Examples of similar or mutually substitutable ingredients are varieties of dried vine fruits; varieties of citrus peel; sources of vegetable oil.

1.2 Remaining flexibility with respect to the labelling of compound ingredients

The former Article 6.8. second sub paragraph, dealing with compound ingredients, including **the 25% rule, is deleted** and completely replaced with the following:

The list referred to in the first sub-paragraph shall not be compulsory.

- (a) Where the composition of the compound ingredient is **defined in current community legislation (see Appendix 4A)**, 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.

Thus the 25% compound ingredient rule is abolished and compound ingredients may only be listed without their constituents in the above, narrowly prescribed cases.

- (a) Compound ingredients “defined in current Community legislation”, which in some cases are also foodstuffs for which a list of ingredients is not required, are those ingredients covered by specific commodity Directives and Regulations (so-called vertical legislation), listed in **Appendix 4A** to this note: e.g.: cake containing less than 2% of dark chocolate (insofar the chocolate does not contain allergenic elements as referred to in Annex IIIa).
- (b) Examples of mixtures of spices and/or herbs are: curry, herbes de Provence.
- (c) Foods for which no ingredient list is required are identified in **Appendix 4B**

1.3 Deletions from Annex 1 (category names)

The category names “crystallised fruits” (definition: all crystallised fruits which make up no more than 10% of the weight of the food) and “vegetables” (definition: mixed vegetables which make up no more than 10% of the food) have been deleted from Annex 1 of Directive 2000/13/EC.

- Crystallised fruits and vegetables must, therefore, be stated separately and in descending order of weight in the list of ingredients.
- However, the term “vegetables” is permitted if followed by a statement of the specific vegetables present (see 1.1.1). It is assumed that the same holds true for “crystallised fruit” if followed by a listing of the specific fruit varieties included: e.g. “crystallised fruits: cherries, oranges, sugar,…”

1.4 Further exclusion from the definition of "ingredients"

A further category of substances not to be regarded as ingredients has been defined by the addition of Article 6.4 (c) subparagraph (iv), as follows:

“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 in an altered form.”

This recognises the use as processing aids of substances that are not food additives. This permits them to be **included** within the scope of allergen labelling, which overrides all the labelling exemptions.

2. **ALLERGEN LABELLING**

2.1 What has changed?

2.1.1 **Labelling of alcoholic beverages- Article 6.3a**

Without prejudice to the rules for the labelling of ingredients to be established for beverages containing more than 1.2% by volume of alcohol, any ingredient, as defined in Article 6.4 (a) and listed in Annex III, shall be indicated on the labelling where it is present in such beverages. 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.

Although there is no legal requirement yet to indicate the ingredients on such beverages, the latter will nevertheless be subject to the same rules as any other foodstuff for the labelling of allergens.

2.1.2 **Annex IIIa**

The definition of ingredients listed in Annex IIIa requires clarification at two levels:

- Scope of the listed ingredient names
- Scope of “products thereof”

(a) The scope of some of the ingredient names listed in Annex IIIa

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

Crustaceans¹ and products thereof

Eggs² and products thereof

Fish and products thereof

Peanuts and products thereof

Soybeans and products thereof

Milk³ 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

Celery⁴ and products thereof

¹ Crustaceans are defined as animals with an outside skeleton. They are a class of arthropod water animals that breath through gills and have 2 pairs of feelers. Crab, shrimp and lobster are crustaceans.

² Eggs of poultry (as meant in Regulation 2771/75 of the Council of 29 October 1975 on the common organization of the market in eggs) either fresh or preserved.

³ Milk of cows and or buffaloes as meant in Directive 92/46 of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products.

⁴ Refers to seeds, celeriac and celery.

Mustard⁵ 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.

(b) The scope of “Products thereof”

There appears to be no limit as to the number of generations of derivation, which are covered by the scope of “products thereof”. The issue is whether or not the derivative still has allergenic potential (see **Appendix 2**).

2.1.3 Extent of the allergen labelling requirements

(a) Scope – Article 6.10

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.

The allergen labelling requirement applies to both ingredients listed in Annex IIIa and substances derived from those ingredients.

This declaration applies without any exemption i.e. when the ingredients listed in Annex IIIa or their derivatives are present as:

- an ingredient
- an ingredient of a compound ingredient
- a food additive (including carry-over additives) or a component (including carriers and solvents) of a food additive
- a processing aid or a component (including carriers and solvents) of a processing aid.

The declaration of derivatives is made by indicating on the label its Annex IIIa origin.

