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GUIDANCE DOCUMENT ON CRITERIA FOR CATEGORISATION OF FOOD ENZYMES

IMPORTANT DISCLAIMER

This guidance document has been produced by the Commission services after consultation with the Member States' experts on food enzymes and the relevant stakeholders with the aim of providing informal guidance for Food Business Operators and competent authorities on criteria for categorisation of food enzymes.

They should be read in conjunction with the appropriate legislation, especially Regulation (EC) No 1332/2008 on food enzymes which constitutes the legal basis for the placing on the market and use of food enzymes in the EU

This Guidance document does not represent the official position of the Commission and is not intended to produce legally binding effects. Only the European Court of Justice has jurisdiction to give preliminary rulings concerning the validity and interpretation of acts of the institutions of the EU pursuant to Article 267 of the Treaty.

The Guidance notes have not been adopted on the basis of Article 9 of Regulation (EC) No 1332/2008.

This Guidance document was endorsed by a majority of the representatives of Member States at the meeting of the Standing Committee on the Food Chain and Animal Health on 20 February 2014

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Purpose

The purpose of this document is to provide food business operators and competent authorities with criteria for determining the status of a food enzyme either as an ingredient or as a processing aid in a given context of use, and hence whether it needs to be listed in the ingredient list of foods intended for the final consumer. Such criteria will help applicants prepare an appropriate application for authorisation of food enzymes. The guidance also includes a decision tree to facilitate this categorisation.

The producer and user of a food enzyme have the responsibility for providing the enforcement authorities with all the information that might be relevant for the categorisation.

Regulation (EC) No 1332/2008¹ (" the food enzyme Regulation") lays down rules on food enzymes used in foods or food processing, including such enzymes used as processing aids. Food enzymes are covered by the definition of food in Regulation (EC) No 178/2002² and are therefore, when used in the manufacture, preparation or treatment of food and still present in the finished product, required to be indicated as ingredients in the labelling of the food in compliance with Directive 2000/13/EC³ (this Directive will be repealed by Regulation (EU) No 1169/2011⁴ from 13 December 2014). However, there are two derogations (Article 6(4)(c)(ii) of Directive 2000/13/EC and Article 20(b) of Regulation(EU) No 1169/2011) from the requirement to include food enzymes in the list of ingredients of foods in cases

- where the food enzyme is present in food only as a result of the carry-over (as referred to in Article 18(1) of Regulation (EC) No 1333/2008⁵) from one or more of the ingredients of the food provided that it performs no technological function in the final product or;
- where it is used as a processing aid.

Background

The issue of categorisation of enzymes was initially discussed at the Scientific Cooperation (SCOOP) Task "Study of the enzymes used in foodstuffs and collation of data on their safety⁶" in 2000. According to the Terms of Reference, the SCOOP Task was asked to prepare, amongst others, an opinion on the following question: "by what objective criteria can a distinction be drawn between enzymes used as food additives, processing aids or food ingredients?" According to the conclusions made in that Task, it was not possible to find common definitions and attitudes. However, a first consensus was reached proposing a categorisation scheme based on the technological functionality of the enzyme in the final product. It was concluded that the use of

¹ OJ L 354, 31.12.2008, p. 7

² OJ L 31, 1.2.2002, p. 1

³ OJ L 109, 6.5.2000, p. 29

⁴ OJ L 304, 22.11.2011, p. 18

⁵ OJ L 354, 31.12.2008, p. 16

⁶ http://ec.europa.eu/food/fs/scoop/7.4.1_en.pdf-chapter 3

enzymes may be categorised in three classes: food ingredients, additives or processing aids.

Food enzymes in the EU

In the EU, food enzymes are currently regulated by Regulation (EC) No 1332/2008 on food enzymes. Article 3 of that Regulation defines a food enzyme as a product obtained from plants, animals or micro-organisms or products thereof including a product obtained by a fermentation process using micro-organisms: a) containing one or more enzymes capable of catalysing a specific biochemical reaction; and b) added to food for a technological purpose at any stage of the manufacturing, processing, preparation, treatment, packaging, transport or storage of foods.

