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Guidelines on Additional Labelling Regarding the Potential Presence of Allergens Due to Cross-contamination

FNLI

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Guidelines on Additional Labelling Regarding the Potential Presence of Allergens Due to Cross-contamination

2. Introduction

The Labelling Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 relating to the labelling, presentation and advertising of foodstuffs was amended by Directive 2003/89/EC of the European Parliament and of the Council of 10 November 2003. Where the obligatory labelling of a number of allergens is concerned, the changes to the labelling requirements introduced by Directive 2003/89/EC only regulate the labelling of allergenic ingredients and allergenic components of ingredients (including processing aids and carriers).

Directive 2005/26/EC gives a list of ingredients or substances in foodstuffs that have been temporarily exempted from Annex IIIa to Directive 2000/13/EC. This means that these ingredients or substances need not to be labelled as allergens for the time being. There is no statutory obligation to label allergens, which may be potentially present as a result of cross-contamination.

Cross-contamination may occur, for example, because allergenic ingredients are used in the same production area or on the same premises, or because a supplier cannot guarantee that a raw material is free from cross-contamination of the allergen concerned.

In the Netherlands, the Labelling Directive has been transposed in the Consumer Goods Act Decree on the Labelling of Foodstuffs [*Warenwetbesluit Etikettering van levensmiddelen (WEL)*].

The present FNLI guidelines deal with the labelling of allergens when there is a real chance that traces of them may find their way into a product due to cross-contamination and when the producer considers this to be an unacceptable risk to public health.

Allergens that have found their way into a product as a result of carry-over or rework constitute ingredients or components of ingredients and it is compulsory to label them. They are outside the scope of the present guidelines.

3. Basic position

These guidelines are based on the 12 categories of foodstuffs that contain potential allergens that require labelling due to their allergenic properties.

These are:

- Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof
- Crustaceans and products thereof
- Eggs and products thereof
- Fish and products thereof
- Peanuts and products thereof
- Soybeans and products thereof

- Milk and products thereof (including lactose)
- Nuts i.e. Almond (*Amygdalus communis L.*), Hazelnut (*Corylus avellana*), Walnut (*Juglans regia*), Cashew (*Anacardium occidentale*), Pecan nut (*Carya illinoensis (Wangenh.) K. Koch*), Brazil nut (*Bertholletia excelsa*), Pistachio nut (*Pistacia vera*), Macadamia nut and Queensland nut (*Macadamia ternifolia*) and products thereof
- Celery and products thereof
- Mustard and products thereof
- Sesame seeds and products thereof
- Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO₂.

The following ingredients or substances in foodstuffs derived from these have been removed from Annex IIIa to Directive 2000/13/EC until 25 November 2007:

Ingredients	Products thereof provisionally excluded
Cereals containing gluten	- wheat based glucose syrups including dextrose ⁽¹⁾ - wheat based maltodextrins ⁽¹⁾ - glucose syrups based on barley - cereals used in distillates for spirits
Eggs	- lysozym (produced from egg) used in wine - albumin (produced from egg) used as fining agent in wine and cider
Fish	- fish gelatine used as carrier for vitamins and flavours - fish gelatin or isinglass used as fining agent in beer, cider and wine
Soybean	- fully refined soybean oil and fat ⁽¹⁾ - natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources - vegetable oils derived phytosterols and phytosterol esters from soybean sources - plant stanol ester produced from vegetable oil sterols from soybean sources
Milk	- whey used in distillates for spirits - lactitol - milk (casein) products used as fining agents in cider and wines
Nuts	- nuts used in distillates for spirits - nuts (almonds, walnuts) used (as flavour) in spirits
Celery	- celery leaf and seed oil - celery seed oleoresin
Mustard	- mustard oil - mustard seed oil - mustard seed oleoresin
⁽¹⁾ and products thereof, in so far as the process that they have undergone is not likely to increase the level of allergenicity assessed by the EFSA for the relevant product from which they originated.	

The legislation regulates only the compulsory labelling of an allergen on the label when it is present due to the recipe used. The legislation does not include any threshold values for the above 12 groups of allergens.

Some consumers, however, react to certain allergens even when they are only present in a low concentration. The wide variety of reactions to an allergen displayed by people with a food allergy means that it is difficult to determine a threshold value. Some people are so sensitive

to a particular allergen that they react to concentrations that cannot be measured by the available equipment. For some allergens, no effective analytic methods are available and little is currently known about them. These guidelines therefore do not include any threshold values for allergens.

Additional allergen labelling for cross-contamination by the producer must be based on an allergens policy supported by an HACCP analysis based on critical *allergen* control points and on an assessment of the health risk if cross-contamination cannot be prevented. Not always does cross-contamination lead to a clear risk to health.

4. HACCP analysis relating to allergens (points to be considered)

A company can gain an understanding of the risks involved in possible cross-contamination by carrying out an analysis based on HACCP principles. That analysis can be carried out within the current HACCP system. Risks should preferably be excluded as far as possible so as to prevent cross-contamination. Underneath are a few points that need to be taken into account in the risk analysis.