⁵ Refers to seeds

(b) Exemptions – Article 6.11

... 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.

See **Appendix 2** for details about the procedure to introduce dossiers requesting temporary exemption from labelling of derivatives.

To avoid consumer confusion and too many label changes, CIAA recommends that companies do not begin labelling derivatives where it appears that EFSA may give a positive opinion on their non-allergenic status. This will become more apparent after the Commission issues its list of “provisional exemptions”, scheduled for 25th November 2004.

Appendix 3 provides a list of the dossiers seeking temporary exemption from labelling which have been introduced by the deadline of 25/08/04. The list should not be interpreted in any broader sense, pending action by the Commission to issue its list of provisional exemptions.

Until the EFSA list of provisional exemptions is issued, CIAA recommends notably:

- To continue to label derivatives from wheat starch as “glucose syrup”, “dextrose” or “maltodextrin”, without reference to wheat;
- To continue to label fully refined soybean oil and fully refined peanut oil as vegetable oil, without reference to “soy” or “peanut”;
- Not to label fully refined soy and peanut oils used as media for flavourings or additives or that are present through carry-over.

2.2 How will the changes apply in practice?

2.2.1 Where on the label, can the declaration be made

- If the name (as defined in Article 5 of Directive 2000/13/EC) under which the product is sold clearly refers to the relevant source ingredient listed in Annex IIIa, no further indication is required elsewhere on the label.

- Example 1: milk powder
- Example 2: wheat flour
- Example 3: egg mayonnaise
- Example 4: oat biscuit

- If a list of ingredients is not required, the label shall read: “contains...”.
- If a list of ingredients is required on the label, the presence of allergenic “ingredients” shall be stated in the list of ingredients. It can also, in addition, be indicated on a voluntary basis, under the list of ingredients, preceded for example by the term “contains...”.

2.2.2 Choosing the name of allergenic “ingredients”

- The presence of allergenic “ingredients” can best be labelled using the name (as defined in Article 5 of Directive 2000/13/EC) under which the product is sold or, alternatively, a customary name.

- Example 1: mentioning the word “salmon” on a salmon salad is enough; no need to mention that salmon is a type of fish.
- Example 2: “cheese” in the list of ingredients of a pizza is considered to clearly refer to the presence of milk ingredients (including lactose) in that product.
- Example 3: nuts should be stated with their specific names: almonds, walnuts, cashew nuts, pecans etc. when added directly to a food product. In the situations referred to under 2.2.3, 2.2.4, 2.2.5 and 2.2.6, the reference to “nuts” is sufficient.
- Example 4: cereals containing gluten should be labelled with their species name for instance, wheat, rye, barley etc.

- If the name referred to above would not be readily understood by the consumer, a more familiar alternative or additional wording to indicate the presence of the allergen should be used.

- Example 1: “casein (from milk)” instead of “casein”.
- Example 2: “peanut” instead of “groundnuts” or “monkey nuts”
- Example 3: Egg lysozyme instead of lysozyme or E 1105
- Example 4: when cheese is designated with a name that is not common to consumers it should be supplemented with the word cheese e.g. Tilsiter cheese instead of Tilsiter. Of course this can be regionally different.
- Example 5: lecithin: to be mentioned as soya lecithin, egg lecithin, E322 (soya) or E322 (egg).
- Example 6: unusual species of fish should be designated “fish”

2.2.3 If the presence of an allergenic “ingredient” arises from a carrier or solvent of an additive, flavouring or vitamin which requires labelling, the allergenic source (using a term provided in Annex IIIa) may be indicated as follows:

- If the allergenic “ingredient” is already mentioned due to the presence of another ingredient the allergenic ingredient does not need to be mentioned once again⁶or,
- It can be placed between brackets behind the additive, flavouring or vitamin (if necessary preceded by the word “contains” or “with”) or,
- It can be listed separately in the list of ingredients or,
- It can also, in addition, be indicated on a voluntary basis, under the list of ingredients, preceded for example by the term “contains...”.

2.2.4 If the presence of an allergenic “ingredient” arises from a material that does not require labelling (technical aids, carriers, solvents, carry-over additives), and that is therefore not already mentioned in the list of ingredients, the allergenic source (using a term provided in Annex IIIa) may be indicated as follows:

- If the allergenic “ingredient” is already mentioned due to the presence of another ingredient the allergenic ingredient does not need to be mentioned once again⁶or,

- Example 1: a peanut biscuit does not have to mention the fact that the carrier of an additive also contains peanut derivatives.
- Example 2: a milky drink does not have to mention the fact that the carrier of an additive is lactose.
- Example 3: a yoghurt product does not have to mention that lactose has been used as media for flavouring.

