Flavourings authorisation guidance

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

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 authorisations

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 are authorised for use in food in Great Britain (GB). Assimilated legislation on the? common authorisation procedure 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?
 Regulation (EC) 1334/2008 are not met
- flavour precursors obtained from source material other than food
- other flavourings referred to in Article 3(2)(g)(ii) of assimilated Regulation (EC) 1334/2008
- source materials other than food referred to in Article 3(2)(j)(ii) of assimilated Regulation (EC) 1334/2008?

Register of flavourings

The FSA maintains a register that accurately reflects the authorisation status of flavourings as determined by the appropriate authority (ministers) in England, Scotland and Wales. The? register of flavourings sets out a list of flavourings permitted for use in GB and provides references to their terms of authorisation. Assimilated? Regulation (EU) 1334/2008 is the legal basis for the authorisation of flavourings.

New authorisations

To apply for an authorisation of a flavouring in GB, use our?<u>regulated products application portal</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

The European Food Safety Authority (EFSA) has previously developed technical guidance on the requirements for application dossiers which is also applicable for dossiers submitted in GB.? However, 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

Flavouring substances under evaluation

A 'flavouring substance under evaluation' is defined in Article 3(2)(m) of assimilated Regulation 1334/2008. These were included in the table in Part A of Annex I of Regulation 1334/2008 and marked with a footnote in column 8, and were permitted to be placed on the market and used in or on foods by Article 4 of Regulation 872/2012. These are sometimes referred to as 'footnote flavourings'.

Flavouring substances under evaluation have not had their evaluation completed and so are not deemed to be 'authorised' but are permitted for use in GB. These need to be assessed and either authorised by ministers or removed from the list.

If companies or trade associations do not intend to provide the studies necessary for the evaluations to be completed, they should submit an application asking for the flavourings to be removed from the list.

We will work with the flavourings industry and 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.

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.