Adopted on 5 March 2018

Fedima Position Paper on Labelling of Allergens

Introduction

EU Regulation 1169/2011 on the provision of food information to consumers (FIC)[1] replaced Directive 2001/13/EC. Article 9.1(c) of this Regulation requires all allergens listed in Annex II of this Regulation to be labelled, including the allergens in processing aids. In the absence of a list of ingredients, Article 21 foresees the mention "contains" followed by the name of the substance or product as listed in Annex II. The information on the presence of allergens allows consumers to make an informed choice which is safe for them (recital 24).
The FIC Regulation applies only to ingredients and substances voluntarily used in a foodstuff (recital 48). The question of adventitious presence of allergenic substances in a food (cross contamination) is not addressed by the new rules. However, the European Commission needs to harmonise the approach for precautionary allergen labelling (PAL). On 13 July 2017, the European Commission published a Commission Notice relating to the provision of information on substances or products causing allergies or intolerances[2], which gives guidance on the labelling of allergens in the context of the FIC regulation.

Fedima approach

Fedima is following the recommendations of the European Commission Notice. Allergen labelling must be clear, accurate and meaningful. Therefore, Fedima welcomes the regular review of the scientific basis for allergen labelling possibly leading to exemptions from allergen labelling requirements of derivatives not able to trigger adverse reactions.

As manufacturers and suppliers of food ingredients, Fedima members will inform their customers by giving the required allergen labelling information on the product label and/or on the product information sheet. Although there's no harmonized European approach on risk assessment with regards to allergen cross contamination, Fedima members commit to provide information on the potential presence of allergens due to cross contamination. This information shall be based upon a risk evaluation (e.g. HACCP, Vital 2.0) in cases where various formulations are produced on the same production line or in the same production room taking into account the cleaning procedures in place.

Fedima's recommendation is to avoid "free from" claims, except for products especially produced and marketed for specific groups of allergic people.
The claim "gluten free" is an exception, because it is officially regulated under Regulation (EU) 1169/2011. Products complying the specific legal requirements (a.o. <20ppm gluten) can be marketed as "gluten free".

[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
[2] COMMISSION NOTICE of 13.7.2017 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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Summary

Fedima members commit to:

- Provide labelling information on allergenic ingredients and substances according to EU Regulation 1169/2011
- Provide information on cross contamination risks in the production process[3]
- (as a matter of policy) avoid "free from" claims except for products produced under a specific regime

[3] Information will be given to direct customers only. Information will be printed on the product label and/or on the product information sheet.

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Annex I: Cross contamination

Fedima members are advised to adopt and implement a policy on allergens which should include measures in place to avoid cross contamination, a risk assessment of possible cross contamination and guidelines used to inform customers on cross contamination risks. The information in this Annex could be used by Fedima members in formulating an allergen policy.

Cross contamination

The Fedima allergen policy requires the transmission of information on cross contamination risks. Cross contamination risks must be analysed in each production location and includes risks in the production of raw materials at the supplier's production site. Production sites should be carefully screened for the risk of cross contamination with allergens of Annex II of Regulation (EU) 1169/2011.

Cross contamination in raw materials

Ingredient suppliers are required to complete raw material specification sheets including allergen information. For each allergen listed the presence or absence via ingredients or via cross contamination must be indicated[4]. The raw material specification sheet should also include information on the existence of a company's allergen policy. During supplier audits the effectiveness of the system should be assessed.
Information on cross contamination from suppliers will undergo a (HACCP) risk evaluation. Based on this risk evaluation it will be decided whether or not the information is transferred to the next link in the chain. Factors to be considered are: probability of cross contamination, maximum concentration of a given allergen through cross contamination in the raw material and in the finished product and the magnitude of adverse health effect. A system like Vital 2.0 is based upon these factors.

In case a Fedima member company has a specific allergen policy to exclude certain allergens in their products or production facility, cross contamination of those allergens in raw materials is unacceptable. Additional guarantees will need to be negotiated with suppliers.
If cross contamination in raw materials is indicated by the supplier and a health risk cannot be excluded this information should be transmitted to the next link in the chain.