- Separately in the list of ingredients or,
- It can also, in addition, be indicated on a voluntary basis, under the list of ingredients, preceded for example by the term “contains...”.

2.2.5 If the allergenic “ingredient” is part of a product which has been regulated by EU law (e.g. spreadable fat products (incl. margarine), chocolate, fruit nectars, jam products and fully or partly dehydrated milk products – See list in Appendix 4A) and which contributes less than 2% to the final product, and therefore does not need to have its components listed, it should be labelled as follows

- No mention if the allergenic “ingredient” has already been mentioned due to the presence of another ingredient⁶or,

- Example: Dairy ice cream containing less than 2% chocolate does not need to mention the fact that the chocolate contains milk ingredients. However, for non-dairy ice cream, the milk from the chocolate would need to be labelled.

- Between brackets after the ingredient/product (if necessary preceded by the word “contains” or “with”) or,

⁶ The strict legal interpretation of Directive 2003/89/EC requires the repetition of the indication of the allergenic “ingredient” as many times as it has been used in the final product. The interpretation above should therefore be validated by the EU Standing Committee on the Food Chain.

- Stated separately in the list of ingredients or,
- It can also, in addition, be indicated on a voluntary basis, under the list of ingredients, preceded for example by the term “contains...”.

2.2.6 Products containing less than 2% of herbs and/or spices can refer to the presence of celery and/or mustard seeds by adding “contains” or “with” behind the designation herbs and/or spices

2.2.7 Labelling of sulphur dioxide and sulphite is required for final products, as consumed, if levels exceed 10mg/kg or 10 mg/l. This threshold does not apply to individual ingredients but to the whole foodstuff, whether compound or not

The level refers to foodstuffs ready for consumption at point of sale or, where appropriate, prepared following manufacturers' instructions (e.g. re-hydration of dried products, dilution of concentrates⁷).

Whilst strict legal interpretation of Directive 2003/89/EC requires labelling only in relation to materials which are intentionally added, CIAA recommends labelling when sulphur dioxide or sulphites have been added and it is reasonable to assume that the total content of sulphur dioxide and sulphites, both added and naturally present, will exceed the threshold of 10mg/litre.

Sulphite and sulphur dioxide exceeding 10mg/kg or 10 mg/l, expressed as SO₂, shall be stated as follows:

- In case of sulphur dioxide, state as such or as “E220 (sulphur dioxide)”.
- In case of sulphite, state the actual name, example: sodium sulphite, potassium metabisulphite etc, or “E221 (sulphite)” and/or “E224 (sulphite)”.

If there is no ingredients list the above has to be preceded by the word “contains...”

⁷ Clarification as to the acceptability of the reference (as appropriate) to the level in foodstuff as prepared following manufacturers' instructions should be sought through the European Standing Committee procedure.

Appendix 1

Consolidated text 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 as amended by Directive 2003/89/EC

1. Ingredients shall be listed in accordance with this Article and Annexes I, II, III and IIIa.
2. Ingredients need not be listed in the case of:
 - (a) - fresh fruit and vegetables, including potatoes, which have not been peeled, cut or similarly treated,
 - carbonated water, the description of which indicates that it has been carbonated,
 - fermentation vinegars derived exclusively from a single basic product, provided that no other ingredient has been added;
 - (b) - cheese,
 - butter,
 - fermented milk and cream,

provided that no ingredient has been added other than lactic products, enzymes and micro-organism cultures essential to manufacture, or the salt needed for the manufacture of cheese other than fresh cheese and processed cheese;

- (c) products comprising a single ingredient, where:
 - the trade name is identical with the ingredient name, or
 - the trade name enables the nature of the ingredient to be clearly identified.

3. In the case of beverages containing more than 1,2 % by volume of alcohol, the Council, acting on a proposal from the Commission, shall, before 22 December 1982, determine the rules for labelling ingredients.

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).

4(a) 'Ingredient' shall mean any substance, including additives, used in the manufacture or preparation of a foodstuff and still present in the finished product, even if in altered form.

(b) Where an ingredient of the foodstuff is itself the product of several ingredients, the latter shall be regarded as ingredients of the foodstuff in question.