- Take measures within the production process to prevent cross-contamination. Important issues include the use of separate hoses; the location during storage; the transport of semi-manufactured products and rejects; and the location of conveyor belts above one another.
- Recognise problem points in the production process. Production may, for example, involve the use of equipment that is difficult to clean. Allergens may remain in such equipment even after cleaning.
- Involve the supplier of the raw material by asking questions about the presence of allergens in the raw material or the potential presence of such allergens due to cross-contamination. Ask the supplier whether it operates a policy on allergens. If it does have a policy, ask for an explanation of it; if it does not, ask it to introduce such a policy.
- Make arrangements as to how to deal with an allergen that does not occur at one's own premises but whose absence in the raw material the supplier cannot guarantee.
- Be critical regarding the information you ask for and receive from suppliers. Compare the list giving information about allergens with the previous list supplied. Audit the supplier's allergen policy.
- Be careful when dealing with test products in the context of production. Test products may contain allergens, meaning that they may contaminate the production line. That may even be the case with substances that are added only in small quantities, for example carriers for additives, vitamins, and/or minerals.

If the HACCP analysis shows that the occurrence of cross-contamination cannot be excluded, the producer must weigh up the seriousness of the cross-contamination against the potential health risks. This may differ from one allergen to another. The existence of a risk of cross-contamination will not always mean that additional labelling is necessary. In weighing up these issues, it may be a good idea to bring in external expertise.

5. Labelling when cross-contamination occurs despite every precaution having been taken and when there is considered to be a risk to public health

Consumers with a food allergy or oversensitivity receive better information when the industry provides clear and uniform labelling. One basic principle here is that the information should clarify the potential presence of the allergens concerned. People with an allergy or oversensitivity also usually have a family and friends and the labelling must be clear, transparent, and understandable for them too. The names given to the various allergens are important here. The word “casein” will not mean much to the average consumer but it will be well understood by someone who is allergic to that substance when it occurs in food. The allergic person’s family and friends may not understand the term “casein” but they will understand the word “milk” perfectly well.

Allergens can occur in foodstuffs in three different ways:

1. An allergen added as (a component of) an ingredient (including processing aids and carriers etc.).
2. An allergen that may be present due to cross-contamination at the production company’s own premises but which has not been added as an ingredient.
3. An allergen that may be present due to cross-contamination at the premises of the supplier of the raw material or semi-manufactured product but which is not present at the production company’s own premises. (Special attention needs to be paid to suppliers of flavourings and other additives, who probably process all the various allergens on their premises.)

Recommendation:

- 1: In this case, labelling is required (Directive 2003/89/EC applies).
- 2: If labelling is considered unavoidable, you are advised to follow these guidelines.
- 3: If labelling is considered unavoidable, you are advised to follow these guidelines.

6. How to carry out labelling and how to communicate with the consumer

Here are some practical examples of additional labelling of allergens on the product label.

A. List of ingredients, followed by the sentence:

“Produced on premises/in a production area/on a production line¹ where eggs and sesame seed are also processed.”

The list of ingredients contains the allergenic ingredients. In addition, only potential cases of cross-contamination are mentioned. All 12 groups of allergens have been taken into account in the HACCP. Any allergens are mentioned that are potentially present and are considered to constitute a risk.

B. List of ingredients, followed by the sentence:

“Produced on premises/in a production area/on a production line² where (specific allergens) are also processed.”

The list of ingredients contains the allergenic ingredients. In addition, only possible cross-contamination by specific allergens is mentioned. Rather than mentioning all 12 groups of specific allergens, the company may decide – for practical reasons – to

¹ You should choose between premises/production area/production line.

² You should choose between premises/production area/production line.

mention only a restricted number. It does this on the basis of a risk analysis. It is then only those specific allergens that are taken into account in the HACCP analysis. This decision can be influenced by such things as the wishes of the customer for the product.

- C List of ingredients ingredients, followed by the sentence:
"May contain traces of nuts."

The list of ingredients contains the allergenic ingredients. In addition, only the possible presence of nuts is mentioned. The statement that nuts may be present gives the consumer a choice so that he/she can decide, on his/her own responsibility, whether to consume the product.

This way of labelling can be taken negatively, i.e. as meaning that the manufacturer does not know what goes on on its own premises or what is present in its product.

This option is often used on multi-language labels

Besides putting it on the label, there are various other ways to provide information, for example on websites, in leaflets, and via the consumer service department of the producer concerned. These are all different ways of explaining the company's policy on allergens. It goes without saying that the information provided via all these different sources must be consistent.

There is another option, which goes beyond the abovementioned options A-C and which makes matters clear to the family and friends of people who are allergic or oversensitive to a particular food.

List of ingredients, followed by the sentence:

Contains wheat, milk, egg, sulphite. Produced on premises/in a production area/on a production line³ where sesame seed and soya beans are also processed.

The list of ingredients includes the allergenic ingredients. The ingredient with allergenic properties is mentioned again. The "Contains..." sentence refers to the basic product in which the allergen occurs. The list of ingredients includes terms that are only comprehensible to well-informed consumers, for example "casein". All 12 groups of allergens have been taken into account in the HACCP analysis. If one or more allergens are potentially present they are mentioned. In addition, only potential cases of cross-contamination are mentioned. Any allergens are mentioned that are potentially present and are considered to constitute a risk.

This method of providing information does of course require more space on the package for the list of ingredients.

³ You should choose between premises/production area/production line.