

Guidelines relating to the provision of information on substances or products causing allergies or intolerances as listed in Annex II of *Regulation (EU) No 1169/2011 on the provision of food information to consumers*

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OPENING REMARKS

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 requirements of Regulation (EU) No 1169/2011 *on the provision of food information to consumers* (“the Regulation”) related to the indication of the presence of certain substances or products causing allergies or intolerances as described in Article 9.1(c) and listed in Annex II of the Regulation.

The guideline should be read in conjunction with the legislation itself.

The examples it contains are given for illustration only.

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 Union.

I. RELEVANT PROVISIONS

Article 9(1) – List of mandatory particulars

1. In accordance with Articles 10 to 35 and subject to the exceptions contained in this Chapter, indication of the following particulars shall be mandatory:

(a) the name of the food;

(b) the list of ingredients;

(c) any ingredient or processing aid listed in Annex II or derived from a substance or product listed in Annex II causing allergies or intolerances used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form;

(d) the quantity of certain ingredients or categories of ingredients;

(e) the net quantity of the food;

(f) the date of minimum durability or the 'use by' date;

(g) any special storage conditions and/or conditions of use;

(h) the name or business name and address of the food business operator referred to in Article 8(1);

(i) the country of origin or place of provenance where provided for in Article 26;

(j) instructions for use where it would be difficult to make appropriate use of the food in the absence of such instructions;

(k) with respect to beverages containing more than 1,2 % by volume of alcohol, the actual alcoholic strength by volume;

(l) a nutrition declaration.

Article 21 - Labelling of certain substances or products causing allergies or intolerances

1. Without prejudice to the rules adopted under Article 44(2), the particulars referred to in point (c) of Article 9(1) shall meet the following requirements:

(a) they shall be indicated in the list of ingredients in accordance with the rules laid down in Article 18(1), with a clear reference to the name of the substance or product as listed in Annex II; and

(b) the name of the substance or product as listed in Annex II shall be emphasised through a typeset that clearly distinguishes it from the rest of the list of ingredients, for example by means of the font, style or background colour.

In the absence of a list of ingredients, the indication of the particulars referred to in point (c) of Article 9(1) shall comprise the word 'contains' followed by the name of the substance or product as listed in Annex II.

Where several ingredients or processing aids of a food originate from a single substance or product listed in Annex II, the labelling shall make it clear for each ingredient or processing aid concerned.

The indication of the particulars referred to in point (c) of Article 9(1) shall not be required in cases where the name of the food clearly refers to the substance or product concerned.

2. In order to ensure better information for consumers and to take account of the most recent scientific progress and technical knowledge, the Commission shall systematically re-examine and, where necessary, update the list in Annex II by means of delegated acts, in accordance with Article 51. Where, in the case of the emergence of a risk to consumers' health, imperative grounds of urgency so require, the procedure provided for in Article 52 shall apply to delegated acts adopted pursuant to this Article.

Article 44 - National measures for non-prepacked food

1. Where foods are offered for sale to the final consumer or to mass caterers without prepackaging, or where foods are packed on the sales premises at the consumer's request or prepacked for direct sale:

(a) the provision of the particulars specified in point (c) of Article 9(1) is mandatory;

(b) the provision of other particulars referred to in Articles 9 and 10 is not mandatory unless Member States adopt national measures requiring the provision of some or all of those particulars or elements of those particulars.

2. Member States may adopt national measures concerning the means through which the particulars or elements of those particulars specified in paragraph 1 are to be made available and, where appropriate, their form of expression and presentation.

3. Member States shall communicate to the Commission the text of the measures referred to in point (b) of paragraph 1 and in paragraph 2 without delay.