The food enzyme Regulation only covers enzymes that are added during food processing or to food including novel food and novel food ingredients to perform a technological function in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food and includes enzymes used as processing aids. However, it does not apply to food enzymes when they are used in the production of food additives falling within the scope of Regulation (EC) No 1333/2008 (food additives Regulation) or in the production of processing aids. Enzymes intended for human consumption such as enzymes for nutritional or digestive purposes are not covered by this Regulation and it does not apply either to microbial cultures that are traditionally used in the production of food and which may incidentally produce enzymes, but which are not specifically used to produce them.

Article 9 of the food enzyme Regulation enables interpretation decisions on whether a substance meets the definition of food enzyme.

Following the transitional measures required in Article 18 of that Regulation, the Union list of food enzymes shall, when drawn up, include the following food enzymes: E 1103 Invertase and E 1105 Lysozyme stating the conditions governing their use as specified in Annex I and Part C of Annex III to Directive 95/2/EC⁷ (currently repealed by Regulation (EU) No 1129/2011⁸), and urease, beta-glucanase and lysozyme for use in wine in accordance with Regulation (EC) No 1493/1999 (currently repealed by Commission Regulation (EC) No 606/2009⁹) and the implementing rules for that Regulation.

In the context of food additives, Article 2.3 of Regulation (EC) No 1333/2008 on food additives states that that Regulation shall not apply to food enzymes falling within the scope of Regulation (EC) No 1332/2008 with effect from the date of adoption of the Union list of food enzymes in accordance with Article 17 of that Regulation. In addition, Article 34 of Regulation (EC) No 1333/2008 stipulates that the authorisations for invertase and lysozyme laid down in Directive 95/2/EC shall be repealed with effect from the date of application of the Union list of food enzymes in accordance with Article 17 of Regulation (EC) No 1332/2008. This means that the use of those two enzymes and any other enzyme authorised under the food additives

⁷ OJ L 61, 18.3.95, p.1

⁸ OJ L 295, 12.11.2011, p.1

⁹ OJ L 193, 24.7.2009, p. 1

Regulation will be no longer considered as food additives once the Union list of food enzymes is established. They will be food enzymes considered as ingredients for these purposes.

In terms of labelling, food enzymes that are used as ingredients should be labelled in accordance with the name of the appropriate category listed in Annex II to Directive 2000/13/EC followed by specific name of the food enzyme (or its E number until the Union list is established)¹⁰. This is similar to the current labelling requirements for food additives. Recital No 8 of the food enzyme Regulation requires, among other things, that food enzymes to be listed in the Union list should specify, where necessary, information on their function in the final food.

The definition of processing aid, as laid down in Article 3.2(b) of the food additive Regulation states that a processing aid is any substance intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing and may result in the unintentional but technically unavoidable presence in the final product of residues of the substance or its derivatives provided they do not present any health risk and do not have any technological effect on the final product. Residues cannot be considered as ingredients following the definition laid down in Regulation (EU) No 1169/2011 on the provision of food information to consumers.

Article 6 of food enzyme Regulation establishes general conditions for inclusion of food enzymes in the Union list i.e there is a reasonable technological need and its use does not mislead the consumer. Article 9 (data required for risk management of food enzymes) of Regulation (EU) No 234/2011 requires that the dossier submitted in support of an application shall include the information necessary to verify whether there is reasonable technological need and whether the proposed use does not mislead the consumer. In order to ensure that verification, appropriate and sufficient information shall be provided, among other things, on the purpose of use (technological function and technological need including a description of the typical process(es) in which the food enzyme may be applied), and on the effect of the food enzyme on the final food.

