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(Information)

INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES
AND AGENCIES

EUROPEAN COMMISSION

COMMISSION NOTICE

of 13 July 2017

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

(2017/C 428/01)

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1. Introduction

1. This Notice is intended to assist businesses and national authorities in the application of the new requirements of Regulation (EU) No 1169/2011 of the European Parliament and of the Council⁽¹⁾ ('the Regulation') related to the indication of the presence of certain substances or products causing allergies or intolerances (Article 9(1), point (c) and Annex II to the Regulation).
2. Regulation (EU) No 1169/2011 on the provisions of food information to consumers lays down new requirements on allergen labelling compared to the former Directive 2000/13/EC of the European Parliament and of the Council⁽²⁾.

⁽¹⁾ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

⁽²⁾ 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 (OJ L 109, 6.5.2000, p. 29).

3. In particular, under the new legislation it is required that the information on the presence of allergens in foods is always provided to the consumers, including on non-prepacked foods (Article 9(1), point (c) and Article 44). The Member States are however allowed to adopt national measures concerning the means through which information on allergens on non-prepacked foods is to be made available. With regard to the prepacked foods, the Regulation lays down the modalities defining how the information on allergens has to be provided on foods (Article 21). Consequently, the existing Guidelines on allergen labelling drafted under the regime of Directive 2000/13/EC needs to be updated as a reflection of this change in the law.
4. This Notice is without prejudice to the interpretation which the Court of Justice of the European Union may provide.

2. List of allergens (Annex II to Regulation (EU) No 1169/2011)

5. Annex II to the Regulation includes a list of food substances or products causing allergies or intolerances. This list has been established on the basis of the scientific opinions adopted by the European Food Safety Authority (EFSA) ⁽¹⁾.
6. In the context of Annex II, the following should be noted:
 - ‘Cereals’ as listed in Annex II, point 1 are to be understood as an exhaustive list.
 - ‘Egg’ in Annex II, point 3 refers to eggs from all farmed birds.
 - ‘Milk’ in Annex II, point 7 refers to milk from the mammary gland of farmed animals.
 - ‘Nuts’ as listed in Annex II, point 8 are to be understood as an exhaustive list.
 - Annex II lists not only substances and products mentioned as such therein but also products thereof. In the case where microorganisms have been fed on a substrate which is a food ingredient included in Annex II, those microorganisms should not be considered as products derived from these substrates.

3. Modalities for the provisions of allergen information for pre-packed foods (in particular Article 21, read in conjunction with Article 18 of the Regulation)

7. According to Article 21(1), point (a):

‘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; (...)
- 3.1. *When the food bears a list of ingredients*
 8. In the case of cereals containing gluten listed in Annex II; where ingredients are produced from cereals containing gluten, they have to be declared under a name making a clear reference to the specific type of the cereal, i.e. wheat, rye, barley, oats.

For example: barley malt vinegar, oats flakes.
 9. Where ‘spelt’, ‘khorasan’ or ‘durum’ is used, a clear reference to the specific type of the cereal, i.e. ‘wheat’ is required. The word ‘wheat’ may be accompanied by the word ‘durum’, ‘spelt’ or ‘khorasan’, added on a voluntary basis.

For example: wheat or wheat (durum) or durum wheat,
wheat or wheat (spelt) or spelt wheat.
 10. The indication of a specific type of the cereal may be accompanied by the word ‘gluten’, added on a voluntary basis.

For example: wheat flour (contains gluten) or wheat flour (gluten).
 11. Where gluten is added as such, as an ingredient, the type of the cereal the gluten is coming from has to be indicated.

For example: gluten (wheat), wheat gluten or gluten (from wheat)
dextrin (wheat) or (wheat gluten); dextrin (contains wheat) or (contains wheat gluten).

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

12. When a product containing one of the cereals mentioned in Annex II (e.g. oats) meets the relevant requirements of Commission Implementing Regulation (EU) No 828/2014 ⁽¹⁾, then the statement 'gluten-free' or 'very low gluten' can be used on the product. However, the cereal mentioned in Annex II has to still be indicated and emphasised in the list of ingredients in accordance with Articles 9 and 21 of the Regulation.
13. In the case of nuts, the specific type as listed in point 8 of Annex II have to be indicated in the list of ingredients, i.e. almonds, hazelnuts, walnuts, cashews, pecan nuts, Brazil nuts, pistachio nuts, macadamia or Queensland nuts. Where ingredients or processing aids derived from nuts listed in Annex II have been used, the ingredient has to be indicated with a clear reference to the specific name of the nut.

For example: flavourings (almond).

14. According to Article 21(1), point (b) of the Regulation:

'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:

(...)

- (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.'
15. Article 21(1), point (b) gives certain flexibility as regards the means for ensuring this emphasis, for example by means of the font, style or background colour. It is left to the food business operator to choose the appropriate manner of differentiating the allergen concerned from the rest of the list of ingredients. However, some clarifications are needed concerning what information has to be emphasised.
16. When the name of an ingredient consists of several separate words (e.g. 'poudre de lait', 'latte in polvere'), it is sufficient to only emphasise the word that corresponds to the substance/product listed in Annex II. When the name of an ingredient includes the name of an allergen in a single word (e.g. the German word 'Milchpulver' for 'milk powder'), it is sufficient to emphasise the part of the name of the ingredient that corresponds to the substance/product listed in Annex II.
17. If a compound ingredient contains substances causing allergies or intolerances listed in Annex II, those substances have to be emphasised in the list of ingredients.