Annex II – Substances or products causing allergies or intolerances

1. Cereals containing gluten, namely: wheat (such as spelt and khorasan wheat), rye, barley, oats or their hybridised strains, and products thereof, except

(a) wheat based glucose syrups including dextrose (1);

(b) wheat based maltodextrins (1);

(c) glucose syrups based on barley;

(d) cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin;

2. Crustaceans and products thereof;

3. Eggs and products thereof;

4. Fish and products thereof, except:

(a) fish gelatine used as carrier for vitamin or carotenoid preparations;

(b) fish gelatine or Isinglass used as fining agent in beer and wine;

5. Peanuts and products thereof;

6. Soybeans and products thereof, except:

(a) fully refined soybean oil and fat (1);

(b) natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, and natural D-alpha tocopherol succinate from soybean sources;

(c) vegetable oils derived phytosterols and phytosterol esters from soybean sources;

(d) plant stanol ester produced from vegetable oil sterols from soybean sources;

7. Milk and products thereof (including lactose), except:

(a) whey used for making alcoholic distillates including ethyl alcohol of agricultural origin;

(b) lactitol;

8. Nuts, namely: almonds (Amygdalus communis L.), hazelnuts (Corylus avellana), walnuts (Juglans regia), cashews (Anacardium occidentale), pecan nuts (Carya illinoensis (Wangenh.) K. Koch), Brazil nuts (Bertholletia excelsa), pistachio nuts (Pistacia vera), macadamia or Queensland nuts (Macadamia ternifolia), and products thereof, except for nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin;

9. Celery and products thereof;

10. Mustard and products thereof;

11. Sesame seeds and products thereof;

12. Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre in terms of the total SO₂ which are to be calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers;

13. Lupin and products thereof;

14. Molluscs and products thereof.

(1) And the products thereof, in so far as the process that they have undergone is not likely to increase the level of allergenicity assessed by the Authority for the relevant product from which they originated.

II. MANDATORY PROVISION OF “ALLERGEN INFORMATION”

When used in the production of foods and still present therein, certain ingredients or other substances or products (such as processing aids) can cause allergies or intolerances in some people, and some of those allergies or intolerances constitute a danger to the health of those concerned. It is important that information on the presence of food additives, processing aids and other substances or products with a scientifically proven allergic or intolerance effect should be given to enable consumers, particularly those suffering from a food allergy or intolerance, to make informed choices which are safe for them.

Therefore, Article 9(1)(c) of the Regulation provides that the indication of any ingredient or processing aid causing allergies or intolerances as listed in its Annex II (or derived from such substance or product) used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form, shall be mandatory.

Under the Regulation, according to Article 44(1)(a), the information on the presence of substances or products causing allergies or intolerances is also mandatory for non-packed foods, including foods prepared and delivered by catering establishments or e.g. restaurants, and for foods which are packed on the sales premises at the consumer’s request or prepacked for direct sale.

III. MODALITIES FOR THE PROVISION OF “ALLERGEN INFORMATION”

Article 21 of the Regulation harmonises the modalities according to which the information about the presence of substances or products causing allergies or intolerances must be provided on foods. The main objective of this requirement is to ensure that consumers suffering from allergy or intolerance shall be able to easily identify the substance they are sensitive to, and in that purpose:

- (a) all substances or products listed in Annex II as well as ingredients or substances originating from those will have to be indicated with a clear reference to the name of the substance or product as listed in Annex II, and
- (b) without prejudice to the rules adopted under Article 44(2), the name of the substance or product listed in Annex II needs to be emphasised through a typeset that clearly distinguishes it from the rest of the list of ingredients, for example by means of the font, style or background colour.

When the food bears a list of ingredients, the allergenic substances have to be indicated in the list of ingredients, in accordance with the rules laid down in Article 18(1). In particular, the list of ingredients must be headed or preceded by a suitable heading which consists of or includes the word “ingredients”. The ingredients have to be indicated in descending order of weight, as recorded at the time of their use in the manufacture of the food.

In the absence of a list of ingredients, the indication of the allergens shall comprise the word “contains” followed by the name of the substance or product listed in Annex II. The Regulation foresees however a derogation from the obligation to provide information on allergens, when the name of the food clearly refers to the substance or product concerned.

