

Legislation on food additives, food enzymes and flavourings in the European Union

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Current Opinion in Food Science 2015, **6**:49–52

This review comes from a themed issue on **Food toxicology**

Edited by **Bruno de Meulenaer**

For a complete overview see the [Issue](#) and the [Editorial](#)

Available online 13th January 2016

<http://dx.doi.org/10.1016/j.cofs.2015.12.001>

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The European Union has a well-developed food safety policy and achieved some of the highest standards in the world in terms of health and food safety. The legislation on food additives, food enzymes and flavourings, also referred to as food improvement agents, ensures high level of human health and consumer protection and fair practices in food trade. The rules on food additives and flavourings are completely harmonised within the EU. The rules on food enzymes will be harmonised with the establishments of the EU list of authorised food enzymes. This paper provides an overview of the main requirements of the EU legislation on food improvement agents.

Introduction

In 2008, a package of regulations that further upgrades and harmonises the rules in the European Union on food additives, food enzymes and flavourings was adopted. In addition a Regulation establishing a common procedure for their authorisation was created. These Regulation are often referred to as the Food Improvement Agent Package (FIAP).

This legislative package replaces earlier directives on food additives and flavourings and introduces rules for the use of enzymes. The Food Improvement Agent Package comprises the following regulations:

- Regulation (EC) No 1333/2008 on food additives.¹
- Regulation (EC) No 1332/2008 on food enzymes.²
- Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties.³

- Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.⁴

Food additives

Regulation (EC) No 1333/2008 on food additives

The framework Regulation (EC) No 1333/2008 on food additives includes:

- Definitions
- General conditions for inclusion and use of food additives in the Union lists:
A food additive may be included in the Union lists if it meets the following conditions:
 - (a) it does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer at the level of use proposed;
 - (b) there is a reasonable technological need that cannot be achieved by other economically and technologically practicable means;
 - (c) its use does not mislead the consumer.
- Specific conditions for the use of sweeteners and colours
- The principle of carry-over.
- Rules for the labelling of food additives sold as such.
- Functional classes of food additives
- Union lists of food additives and conditions of use.

List of authorised additives

The Union list of food additives authorised in food is included in Annex II to Regulation (EC) No 1333/2008.

Food additives that were permitted for use in foods under Directives 94/35/EC on sweeteners, 94/36/EC on colours 95/2/EC on food additives other than colours and sweeteners are included in the Union list in Annex II after a review of their compliance with the conditions of use in the Regulation. Food additives and uses that were no longer needed have not been entered in the list.

Transparency is the major benefit of the new legislation. The additives are listed in a clear way, according to the category of food to which they may be added. For example, fish and fish products, fruit and vegetables, dairy products, confectionery, among others.

¹ OJ L 354, 31.12.2008; p 16–33.

² OJ L 354, 31.12.2008; p 7–15.

³ OJ L 354, 31.12.2008; p 34–50.

⁴ OJ L 354, 31.12.2008; p 1–6.

The new list is more accessible for all persons involved in any component of the food chain, be it as consumer, control authorities or food industry. The improved transparency allows correct and therefore safer use of food additives.

This Union list includes:

- the name of the food additive and its E number;
- the foods to which the food additive may be added;
- the conditions under which the food additive may be used;
- restrictions on the sale of the food additive directly to the final consumer.

The Union list of food additives authorised in food and their conditions of use can be consulted via the food additives database that is available online.⁵

Annex III to Regulation (EC) No 1333/2008 contains the Union list of food additives including carriers, approved for use in food additives, food enzymes, food flavourings, nutrients and their conditions of use.

The principle of carry over

The presence of food additives in foodstuffs not specified in Annex II may be accepted by virtue of the carry-over principle that is laid down in Article 18 of Regulation (EC) No 1333/2008.

Three basic possibilities are provided leading to a legal presence of additives in foods via carry-over:

- a. The use of the additive is permitted in one of the ingredients of the compound food;
- b. The additive is present as a result of its authorised use in food additives, food enzymes and flavourings in accordance with Annex III use and has no technological function in the final food;
- c. The additive is used in an ingredient where such use was not authorised, but is authorised in the compound food for which this ingredient is destined.

Regulation (EU) No 1169/2011 on the provision of food information to consumers,⁶ does not require that food additives, whose presence in a food is solely due to carry-over, to be included in the list of ingredients, provided that they serve no technological function in the finished product

Specifications for food additives

Specifications for food additives that are listed in the Union lists in Annex II and III to Regulation (EC) No 1333/2008 relating to origin, purity criteria and any other

necessary information were adopted by Regulation (EU) No 231/2012.⁷

Re-evaluation of food additives

Regulation (EU) No 257/2010⁸ sets up a programme for the re-evaluation by the European Food Safety Authority (EFSA) of the safety of food additives that were already permitted in the Union before 20 January 2009.

The deadlines for these re-evaluations are:

- All food colours by the end of 2015;
- Preservatives, antioxidants, glutamates, silicon dioxide by end of 2016;
- All other additives except sweeteners by the end of 2018;
- Sweeteners by the end 2020.

When re-evaluating an approved food additive EFSA examines the original opinion of the Scientific Committee on Food ('SCF'); where available, the original dossier; data submitted by the interested business operator(s); data made available by the Commission and Member States and identifies any relevant literature published since the last evaluation of each food additive.

Food enzymes

Introduction

Enzymes are naturally-occurring proteins that enhance chemical reactions. They can be obtained by extraction from plants or animals or by fermentation from micro-organisms. They are normally added to perform a technological function in the manufacture, processing, preparation and treatment of foods.

Enzymes are classified by the type of reaction they catalyse and the substrate they act upon.

Background

Over the last thirty years, the use of enzymes and enzyme preparations has steadily increased in all sectors of the food industry. Enzymes are generally used and considered as processing aids. Food enzymes other than those used as food additives were not regulated or were regulated as processing aids under the legislation of the Member States (MS). Only two food enzymes (invertase and lysozyme) fell within the definition of food additives in accordance with Regulation (EC) No 1333/2008 on food.

Two MS, Denmark and France, have an official list of food enzymes that are permitted for use in accordance with their national regulations. Due to the fact that

⁵ https://webgate.ec.europa.eu/sanco_foods/main/?event=display.

⁶ OJ L 304, 22.11.2011, p. 18–63.

⁷ OJ L 83, 22.3.2012; p 1–295.

⁸ OJ L 80, 26.3.2010; p 19–27.

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