

Food enzymes authorisation guidance

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

This page is part of the [Regulated products application guidance](#)

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, 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

Placing food enzymes on the market in Great Britain

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.

For most regulated product types, once products or processes are authorised, they are listed in relevant legislation, which also sets out how they can be used. These lists are referred to as positive lists.

The positive list for food enzymes is not yet established. Until the positive 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](#)
- [the enzyme legislation](#)

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

Call for applications and first positive list

We will publish a call for applications setting up the deadline for submission of the food enzymes applications. After this date all valid applications will be evaluated and considered for inclusion on the initial positive 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 you will need use our [regulated products application service](#). 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](#)

Ongoing applications

If you submitted a food enzyme application to the EU before 1 January 2021, you will need to submit your full application to us using our [regulated products application service](#). This should be done once the deadline for applications for the first positive list has been set. When completing the application form, you will be asked to provide your EFSA question number.

How long will my application take?

The legislation includes deadlines for key steps in the process. In most cases, applications will take at least a year. However, the deadlines only apply for new enzyme applications after the first positive list has been established. The deadlines then will be 9 months for the risk assessment (provided that no further information is requested from applicants), and 9 months for risk management discussions.

The quality of the dossier, and the information provided, will significantly affect the time needed for assessment and authorisation. We encourage applicants to follow the guidance and provide as much information as possible to ensure we can process your request as efficiently as possible.

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](#).

Northern Ireland

The EU law that applies to Northern Ireland after the transition period is specified in Annex II to the Northern Ireland Protocol. This means that for food enzymes to be placed on the Northern Ireland market you will have to continue to follow EU rules.