

Food additives authorisation guidance

Food additives authorisation requirements and what you need to submit as part of your application.

This page is part of the Regulated products application guidance.

Food additives are substances added to food to perform a specific technological function. This includes:

- making food look or taste better
- extending the storage and shelf-life of food
- maintaining the nutritional composition of food
- helping the food production process

Additives are used, among other things, as:

- colours
- preservatives
- antioxidants
- sweeteners
- emulsifiers
- flour treatment agents

Legislative requirements

Food additives need to be authorised before they can be placed on the market in Great Britain (GB). Assimilated law on the <u>common authorisation procedure</u> for food additives, food enzymes and food flavourings outlines the authorisation procedure.

Most additives are only permitted to be used in certain foods and only in specific quantities. You can find a full list of authorised food additives and the conditions of use in assimilated <u>Regulation</u> (EC) 1333/2008. The list of approved additives with their assigned E numbers is also available on our <u>Approved additives and E numbers</u> page. You should also make sure that any food additive being used also complies with the <u>specification requirements</u>.

New authorisations

To apply for the authorisation of a new food additive or to apply for a new use of an already authorised food additive in GB use our <u>regulated products application service</u>. 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 food additive authorisation application should consist of:

- an accompanying letter providing an outline of the application (identifying the substance, 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 also needs to include:

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

Detailed information about all the general and specific data and information required for your application is provided in the assimilated <u>Regulation (EU) 234/2011</u>.

Detailed guidance

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 for submission of food additive evaluations
- EFSA data requirements for the evaluation of food additive applications

Ongoing applications

If you submitted a food additive application to the EU before 1 January 2021 and the assessment process for this application has not been completed, you will need to submit your application to us, using our <u>regulated products application service</u>. When completing the application form, you will be asked to provide your EFSA question number.

How long will my application take?

The law includes deadlines for key steps in the process. In most cases, applications will take at least a year.

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 all the required information to ensure we can process your request as efficiently as possible.

Re-evaluation of food additives

The programme of re-evaluation for food additives is not in assimilated law. However, we will be monitoring developments in the scientific evidence supporting the safety of food additives. Where necessary, we may request additional information from interested parties to be provided on a case-by-case basis.

Existing authorisations

If your food additive has been authorised by the European Commission before 1 January 2021 and the necessary legislation is in place, that authorisation will remain valid in Great Britain.

Getting help

If you have any questions about the authorisation procedure or application requirements, 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 <u>Northern Ireland Protocol</u>. This means that if you're seeking a new authorisation for a food additive to be placed on the Northern Ireland market you will have to continue to follow EU rules.