Consequently, under the Regulation it is not possible to voluntarily declare additional allergen information such as “contains: milk, wheat flour”, or use warning symbols outside of the list of ingredients. The purpose of this harmonisation was to avoid the consumer being confused by different ways of labelling of allergens in food. In this regard, it should be noted that substances listed in Annex II of the Regulation are considered as part of the most common allergens present in the EU. Nevertheless, also other food ingredients can trigger allergic reactions by certain groups of consumers. Taking this into, it is important that such consumers always check the list of ingredients.

III. 1. Pre-packed foods

III. 1.a) With a clear reference to the name of the substance or product listed in Annex II

When indicating the allergens in the list of ingredients, the names under which such substances are indicated shall refer to the name of the substance or product as listed in Annex II. Where several ingredients or processing aids of a food originate from a single substance or product listed in Annex II, the labelling shall make it clear for each ingredient or processing aid concerned.

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

Any presentation making clear that different ingredients originate from a single ingredient included in Annex II would fulfil the requirement and would be acceptable.

For example:

A food including food 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**”.

For the purpose of this requirement, when indicating the substances or products of Annex II or ingredients deriving thereof, *a priori*, the designations provided in Annex II shall be used.

Nevertheless, in some cases, the specific names of foods could be as comprehensible for the consumer as the generic ones provided in the Annex II. This is in particular true for substances listed under the name referring to a category of foods, as for example fish or molluscs. As the objective of the provision of Article 21(1)(a) is to enable the consumer to identify the food ingredients which are likely to trigger the allergic reactions, in cases as mentioned above, providing the names other than those enumerated in the Annex could be allowed.

For example: “**cod**” instead of fish; “**oyster**”, “**mussels**” instead of molluscs.

Other possible examples:

- Milk: butter, cream, cheese, yoghurt ...
- Fish: salmon, tuna...
- Crustaceans: prawn, lobster, crab, ...

As the consumer understanding of the name of the foods in question is likely to vary among the Member States, an assessment on a case-by-case basis is necessary. Given the important risk associated with food allergies, if there is any doubt about the understanding of the consumer and the possibility of cross reaction between species, the generic names as enumerated in Annex II should be provided and emphasised.

➔ In the case of ingredients and processing aids derived from nuts listed in Annex II, which terms have to be indicated as ‘a clear reference’: ‘nut’ or their specific names?

Nuts are to be declared in the ingredients list using their specific names, i.e. almonds, hazelnuts, walnuts, cashews, pecan nuts, Brazil nuts, pistachio nuts, macadamia or Queensland nuts.

For example: roasted **hazelnuts**, flavourings (**almonds**)

➔ In the case of ingredients derived from cereals containing gluten listed in Annex II, which terms have to be indicated as ‘a clear reference’: ‘gluten’ or the specific names of the cereals?

Cereals containing gluten should be declared in the ingredients list using the specific name of the cereal, i.e. wheat (such as spelt and khorasan wheat), rye, barley, oats.

For example: **wheat flour, barley malt vinegar, oats flakes**

The word 'gluten' can be added on a voluntary basis, but it is the specific name of the cereal that has to be emphasised, and not 'gluten'.

For example: **wheat flour (contains gluten)**

If gluten is added as such, as an ingredient, the name of the cereal the gluten is coming from should be also indicated. This is due to the fact that consumers may be allergic or intolerant to cereals protein other than gluten.

For example: **gluten (wheat), wheat gluten or gluten (from wheat)**

In case of ingredients originating from cereals containing gluten, such as "plant protein hydrolysate", the reference to the cereal in question should also be made.

For example: **plant protein hydrolysate (wheat) or (wheat gluten),
plant protein hydrolysate (contains wheat) or (contains wheat gluten)**

III. 1.b) Emphasizing the name

The emphasis on substances causing allergies or intolerances in the list of ingredients ensures that consumers continue to check the list of ingredients. So, consumers suffering from a food allergy or intolerance (will be able to make informed choices, which are safe for them.

