GUIDELINES RELATING TO

Article 6 paragraph 10 of Directive 2000/13/EC as amended by Directive 2003/89/EC

GUIDELINES REGARDING/RELATING TO ARTICLE 6, PARAGRAPH 10 OF DIRECTIVE 2000/13/EC AS AMENDED BY DIRECTIVE 2003/89/EC

Opening remarks

1. This document has been drawn up by the Commission services and the representatives of the Member States with the aim of providing informal guidelines regarding the provisions set out in Article 6, paragraph 10 of Directive 2000/13/EC as amended by Directive 2003/89/EC, relating to the indication of the ingredients listed in Annex IIIa of the Directive.

2. The examples it contains are given for illustration only.

3. The guidelines and examples given in this document cannot be regarded as official interpretation of the legislation, this being the exclusive reserve of the Court of Justice of the European Communities.

Article 6, paragraph 10 of Directive 2000/13/EC (hereafter referred to as "Paragraph 10") reads as follows:

"10. Notwithstanding paragraph 2, the second subparagraph 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."

Paragraph 10 lays down specific labelling requirements for ingredients listed in Annex IIIa of the Directive (ingredients known as likely to trigger adverse effects in sensitive individuals).

The first objective of Paragraph 10 is to ensure that all ingredients or substances used in production of a foodstuff and still present in the finished product will appear on the label where they are listed in Annex IIIa, or originating from an ingredient listed in that annex.

The second objective of Paragraph 10 is that consumers suffering from allergy or intolerance shall be able to identify the ingredient they are sensitive to, and, in that purpose, all ingredients listed in Annex IIIa as well as ingredients or substances originating from these ingredients will have to be indicated with a clear reference to the name under which the allergen is known.

To these ends, paragraph 10 states that no labelling derogation will be allowed for ingredients or substances listed in Annex IIIa or originating from an ingredient listed in that annex.

However, it must be noted that these derogations will continue to be accepted for ingredients or substances excluded from annex IIIa in compliance with the procedure referred to in Paragraph 11 of Article 6.

The possible derogations for labelling ingredients are set out in Article 6 of Directive 2000/13/EC and cover the following cases:

(a) **Foodstuffs for which no ingredient list is required**, because they comprise a single ingredient, or are almost exclusively derived from a single basic product.
These foodstuffs are listed in paragraph 2 of Article 6.

(b) **Sub ingredients of certain compound ingredients** as mentioned in paragraph 8 of Article 6 may not be listed.

(c) **Ingredients which belong to well defined categories** may be designated under their category name, as stated in paragraph 6 of Article 6.

(d) **Substances that are not regarded as ingredients**, as mentioned in paragraph 4 (c) of Article 6 and are thus not mandatorily indicated on the label.

Paragraph 10 has given rise to questions which are addressed hereafter.

1. Indication or repetition of an ingredient and/or of the source of that ingredient.

1.1. Subparagraph 1 of Paragraph 10 requests in substance that, unlike "normal" ingredients, ingredients listed in Annex IIIa shall not be admitted to derogations (a), (b) and (c), as detailed above.

Therefore, these ingredients shall be indicated on the label with a clear reference to the name of the ingredient from which they originate.

However, Subparagraph 2 of Paragraph 10 states that the indication referred to in subparagraph 1 is not needed if the name under which the product is sold clearly refers to the ingredient concerned.

The consequences are clearly that, where that condition is met, derogations (a), (b) or (c) can also continue to be admitted for ingredients from Annex IIIa, as well as for all other ingredients.

For example:

- A foodstuff sold under the name "cake flavoured with almonds" will be admitted for derogation (c) and could include the category name "flavour" alone in the list of ingredients, even where the flavour has been made with the use of almond extracts.

- A foodstuff sold under the name "fish sticks" will be admitted for derogation (c) and could include, should the case occur, the category name "gelling agent", only followed by the specific name or EC number, without reference to "fish" even where it has been made from fish products.

- Dairy products sold under names such as cheese, butter or yoghurt can continue to be admitted for derogation (a) because these names refer clearly to "milk" which is included in Annex IIIa.

1.2. Subparagraph 3 of Paragraph 10 requests that substances originated in ingredients listed in Annex IIIa shall not be admitted for derogation (d).