For example: in the case of banana filling containing egg yolks, strawberry, sugar, water, (...), the word 'egg' has to be emphasised. In the case of a sandwich with mayonnaise made of eggs, the presence of 'eggs' has to be emphasised.

3.2. *In the absence of a list of ingredients*

18. Article 21(1), second subparagraph provides that:

'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.'

19. In the case of foods exempted from the obligation to bear the list of ingredients (such as wine) but used as an ingredient in the manufacture or preparation of another food for which the list of ingredients is provided, the allergens present in that food have to be emphasised in order to distinguish them from the rest of the list of ingredients (Article 21(1) applies).

For example: ingredients: ... wine (contains sulphites) where the word 'sulphites' is emphasised.

3.3. *Labelling of derivatives from the same allergen*

20. Article 21(1), third subparagraph provides that:

'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.'

⁽¹⁾ Commission Implementing Regulation (EU) No 828/2014 of 30 July 2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food (OJ L 228, 31.7.2014, p. 5).

21. For the purpose of this requirement, the reference to the substance(s) or product(s) listed in Annex II must not necessarily be repeated as many times as these substances are present. Any presentation making clear that different ingredients originate from a single substance or product included in Annex II, would fulfil the requirement and would be acceptable. The reference must, however, always be directly linked to the list of ingredients, e.g. by placing the referred information at the end of the list of ingredients or in close proximity to the list of ingredients.

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 (where “wheat” has to be emphasised).’

3.4. Exemption

22. Article 21(1), last subparagraph provides that:

‘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.’

23. According to this requirement, where a food is sold under a name such as ‘cheese’, ‘cream’ which clearly refers to one of the allergens listed in Annex II (e.g. milk) and for which it is not required to bear a list of ingredients pursuant to Article 19(1), point (d) of the Regulation, the allergen in question does not have to be indicated on the label.
24. However if such food is sold under a trade mark/brand name which as such does not clearly refer to one of the allergens of Annex II, the name concerned should be supplemented by additional information which provides the ‘clear reference’ to the allergen concerned as requested by Article 21(1), last subparagraph.

For example:

‘Ambert’ (as the name of the food) together with ‘farmhouse blue cheese’ (as additional text to the name of the food, displayed in close proximity to the name of the food), where cheese is the clear reference to the substance in Annex II.

As the consumer understanding of the name of the foods in question is likely to vary among Member States, an assessment on a case-by-case basis is necessary.

25. If the name of the food clearly refers to one of the allergens listed in Annex II and that food provides a list of ingredients (no matter whether on a voluntary or mandatory basis), the allergen present in that food has to be emphasised in the list of ingredients.

For example: ‘Cheese (milk, salt, rennet, ...)’ where milk is emphasised.

26. In the case where the name of the food on a product clearly refers to a substance or product of Annex II but the product also contains other substances or products from Annex II, those allergens must be indicated to enable consumers to make informed food choices which are safe for them.

3.5. Voluntary repetition

27. Without prejudice to existing Union provisions applicable to specific foods ⁽¹⁾, it is not possible to voluntarily repeat the allergen information outside the list of ingredients; or using the word ‘contains’ followed by the name of the substance or products listed in Annex II; or using symbols or text boxes (see Recital 47, Article 21(1) read in conjunction with Article 36(1) of the Regulation).

⁽¹⁾ Such as provisions of Article 51(2) of Commission Regulation (EC) No 607/2009 of 14 July 2009 laying down certain detailed rules for the implementation of Council Regulation (EC) No 479/2008 as regards protected designations of origin and geographical indications, traditional terms, labelling and presentation of certain wine sector products (OJ L 193, 24.7.2009, p. 60).

4. Allergen information for non-prepacked foods

28. Article 44 of Regulation (EU) No 1169/2011 states:

'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;

(...)

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.'

29. The Regulation provides for mandatory allergen information for non-prepacked foods.

30. Member States remain competent to adopt national provision on the means through which allergen information is to be made available on such foods. In principle all means of communication as regards the provision of allergen 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).

31. In the absence of those national measures, the provisions of the Regulation concerning prepacked food are applicable to non-prepacked food. Accordingly, in accordance with Article 13 of the Regulation the information about allergens must be easily visible, clearly legible and, where appropriate, indelible and be provided in a written form. Therefore, it is not possible to provide allergen information only upon request by the consumer. Furthermore, the labelling requirements laid down in Article 21 of the Regulation apply (points 3-21 above).

5. Updating of Annex II

32. Article 21(2) of the Regulation states:

'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.

(...).'

33. The update of the list in Annex II may consist in adding a substance to the list or removing a substance from that list. With regard to the deletion from the list of food allergens, Directive 2000/13/EC⁽¹⁾ had provided specific provisions according to which interested parties could submit to the Commission studies demonstrating that for certain allergens it has been scientifically established that it is impossible to cause adverse reactions. These specific provisions have not been maintained in the Regulation. This however does not prevent potentially interested parties to communicate to the Commission evidence establishing that products derived from substances listed in Annex II are not likely, under certain circumstances, to trigger adverse reactions in individuals.

34. Such submissions may be prepared in accordance with the EFSA 'Guidance on the preparation and presentation of applications pursuant to Article 6 paragraph 11 of Directive 2000/13/EC'⁽²⁾ and sent to the Commission in, at least, two copies on electronic support (CD's or memory sticks) at the following address:

Directorate-General for Health and Food Safety, Unit E1
European Commission
1049 Bruxelles/Brussel
BELGIQUE/BELGIË

⁽¹⁾ See Article 6(11), second subparagraph of Directive 2000/13/EC.

⁽²⁾ EFSA *Journal* 2013;11(10):3417.