

Food enzymes authorisation guidance

Food enzymes authorisation guidance and what you need to submit as part of a food enzyme application.

Enzymes are present in microorganisms, plants and animals and act as catalysts in various chemical reactions. This means that they increase the rate of the reactions. Because of this they can be useful in the production of food or certain food ingredients (i.e. flavourings), achieving increased yields or more efficient production processes.

Food enzymes are mainly used in:

- baking industry
- wine making and brewing
- cheese manufacturing
- production of fruit juices

Food enzyme authorisations

Assimilated law on the common authorisation process for food additives, food enzymes and food flavourings in? [Regulation?1331/2008?](#)and? [Regulation?234/2011](#) outline the authorisation procedure for these substances as regulated products. This requires the FSA to maintain a register of that accurately represents the authorisation status of these products as determined by the appropriate authority (ministers) in England, Scotland and Wales.

The domestic list for food enzymes is not yet established. Until the list is in place, enzymes may continue to be used in food if they meet the requirements of the following assimilated law:

- [General Food Law](#)
- Assimilated [Regulation \(EC\) No. 1332/2008 on food enzymes?](#)

However, if an enzyme use falls within the scope of? [food additives](#) or? [novel food](#) legislation it?will need to be approved before it can be used, if?it is not already permitted under the relevant

legislation.

Once the list is established, new food enzymes will need to be authorised to be placed on the market in Great Britain (GB).

Call for applications

We will publish a call for applications setting the deadline for submission of food enzyme applications. After this date, all valid applications will be evaluated and considered for inclusion on the initial list.

We can accept applications before the call is published, however they may not be evaluated immediately.

New authorisations

To apply for an authorisation of a food enzyme in GB, use our [regulated products application portal](#). This is where you will be asked to upload all the documents to support your application, which will form your dossier. There is no fee for the application.

Your enzyme authorisation application will need to consist of:

- an accompanying letter providing an outline of the application (identifying the enzyme, its proposed use, and the relevant food categories to which the application relates)
- a technical dossier
- a summary of the dossier
- a public summary of the dossier
- contact information for the applicant(s) and technical experts

If you want some parts of the dossier to be treated as confidential, your application will need to include also:

- a list of parts of the dossier requested to be treated as confidential
- a verifiable justification for each part for which a confidential treatment is required
- complete dossiers without confidential parts

Detailed guidance

The application requirements are set out in assimilated law:

- [Regulation 1331/2008](#)
- [Regulation 562/2012](#)

Guidance has also previously been developed by the European Food Safety Authority (EFSA). This guidance remains relevant as our approach is based on EU processes. You should follow the parts that relate to the development of dossiers only and not the application process:

- [EFSA guidance on the submission of a dossier on food enzymes](#)

Getting help

If you have any questions about the authorisation procedure or process, you can contact us at? regulatedproducts@food.gov.uk

Apply for authorisation

You can now use our online service to make a? [regulated product application](#).