(c) The following shall not be regarded as ingredients:

(i) the constituents of an ingredient which have been temporarily separated during the manufacturing process and later reintroduced but not in excess of their original proportions;

(ii) additives:

- whose presence in a given foodstuff is solely due to the fact that they were contained in one or more ingredients of that foodstuff, provided that they serve no technological function in the finished product,
- which are used as processing aids;

(iii) substances used in the quantities strictly necessary as solvents or media for additives or flavouring.

(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) In certain cases Decisions may be taken in accordance with the procedure laid down in Article 20(2) as to whether the conditions described in point (c)(ii) and (iii) are satisfied.

5. The list of ingredients shall include all the ingredients of the foodstuff, in descending order of weight, as recorded at the time of their use in the manufacture of the foodstuff. It shall appear preceded by a suitable heading which includes the word 'ingredients'.

However:

- added water and volatile products shall be listed in order of their weight in the finished product; the amount of water added as an ingredient in a foodstuff shall be calculated by deducting from the total amount of the finished product the total amount of the other ingredients used. This amount need not be taken into consideration if it does not exceed 5% by weight of the finished product,
- ingredients used in concentrated or dehydrated form and reconstituted at the time of manufacture may be listed in order of weight as recorded before their concentration or dehydration,
- in the case of concentrated or dehydrated foods which are intended to be reconstituted by the addition of water, the ingredients may be listed in order of proportion in the reconstituted product provided that the list of ingredients is accompanied by an expression such as 'ingredients of the reconstituted product', or 'ingredients of the ready-to-use product'

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

6. Ingredients shall be designated by their specific name, where applicable, in accordance with the rules laid down in Article 5.

However:

- ingredients which belong to one of the categories listed in Annex I and are constituents of another foodstuff need only be designated by the name of that category.
Alterations to the list of categories in Annex I may be effected in accordance with the procedure laid down in Article 20(2).

However, the designation 'starch' listed in Annex I must always be complemented by the indication of its specific vegetable origin, when that ingredient may contain gluten,

- ingredients belonging to one of the categories listed in Annex II must be designated by the name of that category, followed by their specific name or EC number; if an ingredient belongs to more than one of the categories, the category appropriate to the principal function in the case of the foodstuff in question shall be indicated.

Amendments to this Annex based on advances in scientific and technical knowledge shall be adopted in accordance with the procedure laid down in Article 20(2).

However, the designation 'modified starch' listed in Annex II must always be complemented by the indication of its specific vegetable origin, when that ingredient may contain gluten,

- flavourings shall be designated in accordance with Annex III,
- the specific Community provisions governing the indication of treatment of an ingredient with ionising radiation shall be adopted subsequently in accordance with Article 95 of the Treaty.

7. Community provisions or, where there are none, national provisions may lay down that the name under which a specific foodstuff is sold is to be accompanied by mention of a particular ingredient or ingredients.

The procedure laid down in Article 19 shall apply to any such national provisions.

The Community provisions referred to in this paragraph shall be adopted in accordance with the procedure laid down in Article 20(2).

8. In the case referred to in paragraph 4(b), a compound ingredient may be included in the list of ingredients, under its own designation in so far as this is laid down by law or established by custom, in terms of its overall weight, provided that it is immediately followed by a list of its ingredients.

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.

9. Notwithstanding paragraph 5 the water content need not be specified:

- (a) where the water is used during the manufacturing process solely for the reconstitution of an ingredient used in concentrated or dehydrated form;
- (b) in the case of a liquid medium which is not normally consumed.

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 reexamined 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).

Appendix 2**Exemption of non-allergenic derivatives of Annex IIIa ingredients**

With reference to Annex IIIa, Article 6.11 provides for it to be updated on the basis of the most recent scientific knowledge. This could include the addition of further ingredients. The second paragraph, however, states that “updating could also be effected by deletion from Annex IIIa of ingredients for which it has been scientifically established and it is not possible for them to cause adverse reactions.”

This paragraph continues by setting out the following timetable for development of an initial list of ingredients or substances derived from Annex IIIa not likely to trigger adverse reactions and therefore excluded from the allergen labelling requirements.











- The Commission can be informed **by 25 August 2004** of studies in hand to establish non-allergenicity of derivatives of Annex IIIa ingredients⁸
- The Commission is to decide **by 25 November 2004** on a provisional list of derivatives excluded from the labelling provisions of Annex IIIa in consultation with the FSA.
- The Commission is to decide **by 25 November 2007** based upon advice from EFSA, whether or not to retain exclusion from Annex IIIa of derivatives for which studies have been completed

Industry sectors are seeking to meet these deadlines in respect of a limited number of potentially non-allergenic derivatives of Annex IIIa ingredients. This is important principally to avoid misleading reference to allergens on labels where there is no allergenic risk to consumers.