In order to better understand these provisions, it should be borne in mind that technological function and effect are two separate concepts which are not defined in the legislation. Being catalysts, enzymes start working as soon as they are in contact with their substrate and conditions (a_w , pH, Temperature) are suitable. The vast majority of enzymes are used during processing or treatment therefore, they do not continue to perform a technological function in the final food. However, in most cases, the effect remains on the final food. This effect, which is the result of the enzymatic transformation of the substrate, remains independent of whether the enzyme is still present in the final food totally, partly or removed. Therefore, the 'effect on the final food' can be considered in two ways:

- 1) Whether the food enzyme or its residues still perform a technological function in the food as marketed or as prepared by the consumer and thus creating an on-going

¹⁰ Article 6(6) and Annex II of Directive 2000/13/EC

effect. In this case, the enzyme is clearly used as an ingredient and is required to be labelled in the ingredients list alongside the appropriate function.

2) If the food enzyme is no longer functioning after food processing but the effect remains on the food as marketed the categorisation of the food enzyme as an ingredient or as a processing aid is more difficult. The use of the decision tree developed in this guidance will facilitate such categorisation. In addition, the type of effect that the ‘*use*’ of the food enzyme during food processing has created on the food as marketed should be considered.

Although the categorisation of food enzymes is not required by the food enzyme Regulation it is important that a food enzyme is appropriately qualified as a processing aid or as an ingredient for labelling purposes.

Primary basis for differentiating food enzymes used as processing aids and as ingredients

The absence/presence of the food enzyme in the final food after processing and the absence/presence of a technological function of the food enzyme in the food as marketed or as prepared by consumer are the two issues that can be considered for differentiating food enzymes used as processing aids and as ingredients that have to be labelled in the ingredient list.

Labelling

With regard to labelling, three options are foreseen:

1. If food enzymes are sold as such or with ingredients to food manufacturers (Business to Business-B2B).
2. If food enzymes are sold as such or with ingredients to final consumers¹¹.
3. If food enzymes are used in the manufacturing /processing of foods intended for final consumers.

Food enzymes sold as such or with ingredients to food manufacturers or to final consumers

For options 1 (B2B) and 2 the legal provisions are laid down in Articles 10-12 of the enzyme Regulation.

In addition, for option 1, Article 8 of Regulation (EU) No 1169/2011 requires that the food business operator responsible for the food information shall ensure the presence and accuracy of the food information in accordance with the applicable food information law and requirements of relevant national provisions.

¹¹ According to Regulation (EC) No 178/2002, final consumer means the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity.

Food enzymes used in the manufacturing/processing of foods intended for final consumers

Recital No 18 of the food enzyme Regulation indicates that food enzymes are covered by the definition of food in Regulation (EC) No 178/2002 (Article 2) and are therefore, when used in the manufacture or preparation of a food and still present in the finished product, even in an altered form, required to be indicated in the list of ingredients of the food in compliance with Directive 2000/13/EC (Article 6(6))¹². Food enzymes used as ingredients should be designated by the name of the appropriate category followed by the specific name of the food enzyme. In this context, the requirements of the functional categories defined in Annex II to Directive 2000/13/EC and part C of Annex VII to Regulation (EU) No 1169/2011 apply. The definitions of the different functional categories are prescribed in Annex I to Regulation (EC) No 1333/2008.

The above rule does not apply to enzymes intended for human consumption such as enzymes for nutritional or digestive purposes as they are not covered by the food enzyme Regulation.

The second part of recital No 18 also indicates that provision should be made for a derogation from the provisions on labelling where the enzyme performs no technological function in the final product but is present in the foodstuff only as a result of carry-over from one or more of the ingredient of the foodstuff referred to in points (a) and (b) of Article 18(1) of Regulation (EC) No 1333/2008, or where it is used as a processing aid (Article 3(2)(b) of that Regulation).

According to the requirements of Article 6.4(c) of Directive 2000/13/EC (hereinafter referred to as "labelling Directive") and Article 20 (b) (ii) of Regulation (EU) No 1169/2011, food enzymes used as processing aids are not required to be declared in the list of ingredients on pre-packed food. If a food enzyme is derived from or contains substances causing allergies or intolerances additional labelling rules apply. In order to not mislead the consumer, the food enzyme Regulation (Article 7(2)(f)) requires that the entry of a food enzyme in the Union list shall specify, among other things, where necessary, specific requirements in respect of the labelling of food in which the food enzyme have been used in order to ensure that the final consumer is informed of the physical condition of the food or the specific treatment it has undergone (i.e. effect-labelling as it is the case with combined pieces of meat in a meat product).

