



Association of Manufacturers and Formulators of Enzyme Products

Amfep/09/14

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Regulatory classification of food enzyme uses as processing aid, additive or ingredient as of 20 January 2009

History

1. Annex I of Council Directive 89/107/EEC concerning food additives authorized for use in foodstuffs intended for human consumption mentions (food) enzymes as a separate category of food additives, when used as additives. When used as processing aid, however, they are exempted from the scope of the above Directive based on Art. 1.3. a).
2. Directive 2000/13 on labelling, presentation and advertising of foodstuffs stipulates that food additives have to be mentioned on the label of the final foodstuff. Article 6.4 (c) (ii) of this Directive, however, exempts food additives used as processing aid from such labelling obligation. Such exemption is based on the fact that the residual amounts of processing aids in food do not have a function there.
3. Consequently, the factor determining whether a food enzyme should be labelled on the final food is not the identity of the food enzyme itself, but the way it is used: as a processing aid or as an additive.
4. Since the publication of Council Directive 89/107/EEC 20 years ago, out of the many food enzyme applications only two, namely invertase in confectionary and lysozyme in cheese, have been classified as additive uses. **All other food enzyme applications are classified as processing aid uses. Therefore, they do not appear on the label of the final foodstuff.**
5. Although the term 'processing aid' is legally defined in Council Directive 89/107/EEC¹, different opinions occurred on the interpretation of this definition. As a result, the European Commission in 1999 initiated a task force on Scientific Cooperation (SCOOP) to establish objective criteria for the distinction between enzymes used as food additives, processing aids or ingredients.
6. Together with the CIAA, Amfep contributed to this exercise by providing a table that explains under which circumstances the use of an enzyme is regarded as processing aid according to current practice. This table is published on page 30 of the SCOOP report (see http://ec.europa.eu/food/fs/scoop/7.4.1_en.pdf)

¹ The legal definition of processing aids has been moved to Regulation (EC) No 1333/2008, Article 3 (b), while the wording has remained virtually unchanged.

7. The classification in this Table reflected the position of the EU Member States represented in the SCOOP task force. Although no final conclusions were drawn, this classification remained standard practice throughout the following years.

Situation as of 20th January 2009

8. The abovementioned Council Directive 89/107/EC has been repealed and replaced by Regulation (EC) No 1333/2008 on Food Additives. In this Regulation, (food) enzymes are no longer mentioned as a separate category of food additive. Instead, food enzymes are regulated separately in Regulation (EC) No 1332/2008 on Food Enzymes.
9. Article 21 of the Regulation on Food Enzymes contains an amendment to Directive 2000/13/EC on labelling, presentation and advertising of foodstuffs. This amendment, which entered into force on 20th January 2009, stipulates that food enzymes previously considered as food additives are now to be labelled as separate ingredients. **The labelling exemption for food enzymes used as processing aids continues to exist** (Art. 6.4 c) ii) of Directive 2000/13).
10. On this basis, Amfep concludes that the classification as mentioned in the Table of the SCOOP report remains current practice, with the only difference that the word 'additive' should now be changed to 'ingredient':

Case	Enzyme use is considered as a
1 – The enzyme is functional in the finished food product (because substrate is present, pH, temperature are suitable)	Additive <i>Food ingredient</i>
2 – The enzyme is not functional in the finished food product	
- 2.1. The enzyme activity can be reverted but the medium conditions are not suitable	Processing aid
- 2.2 The enzyme is denatured (e.g. by thermal or chemical treatment), but the protein remains present	Processing aid
- 2.3 The enzyme is definitively removed (no activity, no enzyme)	Processing aid

11. In order to maintain legal security and consistency, Amfep is firmly opposed to any deviation of the current practice the use of enzymes through this classification.

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