The name of the allergens needs to be emphasised through a typeset that distinguishes it from the rest of the list of ingredients. The Regulation gives certain flexibility as regards the means for ensuring this emphasis, for example by means of the font, style or background color.

If the name of an ingredient partly includes the name of a substance/product causing allergies or intolerances in a single word (e.g. the German word "Milchpulver" for "milk powder"), the part of the name of the ingredient that corresponds to the substances/products listed in Annex II should be emphasised (e.g. "**Milch**pulver"). However, in the spirit of a pragmatic approach, highlighting the entire name of the ingredient concerned (e.g. '**Milchpulver**') would also be considered as complying with the legal requirements. Obviously, when the name of an ingredient consists of several separate words, only the substance/product causing allergies or intolerances should be emphasised (e.g. 'poudre de **lait**', '**latte** in polvere').

In cases where all the ingredients of a food are substances or products causing allergies or intolerances as listed in Annex II of the Regulation, they must all be indicated in the list of ingredients and be emphasised. If all the ingredients are in the Annex II list, they need to be emphasised against other mandatory information such as the word 'ingredients' where it introduces the ingredients list.

→ In the case of compound ingredients containing substances listed in Annex II, which part should be emphasised: the name of the compound ingredient or its individual ingredients listed in the Annex?

If a compound ingredient contains substances causing allergies or intolerances as listed in Annex II, the latter should be emphasised in the list of ingredients.

For example: Ingredients:

- margarine, cream filling (**egg yolks, cream, sugar, water, ...**)

III.2. Non-prepacked foods

According to Article 44(2) of the Regulation, where foods are offered for sale to the final consumer or to mass caterers without packaging, or where foods are packed on the sales premises at the consumer's request or prepacked for direct sale, Member States may adopt national measures concerning the means through which information on allergens will be made available and, where appropriate, their form of expression and presentation.

→ Can a food business operator provide information on substances or products causing allergies or intolerances used in the manufacture or preparation of a non-prepacked food, only and simply upon request by the consumer?

No. The provision of allergen/intolerance information, where substances in Annex II are used in the manufacture of a non-prepacked food, is mandatory. It must be available and easily accessible, so that the consumer is informed that the non-prepacked food raises issues relating to allergens and intolerances. Therefore, it is not possible to provide allergen/intolerance information only and simply upon request by the consumer.

→ Can a food business operator provide information on substances or products causing allergies or intolerances used in the manufacture or preparation of a non-prepacked food by means other than a label, including modern technology tools or verbal communication?

Member States may adopt national measures concerning the means through which information on allergens is to be made available. In principle all means of communication as regards the provision of food information, including allergen/intolerance information are allowed to enable the consumer to make an informed choice, e.g. a label, other accompanying material, or any other means including modern technology tools or verbal communication (i.e. verifiable oral information).

In the absence of national measures, the provisions of the FIC Regulation concerning prepacked food are applicable to non-prepacked food as regards the labelling of substances or products causing allergies or intolerances. Therefore, this information must be easily visible, clearly legible and, where appropriate, indelible. This means that information on allergens/intolerances must be provided in a written form as long as Member States have not adopted specific national measures.

→ Can Member States allow, through national measures, the provision of information on substances or products causing allergies or intolerances used in the manufacture or preparation of a non-prepacked food, only and simply upon request by the consumer?

The provision of allergen information "upon request" is not to be considered as a "means of providing information". However, in a spirit of a pragmatic approach, indicatively, national measures may stipulate that detailed allergen/intolerance information regarding the manufacture or preparation of a non-prepacked food may be given upon request by the consumer, provided that the food business operator indicates in a conspicuous place and in such a way as to be easily visible,

clearly legible and, where appropriate, indelible, that such information can be obtained upon request. This combination would already indicate to the consumer that the non-prepacked food concerned raises issues relating to allergen/intolerances and that such information is available and easily accessible.