In the context of meat products, meat preparations and fishery products which may give an impression that they are made of a whole piece of meat or fish but actually consist of different pieces combined together by other ingredients (e.g. food enzymes) or by other means shall bear the indication "formed meat" or "formed fish". This is prescribed in Annex VI Part A point 5 of Regulation (EU) No 1169/2011.

Other possible misleading characters of the label will be decided on a case-by-case basis depending on the process and in particular, taking into account the requirements of the following pieces of legislation: Article 7.2(f) of Reg 1332/2008, Articles

¹² Directive 2000/13/EC will be repealed by Regulation (EU) No 1169/2011 from December 2014.

2.1(a)(i) and 5 of labelling Directive, and Articles 7.1(a) and 17 of Regulation (EU) No 1169/2011.

In the context of food enzymes used in some dairy products, it should be borne in mind that the following provisions allow the omission of the list of ingredients. Article 6.2(b) of the labelling Directive and Article 19 of Regulation (EU) No 1169/2011 lay down that the following foods shall not be required to bear a list of ingredients: cheese, butter, fermented milk and cream, to which no ingredient has been added other than lactic products, food enzymes and micro-organism cultures essential to manufacture, or in the case of cheese other than fresh cheese and processed cheese the salt needed for its manufacture.

It should be borne in mind that the Union list of food enzymes should apply without prejudice to more restrictive rules linked to the use of certain designations under Regulation (EU) No 1151/2012¹³ of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs.

According to Article 6(10) of the labelling Directive and Article 21 of Regulation (EU) No 1169/2011, the presence of food enzymes used as food ingredients or as processing aids (e.g. lysozyme obtained from hen's eggs) listed or originated from substance(s) enumerated in Annex IIIa to Directive 2000/13/EC (or in Annex II to Regulation (EU) No 1169/2011) and used in the production of a food has to be always indicated on the label because of their ability to cause allergies or intolerances.

Labelling of GM derived enzymes

Enzymes used as food ingredients which are produced from genetically modified plants or animals are considered genetically modified food and therefore their labelling should comply with the requirements of Article 12 of Regulation (EC) No 1829/2003¹⁴.

Recital 16 of that Regulation states that this Regulation should only cover food and feed produced "from" a GMO but not food and feed "with" a GMO. The determining criterion is whether or not material derived from the genetically modified source material is present in the food or in the feed. It also states that processing aids which are only used during the food or feed production process are not covered by the definition of food or feed and not included in the scope of the Regulation. According to the report (COM(2006)626)¹⁵ from the Commission to the Council and Parliament on the implementation of Regulation (EC) No 1829/2003, when the GM micro-organism is used as a processing aid (the GMM is removed during the downstream processing), the food and feed resulting from such production process are not to be considered as falling under the scope of the Regulation and consequently not subjected to GMO labelling. If the food enzyme is obtained from GMM which is not removed it falls under the scope of Regulation (EC) No 1829/2003.

¹³ OJ L 343, 14.12.2012, p. 1

¹⁴ OJ L 268, 18.10.2003, p. 1

¹⁵ http://ec.europa.eu/food/food/biotechnology/reports_studies/docs/COM_2006_626_en.pdf

It should be borne in mind that in the case of organic farming, Article 9 of Regulation (EC) No 834/2007¹⁶ prohibits the use of products produced by GMOs (i.e. with the aid of a GMO, such as enzymes produced with the aid of a GMM). Exemptions on the prohibition of such use may be granted (Article 22(2)(g)) when substances are not available on the market other than produced by GMOs. Since these products are not subject to the labelling obligation under Regulation (EC) No 1829/2003, the supplier must guarantee that the food enzyme has not been produced by GMOs (with the aid of a GMO) by means of the model of a vendor declaration as regulated in Annex XIII to Regulation (EC) No 889/2008¹⁷.

