



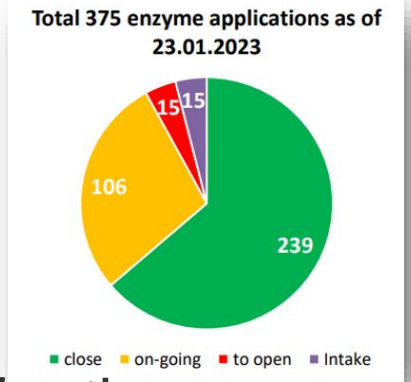
Food manufacturing processes in the food enzyme Union list

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Legal context



Article 17 of the Regulation (EC) No 1332/2008 lays down rules for the establishment of the Union list of food enzymes in one single step

- Once EFSA has issued an opinion on each food enzyme included in the Register in accordance with the procedure laid down in article 3 of Regulation (EC) No 1331/2008.
- Without prejudice to other applicable Union legislation, including Regulation (EC) No 178/2002, until the date of application of the Union list of food enzymes, national provisions in force concerning the placing on the market and use of food enzymes and food produced with food enzymes continue to apply in the Member States, in accordance with Article 24 of that Regulation.

Legal context

A food enzyme may be **included in the Union list** only if it meets the following conditions and, where relevant, other legitimate factors:

- (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, and
- (c) its use does not mislead the consumer.

The information to be included in the opinion of EFSA is specified in **Article 13 of Regulation (EC) No 234/2011**

Legal context

Article 7 of Regulation (EC) No 1332/2008 lays down that the entry of a food enzyme in the Union list shall specify: (c) the foods to which the food enzyme may be added; (d) the conditions under which the food enzyme may be used;

As per Article 4 of the Regulation on Food Enzymes, from the date of application of the Union list, only food enzymes included in that list may be placed on the EU market as such and used in foods, in accordance with the specifications and conditions of use provided for in the list.

Article 9 of Regulation (EC) No 1332/2008 provides for legally binding interpretation decisions for individual cases on whether a food belongs to a given category. Such decision can only be taken after the Union list is adopted.

**VERSION 7
DOES NOT NECESSARILY REPRESENT THE
OFFICIAL VIEWS OF THE COMMISSION**

January 2023



This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission. Circumstances be regarded as stating an official position. The information transmitted is intended only for the Member State or for the purposes of discussions and may contain confidential and/or privileged information.

**Working document describing the
which food enzymes are intended**

*The working document describing the food processes
is not a legally binding document*

*Version 7 has been aligned with the categorisation of
food manufacturing processes developed by EFSA for
the safety assessment of food enzymes*

IMPORTANT DISCLAIMER

The descriptions of the food processes in this working document are based on the information provided in the application for the evaluation of food enzyme by EFSA and the drafting of the document may be reviewed in the future, taking into account the views of experts, the Commission and stakeholders.

The indication of the use of certain enzymes under the proposed food processes reflects uses proposed by the applicants and under no circumstances may it be considered as an authorization.

The working document 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 working 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

EC working document describing the food processes

- Most of the food enzyme applications refer to food processes instead of food. It is therefore necessary to describe the different food processes in which food enzymes are intended to be used in order to facilitate the safety evaluation by EFSA and the drafting of the Union list.
- The indication of the use of certain enzymes under the proposed food processes reflects uses proposed by the applicants and under no circumstances may be considered as an authorisation.
- For each food process, a non-exhaustive list of technological effects and food enzymes are described in the Annex to this document.
- More food processes may be added on the basis of new information.

Name	Specifications	Foods	Conditions of use	Restrictions on the sale of the food enzyme to the final consumer	Specific requirement in respect of labelling of food

How will it be used for the drafting of the Union list ?

SECTION 1 Content of the list

Column 4 (Foods/Food processing): the foods/food processing to which the food enzyme may be added

Food enzymes may only be used in the foods/food processing and under the conditions of use set out in Table1.

For the purpose of the restrictions the following foods/food processing, shall be referred to:

01	Processing of dairy products
01.01	Production of lactose reduced milk
01.02	Production of cheese
01.03	Production of fermented dairy products
01.04	Production of flavouring preparation from dairy products
01.05	Production of whey concentrates and whey protein isolates
01.06	Production of whey protein hydrolysates
02	Processing of eggs and egg products
03	Processing of meat and fish products
...	...
10	Prevention of acrylamide formation in foods

How will it be used for the drafting of the Union list

Example: EFSA-Q-2014-00669 Beta-galactosidase from *K. lactis* AE-KL

- Processes as submitted by the applicant: Flavouring production, Milk/dairy processing
- Processes assessed by EFSA on the basis of additional information provided by the applicant in 2022 and according to the 'EC working document describing the food processes in which food enzymes are intended to be used'

Manufacture of galacto-oligosaccharides, Lactose hydrolysis in milk processing (including infant formulae), Production of fermented milk products

- **Column 4(Foods/Food processing) of the UL:** according to the latest version of the 'EC working document describing the food processes in which food enzymes are intended to be used' and the processes reflected in the EFSA opinion

Production of galacto-oligosaccharides, production of lactose reduced milk (including infant formulae), Production of fermented dairy products

Food process description

Example: 01. Processing of dairy products

01.01 Production of lactose reduced milk

This food manufacturing process relies on milk as the raw material and leads to the production of dairy foods such as, but not limited to lactose reduced milk, cheese and dairy ice cream.

Food enzymes may be used to hydrolyse lactose in milk for purposes such as:

- to reduce lactose content,
- to increase sweetness,
- to reduce sandiness of ice creams.

The food enzyme that can typically be used in these processes is β -galactosidase (lactase).

Lactose-reduced whey and lactose-reduced milk used in the production of infant formulae and follow-on formulae are excluded. Fermented milk products such as yoghurt and kefir are also excluded.

Request for extension of use

- A request for an extension of use may be submitted at any time through the ESFC platform.
- Part B of the updated ‘Scientific Guidance for the submission of dossiers on food enzymes’ is dedicated to Data required for the safety assessment of modifications to an existing authorisation.

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