# Flavourings authorisation guidance

Flavourings authorisation requirements and what you need to submit as part of your application. This page is part of the Regulated products application guidance

Flavourings are used to:

- add a new taste or odour to a food
- improve the existing taste or odour of a food

A commercial flavouring is often a complex mixture of different substances selected to provide the desired flavour.

#### Flavourings legislation

All flavourings and each constituent of a flavouring blend must be safe under general food law. In addition, some flavourings must undergo a safety evaluation before they're authorised for use in food in Great Britain (GB). Assimilated legislation on the <u>common authorisation procedure</u> for food additives, food enzymes and food flavourings outlines the authorisation procedure for these substances.

The following types of flavourings need to be authorised:

- flavouring substances
- flavouring preparations obtained from material other than food
- thermal process flavourings if ingredients are from source materials other than food or the production conditions or limits set in Annex V of assimilated <u>Regulation (EC) 1334/2008</u> are not met
- flavour precursors obtained from source material other than food
- other flavourings
- · source materials other than food

## Register of flavourings

The <u>register of flavourings</u> sets out a list of flavourings permitted for use in GB. The register does not replace assimilated <u>Regulation (EC) 1334/2008</u> or assimilated legislation on the <u>common authorisation procedure</u> which are the legal basis for the placing on the market and use of flavourings.

#### 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 if you're seeking a new authorisation for a flavouring to be placed on the Northern Ireland market you will have to continue to follow EU rules.

#### **New authorisation**

To apply for an authorisation of a flavouring 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 flavouring 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 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**

Detailed guidance has previously been developed by the European Food Safety Authority (EFSA) and 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 data required for the risk assessment of flavourings

#### **Ongoing applications**

If you submitted a flavouring application to the European Union (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, you will be asked to provide your EFSA question number.

### **Authorisation of footnote flavourings**

If your flavouring was included in Annex I of Regulation 1334/2008 by the European Commission (EC) before 1 January 2021 and the necessary legislation applies, that authorisation will remain valid in GB.

Flavouring substances marked with a footnote in Annex I Part A of Regulation 1334/2008 have not had their evaluation completed by EFSA. These substances will continue to be permitted in GB until their evaluation is completed by the FSA. We will in due course set out our plans for finalising the evaluation of these substances and requesting the submission of information to allow the evaluations to be completed. In the interim we may request information on individual flavouring substances on a case by case basis.

### **Existing authorisations**

If your flavouring was authorised by the European Commission (EC) before 1 January 2021 and the necessary legislation applies, that authorisation will remain valid in GB and you don't need to

apply for an authorisation.

#### How long will my application take?

The legislation includes deadlines for key steps in the process for risk assessment and risk management considerations. In most cases, applications will take at least a year. The timelines do not apply for footnote substances.

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 <a href="mailto:regulatedproducts@food.gov.uk">regulatedproducts@food.gov.uk</a>

## Apply for authorisation

Apply for a flavouring authorisation using our regulated product service.