Decision tree to identify food enzymes used as ingredients and as processing aids

Figure 1 is a decision tree to identify food enzymes used as ingredients (that have to be labelled in the ingredient list) and as processing aids (that may be subject to effect labelling in order not to mislead the consumer). The questions in the tree should be answered by following the principles outlined under "Principles for using the decision tree". This decision tree is only a tool and it is not intended to cover all the cases.

Principles for using the decision tree

Question 1: Does the substance fall under the the definition of food enzyme?

If a substance is not under the scope of the food enzyme Regulation, the decision tree cannot be applied.

The list of exclusions of EU definition of food enzyme is established in Articles 2.2(a), 2.2(b) and 2.4 of food enzyme Regulation. Enzymes intended for human consumption such as enzymes for nutritional or digestive purposes are also excluded from the food enzyme Regulation.

Question 2: Is there any presence of the food enzyme in the final food after manufacture, processing or treatment?

When a food enzyme is added to food to perform a technological function during the manufacture, processing or treatment of the food the enzyme as such or its residue might be present or absent in the final food after the result of the enzymatic reaction.

Principle 2.1: At some point during food processing the enzyme is removed. The final food thus contains either no or only trace amounts of residual enzyme protein. These traces are not intended/expected to have any technological effect on the final food. In this case the food enzyme should be considered as a processing aid. It should be borne in mind that the presence of the food enzyme in the final food could be difficult to assess.

Some examples of steps where enzymes are removed are provided as follows:

- Processes where the food product is subject to purification steps that, although not intended for this purpose, also have the effect of removing the enzyme (e.g. ion-exchange or carbon columns for glucose syrups).

¹⁶ OJ L 189, 20.7.2007, p. 1

¹⁷ OJ L 250, 18.9.2008, p. 1

- Distillation (e.g. alcohol beverage).
- Processes where a physical separation of the food into several phases causes the enzyme to remain adsorbed on a by-product or retained on a membrane (e.g. beer filtration, fruit juice ultra-filtration, vegetable oil extraction and filtration).
- Immobilized enzymes. The enzyme is linked by chemical bonds to an insoluble support material.

If the enzyme is present in the final food after manufacture, processing or treatment, the next step is to know whether the enzyme has undergone any treatment that irreversibly denatures or degrades it. Therefore, the question 3 applies.

Question 3: Has the enzyme been irreversibly denatured or degraded?

Principle 3.1: If the enzyme concerned is irreversibly denatured or degraded during processing it should be considered as a processing aid.

Examples of steps where enzymes may be irreversibly denatured or degraded (Different consideration may be needed for heat-stable enzymes):

- Baking of e.g. bread, biscuits, cookies, pastries.
- Processes that contain a high temperature step for another reason (starch liquefaction in a jet-cooker. Mash boiling in the brewing process).
- Processes that contain a pasteurisation step or a similar heat treatment.

If the enzyme has not been irreversibly denatured or degraded the next step is to know whether the enzyme is present as a result of carry-over. Therefore, the question 4 applies.

Question 4: Is the presence of a food enzyme in a given food due to the fact it was contained in one or more ingredients of that food, in accordance with the carry-over principle?

If the food enzyme is present as a result of carry-over, the next step is to know whether such presence has a function in the final food. Therefore, question 5 applies.

Question 5: Does the presence of the food enzyme as carry-over perform a technological function in the final food?

Principle 5.1: If the presence of the food enzyme as a result of the carry-over principle does perform a technological function in the food as marketed or as prepared by the consumer, it will be considered as an ingredient.

Principle 5.2: If the presence of the food enzyme as a result of the carry-over principle does not perform a technological function in the food as marketed or as prepared by the consumer, no labelling will be required.

If the enzyme is not present as a result of carry-over, question 6 applies.

Question 6: Does the presence of the food enzyme perform a technological function in the food as marketed or as prepared by the consumer?

Principle 6.1: If the food enzyme continues to perform a technological function, resulting in an effect in the food as marketed or as prepared by the consumer, it should be considered as an ingredient. Food enzymes used as ingredients should be labelled in the ingredient list.