➔ *In the case of non-prepacked foods containing a compound ingredient consisting of one or more substances listed in Annex II, which terms have to be indicated: the ingredient or its single ingredient(s) included in Annex II?*

When indicating the allergens, the names under which such substances are indicated shall refer to the name of the substance or product as listed in Annex II. In the case of the compound ingredients used in the non-prepacked foods for which the list of ingredients is not required following the national provisions under Article 44(1)(b), the indication of the allergens shall refer to the presence of substance or products listed in Annex II (single ingredients) and not the compound ingredient with the allergens highlighted.

For example: in the case of a sandwich with mayonnaise made of eggs, the information given should be “egg”

IV. DEROGATIONS FROM THE OBLIGATION TO INFORM ON THE PRESENCE OF SUBSTANCES OR PRODUCTS LIKELY TO CAUSE ALLERGIES OR INTOLERANCES

The indication of allergenic substances or products is not required when the name of the food clearly refers to the substance or product concerned.

IV.1. Foods without a list of ingredients

In the absence of a list of ingredients, information on substances or products listed in Annex II shall be provided. In this regard, the indication of allergens shall compromise the word “contains” followed by the name of product as listed in Annex II. No highlighting or other emphasis according to Article 21(1)(b) is needed in such a case.

However, in the case where the name of the food clearly refers to the substance or product of Annex II, the latter do not need to be indicated on the label. Milk based products (cheese, butter, fermented milk and cream) are particularly concerned by that provision because, subject to certain conditions, they are not required to bear a list of ingredients pursuant to Article 19(d). Other products might also be concerned.

Nevertheless, it could be difficult in practice to know whether the condition “clearly refers to the substance or product 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 should therefore apply.

- It can be accepted that the condition “*where the name of food clearly refers to the substance or product concerned*”, will be fulfilled if the name includes any supplement, consisting in words additional text that clearly refers to the ingredient of Annex II.

For example:

“Ambert” (as the name of the product)

“farmhouse blue cheese” (as additional text)

- In cases where the name of a food such as kefir, does not clearly refer to an ingredient of Annex II (milk), none of the conditions described above being met, and consumers in certain Member States being possibly unaware of the presence of that ingredient, food business operators have to ensure that the objectives of Article 21 are achieved, and, to that effect, Member States 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 17(2) of Regulation (EU) No 1169/2011 regarding the name under which a foodstuff is sold. This means that requesting additional information is fully justified and necessary, and implemented in a non-discriminatory and proportionate way.

V. UPDATING OF ANNEX II

The list of substances enumerated in Annex II of the Regulation has been established on the basis of the scientific opinions adopted by the European Food Safety Authority (EFSA)¹. According to the latter, those substances are considered as part of the most common food allergens and there is ample evidence to support their inclusion into the list.

In order to ensure better information to consumers and take account of the most recent scientific progress and technical knowledge, Article 21 paragraph 2 of the Regulation foresees a procedure to examine and, where necessary, update the list of substances enumerated in Annex. Accordingly, the EU list of substances or products causing allergies or intolerances as listed in the Annex can be amended by means of delegated acts, in accordance with Article 51 of the Regulation, after an opinion has been obtained from EFSA issued on the basis of Article 29 of Regulation (EC) No 178/2002². In addition, Article 21(2) provides that where, in the case of the emergence of a risk to consumers' health, imperative grounds of urgency so require, the urgency procedure as laid down in Article 52 of the Regulation shall apply to the delegated acts to be adopted in view of the updating of Annex II.

Updating of the list would consist not only in adding but also in deleting or exempting certain substances or products from Annex II for which it has been scientifically established that it is not likely for them to cause adverse reactions. In this context, the Commission may be notified by food business operators, who are seeking the exclusion from Annex II, of the conducted studies proving that substance(s) concerned is/are not likely, under certain circumstances, to trigger allergic reactions. In order to assist the applicants in the preparation and presentation of well-structured applications in this regard, the Commission has published an "Administrative guidance" to be found under the following link:

***** (the link to be added)

¹ http://www.efsa.europa.eu/EFSA/Scientific_Opinion/opinion_nda_04_en1,1.pdf

² 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, OJ L 31 of 1.2.2002.