As explained in point 1.1., Subparagraph 2 of Paragraph 10 only refers to Subparagraph 1, and this means that derogations (d) could not be accepted for substances originating from ingredients listed in Annex IIIa, even where the name of the foodstuff refers to the name of the ingredient.

Therefore, carry over additives, solvents and carriers for additives or processing aids shall be regarded as ingredients where they originate from ingredients listed in Annex IIIa, and indicated "on the label" with a clear reference to the name of the ingredient from which they originate.

However, this does not mean that the reference to that ingredient shall be repeated as many times as these substances are present.

Any presentation making clear that different ingredients or substances originate from a single ingredient included in Annex IIIa would fulfil the requirement of subparagraph 3 and would be acceptable.

For example:

A foodstuff including additives, carriers and processing aids derived from wheat could be labelled as follows:

"…

- *Additive* (1)
- *Additive* (1)
- *Carrier* (1)
- *Processing aid* (1)
- …

(1) from wheat".

Finally, **it is also emphasised that, taking into account the list of derivatives exempted from labelling in compliance with Paragraph 11, derogations (a), (b), (c) and (d) will continue to be accepted in many cases and such situation will not be frequent.**

2. Name under which the foodstuff is sold.

As explained in point 1, subparagraph 2 of Paragraph 10 allows derogations (a), (b) and (c) where the name under which the foodstuff is sold clearly refers to the ingredient concerned.

Milk based products (cheese, butter, fermented milk and cream) are particularly concerned by that provision because, subject to certain conditions, they are exempted from ingredient lists pursuant to Article 6 paragraph 2 point (b). Other products might also be concerned.

However, it could be difficult in practice to know whether the condition "*clearly refers to the ingredient concerned"* is fulfilled. Indeed, while it is clear that products sold under names such as "cheese, butter, cream or yoghurt" refer to milk, many examples of cheeses sold under a trade name, or an appellation, protected or not, might be found. In general, such names do not explicitly refer to milk.

The following rules should therefore apply.

- It can be accepted that the condition "*the name under which the foodstuff is sold clearly refers to the ingredient concerned*", will be fulfilled if the name includes any supplement, consisting in words, that clearly refers to the ingredient of Annex IIIa.

  For example:

  "*Name of the product*"
  "… cheese…"

- Finally, in cases where products such as cheese are sold under a name which does not clearly refer to an ingredient of Annex IIIa (for example milk), none of the conditions described above being met, and consumers in certain Member States being possibly unaware of the presence of that ingredient, National Authorities will have to ensure that the objectives of paragraph 10 are achieved and, to that effect, could request that additional information should appear on the label.

  In such situations, National Authorities will have to act by analogy with the rules laid down at Article 5 Paragraph 1 point b) of Directive 2000/13/EC regarding the name under which a foodstuff is sold. This means that requesting additional information shall be fully justified and necessary, and implemented in a non discriminatory and proportionate way.

3. Other Questions

3.1. sulphur dioxide and sulphite.

This substance shall appear on the label under its full name, where it is present at levels exceeding 10mg/kg or 10mg/l expressed as SO2 (see end of Annex IIIa).

There is a need to clarify whether that level shall be calculated for products as consumed or as sold.

Other labelling requirements can be considered in that purpose:

- Directive 1999/10/EC, laying down implementing rules for the indication of the quantity of certain ingredients, states at Article 2 paragraph 3 that:
  "In the case of concentrated or dehydrated foods which are intended to be reconstituted by the addition of water, the quantity of the ingredient may be indicated on the basis of their proportion by weight in the reconstituted product".

- Directive 2004/77/EC imposes a statement on the label of, inter alia, beverages containing glycyrrhizinic acid at a given concentration, but states that the level shall apply to the products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers.

By analogy with these provisions, the above-mentioned level of 10mg/kg or 10mg/l is to be calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers

3.2. Definition of "products thereof" (in Annex IIIa).

Questions are likely to arise regarding the scope of this definition, due to different wordings in other official languages.

As it is internationally admitted, "products thereof" include all derived products, originating from an ingredient included in Annex IIIa, obtained after one or several processing stages.

Therefore, ingredients such as micro organisms that have been fed on substrates cannot be considered as derived from these substrates.

In the case where such a substrate is a food ingredient included in Annex IIIa, and possible traces of that substrate, are likely to contaminate a foodstuff prepared with micro organism, manufacturers will have to decide whether a precaution labelling is necessary.

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