Bread mixes. In bread mixes, the enzyme starts its technological function when the following steps are undertaken by the consumer: water addition, dough rise and baking. In this case, the enzyme should be considered as an ingredient.

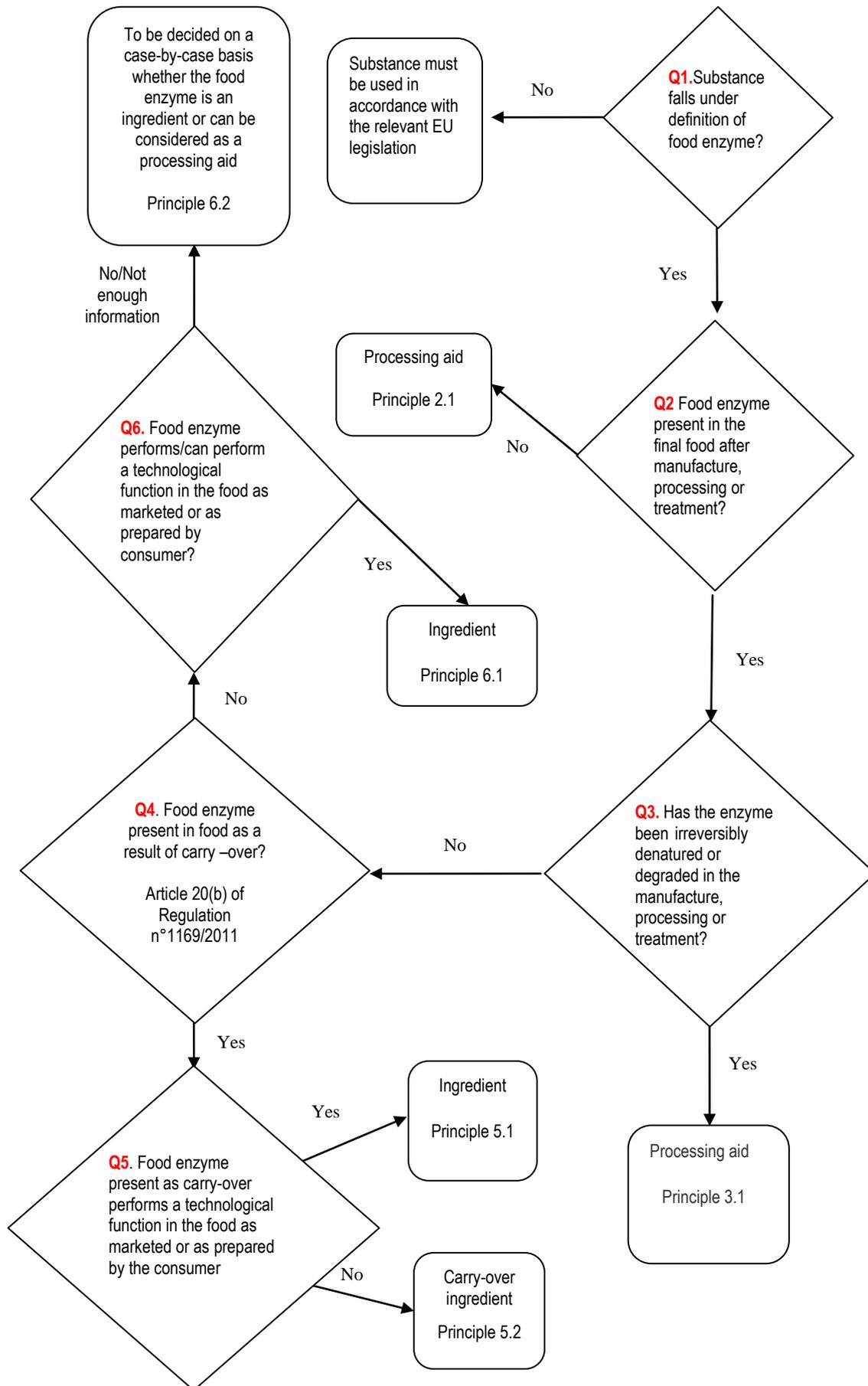
Principle 6.2: If the answer to question 6 is "No" or if the information received is not sufficient to assure that the food enzyme does not perform a technological function, resulting in an effect in the food as marketed or as prepared by the consumer its classification should be decided on a case-by-case basis. The information on technological need and the effect of the food enzyme on the final food provided in the dossier will facilitate the decision.

