



December 2016

AMFEP statement on labelling of substances capable of causing allergies or intolerances present in food enzyme preparations

Labelling of substances present in the final food

Regulation (EU) No. 1169/2011⁽¹⁾ establishes the rules for providing food information to consumers. One of the general objectives of the Regulation is that the provisions shall pursue a high level of protection of the consumer. This includes labelling of substances that can cause allergies or intolerances when present in the final food. The list of substances adopted in the EU as substances with a scientifically proven allergenic or intolerance effect is included below⁽²⁾.

According to Article 9 of Regulation (EU) No. 1169/2011⁽¹⁾, it is mandatory to indicate on the labelling of a final food any ingredient or processing aid mentioned in the list of substances causing allergies or intolerances⁽²⁾, as well as any ingredient or processing aid derived from such substances, in case these substances are used in the production of a food and are *still present* in the finished product.

It is the responsibility of the final foods' manufacturer to ensure that these products are labelled in compliance with the provisions mentioned above.

In addition, it is the responsibility of food business operators that supply to manufacturers of final foods to ensure that those manufacturers are provided with sufficient information to enable them to meet their labelling obligations (art. 8.8 in Regulation (EU) No. 1169/2011).

Labelling of substances in food enzyme preparations

Food enzymes are in most cases used as processing aids in the production of food ingredients or final foods. The majority of commercial food enzymes is produced by fermentation with the help of selected microorganisms. For the growth of such microorganisms, a variety of nutrients can be used, which may include some of the substances listed below⁽²⁾. During the fermentation process the majority of nutrients is consumed by the microorganisms and further down-stream processing typically includes washing and filtration steps. Thus, the final food enzyme will typically not contain significant residual amounts of the nutrients used during fermentation.

Most food enzymes are placed on the market as food enzyme preparations. Besides food enzymes, these contain food additives or other food ingredients, which are added after fermentation.

Labelling of allergen substances that are added *during* fermentation

Labelling provisions for food enzymes and food enzyme preparations are established by **www.amfep.org**

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Regulation (EC) No 1332/2008⁽³⁾. Article 11 of said regulation states that food enzymes and food enzyme preparations which are *not* intended for the final consumer shall be labelled, *where relevant*, with information about the presence of substances that are listed as substances with allergenic or intolerance effects⁽²⁾. It is the responsibility of the food enzyme manufacturer to comply with the labelling provisions for food enzymes and food enzyme preparations. The relevance of labeling those substances listed below⁽²⁾ when added during fermentation should be addressed in a risk assessment.

Labelling of allergenic substances that are added to the food enzyme *after* fermentation

Substances⁽²⁾ added to the food enzyme after fermentation must be labelled with information about these substances.

References:

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. List of substances or products causing allergies or intolerances cf. (EU) No 1169/2011, Annex II:
 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;

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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.

3. Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97