⁸ See: “Guidelines from the Commission’s services for the contents of the notifications requested by new paragraph 11 of Directive 2000/13/EC, as amended by Directive 2003/89/EC” Brussels, 18 December 2003. [European Commission Directorate D–D4 - Food Law and Biotechnology]

Appendix 3

List of requested opinions on exemption as published on EFSA website on 14/09/04 (to be completed by members as appropriate)

EFSA Question Number	Sub-Area	Subject	Date of Reception	Date of Acceptance	Expected Date of Completion	
EFSA-Q-2004-084	Food allergy - applications submitted for temporary labelling exemption (Art 6, par 11, Directive 2003/13/EC)	Request for the following substances used in the manufacture of wine and removed: casein; potassium caseinate; skimmed milk; egg white; lysozyme; Isinglass; and chesnut-derived tannins	18 June 2004	5 July 2004	(being reconsidered)	
EFSA-Q-2004-091		Wheat-based glucose syrups, including dextrose, and wheat-based maltodextrins	29 June 2004	12 July 2004	(being reconsidered)	
EFSA-Q-2004-092		Glucose syrups based on barley	2 July 2004	12 July 2004	(being reconsidered)	
EFSA-Q-2004-098		Fully refined soybean oil and fat	15 July 2004	23 August 2004	(being reconsidered)	
EFSA-Q-2004-117		Lactitol	23 August 2004		(being reconsidered)	
EFSA-Q-2004-118		Distillates made with nuts	24 August 2004		(being reconsidered)	
EFSA-Q-2004-119		Distillates made from whey	24 August 2004		(being reconsidered)	
EFSA-Q-2004-120		Distillates made from cereals	24 August 2004		(being reconsidered)	
EFSA-Q-2004-121		Request for a temporary labelling exemption regarding fish gelatine for use as a formulation (carrier) aid in vitamin and carotenoid preparations	1 September 2004		29 October 2004	
EFSA-Q-2004-122		Request for a temporary labelling exemption regarding fully refined peanut oil and fat	1 September 2004		29 October 2004	
EFSA-Q-2004-123		Isinglass	10 September 2004	10 September 2004	(being reconsidered)	

Appendix 4

Exemptions from ingredient listing of specified compound ingredients**A. Community legislation defining foodstuffs, relevant to the ingredient labelling exemption provided in Article 6.8 second sub-paragraph, indent (a)⁹**

Regulation (EC) No 2991/1994 of 5 December 1994 (as amended) laying down standards for **spreadable fats**

Directive 2001/114/EC of 20 December 2001 relating to certain **partly or wholly dehydrated preserved milk for human consumption**

Regulation (EEC) No 1898/1987 of 2 July 1987 on the protection of designations used in marketing of **milk and milk products**

Directive 2001/113/EC of 20 December 2001 relating to **fruit jams, jellies and marmalades and chestnut purée**

Directive 2001/112/EC of 20 December 2001 relating to **fruit juices and certain similar products**

Directive 2000/36/EC relating to **cocoa and chocolate products** intended for human consumption

Directive 99/4/ EC of 22 February 1999 relating to **coffee extracts and chicory extracts**

Directive 2001/110/EC of 20 December 2001 to **honey** *

Regulation (EEC) No 1601/1991 of 10 June 1991 laying down general rules on the definition, description and presentation of **aromatized wines, aromatized wine-based drinks and aromatized wine-product cocktails** *

B. Foodstuffs for which an ingredients list is not required, relevant to the ingredient labelling exemption provided in Article 6.8 second sub-paragraph, indent (c)

* The instruments asterisked above also provide that no ingredients list is required for the products concerned.

Other compound manufactured products for which the Labelling Directive (Article 6.2) does not require a list of ingredients are:

Carbonated water, the description of which indicates that it has been carbonated;

Fermentation vinegars derived exclusively from a single basic product, provided that no other ingredient has been added;

Cheese, butter, fermented milk and cream, provided that no ingredient has been added other than lactic products, enzymes and micro-organism cultures essential to manufacture, or the salt needed for the manufacture of cheese other than fresh cheese and processed cheese.

Article 6.3 also indicates that ingredient labelling requirements still have to be introduced for beverages containing more than 1.2% by volume of alcohol.

⁹ According to DG Sanco only Directive 2001/113/EC, 2001/112/EC, 2000/36/EC should be listed under this section.