Some food enzymes could be used either as ingredients or as processing aids (e.g. Glucose-oxidase).

Examples of conditions affecting enzyme functionality.

Criteria: The enzyme is not able to perform a technological function in the final food because of reversible inhibition. Examples are depletion of the substrate or the enzyme protein molecules are entrapped inside the food matrix. Other causes are wrong pH, wrong temperature or water activity is too low to permit enzymatic activity from any remaining active enzyme. However, if an enzyme is used in the manufacturing of a food ingredient which will be eventually used in a composite food, it might find a substrate for having the enzymatic activity. In this specific case, the enzyme may be considered as an ingredient.

Decision tree-identifying food enzymes as ingredients or as processing aids



Examples of food enzymes used as food ingredients

The following examples show how the decision tree and the approaches outlined in this document can be used to identify food enzymes used as food ingredients. The two substances below are food enzymes which are not excluded from the scope of the food enzyme Regulation.

Invertase in confectionery. After the result of the enzymatic reaction the presence of the enzyme continues performing a technological function in the final food due the fact the substrate sucrose is continuously reformed during storage and therefore is not depleted. This enzyme can be used at a very low dosage to hydrolyse the substrate sucrose into glucose and fructose. The presence of the enzyme is currently authorised for this purpose under the EU Food additives legislation and will be carried over to the Union list of food enzymes.

Glucose-oxidase in bottled beverages. This enzyme can be used to remove oxygen from bottled drinks (e.g. citrus based soft drinks) in order to reduce browning due to oxidation. The enzyme is added just before bottling, canning or packaging of the beverage and removes oxygen from the liquid and the headspace. When the oxygen in the head space is depleted, the enzyme does not perform a technological function. However, as soon as the bottle, can or pack is opened by the consumer at home and the beverage comes in contact with oxygen again, the enzyme resumes its catalytic activity (provided that the beverage still contains some glucose) due to the presence of oxygen substrate. This enzyme is not currently authorised under the EU Food additives legislation.

Examples of food enzymes used as processing aids

The following examples show how the decision tree and the principles outlined in this document can be used to identify food enzymes used as processing aids. The substances below are enzymes which are not excluded from the scope of the food enzyme Regulation.

Glucose-oxidase in liquid eggs. This enzyme is used to prevent off-flavours and unwanted browning due to Maillard reactions in spray dried egg powder. When the enzyme is added before the spray drying, the glucose present in the liquid egg is converted into gluconic acid, thereby preventing the formation of Maillard reaction products. Pasteurisation of the liquid egg before spray drying destroys the enzyme.

Pectinases/hemicellulases in vegetable oil extraction. The amount of oil and process efficiency can be enhanced by the use of enzymes. These enzymes are able to degrade the plant cell structure and thereby improve the pressing. During the extraction of oil the enzymes remain in the water layer and therefore, are separated from the final product.

Some enzymes in bread: The enzyme is functional in the dough during the steps of fermentation and dough leavening. During the baking process, the heat denatures the enzyme in the bread.

Pectinases in fruit juice processing: Their application is needed to produce clear juices (removal of pectins) and to facilitate processing (such as juice filtration) to result in a high quality juice. After their performance, the enzymes are denatured by heat treatment, precipitated and removed by filtration.

Immobilized enzymes: The enzymes remain bound to a support and are not present in the final food. Examples: Invertase to produce a glucose-fructose syrup; Glucose isomerase to produce high fructose corn syrup; Lactase (beta galactosidase) is used industrially to hydrolyse lactose in whey and similar substrates.