Cross contamination in production

If the result of a risk assessment is that cross contamination in production cannot be avoided and a health risk cannot be excluded, this information should be transmitted to the next link in the chain.

When the product is fully labelled, a Precautionary Allergen Labelling (PAL) will be applied. The advice is not to use a variety of different wordings, but us the words "May contain [allergen]". This advice follows the Technical Report from DG SANTE and Joint Research Center workshop (June 2016) (Fedima/17/143).

The information will also be transmitted via the product information sheet.

[4] To collect and provide detailed information on cross contamination, it can be recommended to use the Allergen Questionnaire as developed by 'Allergenenconsultancy'

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Test production

Test productions with new ingredients containing allergens that have not been present on the given production line can only take place when the line is thoroughly cleaned after the test run and validated for release.

Production lines

When moving products between production lines it must be avoided that the cross contamination risk is increased. Before a decision is made to produce a given product on a non-assigned production line a risk analysis on allergen cross contamination must be carried out.

Rework

It is best practice that rework only contains the same or less allergens then the product where it is used in.
If a rework product contains more allergens, this should be part of the risk assessment and consequently the ingredient list must be amended following the labelling Regulation. A thorough cleaning and validation have to be carried out after this rework operation.

Products with "free from" claim

For products carrying a "free from" claim a special production regime must be in place and ingredients used may not be cross contaminated with the allergen for which the claim is made. The production regime includes dedicated production lines and/or thorough cleaning before the "free from" production begins. These procedures should be well documented and the effectiveness of the cleaning must be verified.

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Annex II: Labelling of enzyme preparations

An enzyme complex is a compound ingredient (ex: WHEAT flour, enzyme 1, enzyme 2). The identical components are added together to form the list of ingredients. All ingredients are mentioned in descending order.

In the case of enzymes used in bakery intermediate foodstuffs (bread improvers, cake mixes etc.) the carrier often contains wheat. The enzyme is not derived *from* an allergen but the allergen is one of the ingredients *in* the enzyme complex**.**

In order to label the final product (e.g. bread/cookie) correctly, the relevant components of the enzyme complex need to be indicated in the list of ingredients. The enzyme itself, being a processing aid in the end product, it is exempted from labelling in the end product ingredient list. Its carrier (e.g. WHEAT flour) is not exempted.

Examples of labelling a bakery raw material and a consumer product can be:

Wheat bread

Recipe
wheat flour (100 gr.), water (56 gr.), yeast (2 gr.), salt (1,5 gr.) and bread improver (3 gr.)
Ingredients bread improver:
WHEAT gluten, WHEAT flour[i], palm oil, malt flour (BARLEY), sourdough devitalised (RYE flour), emulsifiers: E471 (SOY), E482, MILK protein, dextrose, enzymes[ii].
Labelling of the bread:
WHEAT flour[iii], water, yeast, WHEAT gluten, salt, palm oil, malt flour (BARLEY), sourdough devitalised(RYE), emulsifiers: E 471 (SOY), E482, MILK protein, dextrose.

Oat cookie

Recipe
1.000 gr. Oat Cookie mix, 500 gr. raisins, 200 gr. barn eggs, 150 gr. water.
Ingredients cookie mix
OATmeal, sugar, glucose syrup, vegetable oil (palm), raising agent E450, E500, thickener E412, salt, MILK protein, flavouring, WHEAT flour[iv], enzymes[v].
Labelling of the cookie
OATmeal, raisins, sugar, barn EGG, water, glucose syrup, vegetable oil (palm), raising agent E450, E500, thickener E412, salt, MILK protein, flavouring, WHEAT flour[vi].

i This term gathers the ingredient in the bread improver + carrier of the enzyme complex
ii Labelling according to Regulation (EC) No 1332/2008 unless specified differently in national legislation
iii This term gathers main ingredient + ingredient in the bread improver + carrier of the enzyme complex
iv The wheat flour is the carrier of the enzyme complex
v Labelling according to Regulation (EC) No 1332/2008 unless specified differently in national legislation
vi The wheat flour is the carrier of the enzyme complex. The enzyme is not labelled because it is a processing aid in the cookie

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