Smoke flavourings authorisation guidance

Smoke flavourings authorisation requirements and what you need to submit as part of a smoke flavouring application.
This page is part of the Regulated products application guidance

Smoke flavourings are added to foods, such as meat or cheese, to give them a ‘smoked’ flavour, as an alternative to traditional smoking. They can also be added to foods which are not traditionally smoked, such as soups, sauces or confectionery. In some cases, smoke flavourings are used at very low levels to add an undertone of a particular flavour only and not the full smoky taste.

Smoke flavourings need to be authorised before they can be placed on the market in Great Britain (GB). Assimilated law on smoke flavourings outlines the authorisation procedure for these types of flavouring. There is a separate authorisation process for flavourings such as flavouring substances.

Smoke flavouring primary product authorisations are applicant specific and are given for 10 years. They can be renewed after this period. Smoke flavourings are controlled under different legislation to other flavourings and so have different timings for the risk analysis process and data requirements for the applications.

Register of smoke flavourings

The register of smoke flavourings sets out a list of smoke flavouring primary products permitted for use in Great Britain. The register does not replace assimilated Regulation (EU) No. 1321/2013 or assimilated Regulation (EU) No. 2065/2013 which are the legal basis for the placing on the market and use of primary products.

New authorisations

To apply for an authorisation of a smoke flavouring in GB, 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 application should consist of:

- an overall summary of the application
- administrative data (part 1)
- technical data (part 2)
- toxicological data (part 3)
- references and reports (part 4)

Detailed guidance

Detailed guidance has previously been developed by 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 submission of a dossier on smoke flavouring primary product

- assimilated Regulation 627/2006 – smoke products covers the quality criteria for validated analytical methods for sampling, identification and characterisation of primary smoke products

Renewals

Deadline for applications for renewals

Renewal applications for all the 10 smoke flavourings currently authorised in GB/UK had to be submitted before the end of June 2022.

We received eight renewal applications by this deadline, covering the following smoke flavourings.

- SF-001 Scansmoke PB 1110, proFagus GmbH
- SF-002 Zesti Smoke Code 10, Kerry Group plc
- SF-003 Smoke Concentrate 809045, Symrise AG
- SF-004 Scansmoke SEF 7525, Azelis Denmark A/S
- SF-005 SmokEZ C-10, Kerry Group plc
- SF-006 SmokEZ Enviro-23, Kerry Group plc
- SF-008 proFagus-Smoke R709, proFagus GmbH
- SF-009 Fumokomp, Kompozicio Kft

Existing authorisations that will lapse from 1 January 2024

The authorisation holders for SF-007 Tradismoke(TM) A MAX (J. Rettenmaier & Söhne GmbH + CO KG) and SF-010 AM 01 (AROMARCO, s.r.o) did not submit renewal applications. From 1 January 2024 the smoke flavourings themselves, any flavourings including them and foods containing these smoke flavourings are not permitted on the UK market.

These smoke flavourings maybe sold under different trade names. Food manufacturers may need to check with their flavouring suppliers which smoke flavourings they are using in food to ensure compliance with assimilated Regulation (EU) No. 1321/2013 and assimilated Regulation (EC) No. 2065/2003.

Studies required for renewals

We would like the original dossier and any other additional information submitted as part of the original approval. However, we appreciate that some organisations may no longer hold this information.

Detailed information on what studies are required for renewal applications can be found in the EFSA guidance.

A complete dataset for the characterisation of the smoke flavouring primary product, exposure data and genotoxicity data must be included. Alternative toxicological studies to those outlined in the guidance may be submitted. Should authorisation holders choose to submit alternative toxicological studies, they must contain a justifiable strategy and the data must address all the safety concerns as outlined in the guidance so to enable the assessment of the safety of the smoke flavouring in relation to the proposed conditions of use.

The UK's Committee on Toxicity encourages applicants to utilise existing data from the original dossier, read-across and non-animal methodologies (NAMs) as a first tier approach to the safety assessment of the smoke flavourings.

Should this not provide enough information, and the relevant Scientific Advisory Committee considers more evidence is required for the risk assessment, then, in line with the EFSA guidance, the following additional studies may be required:

- An extended One Generation reproductive Toxicity Study (EORGT) (OECD TG 443) or the two following studies:

a) An enhanced 90-day oral toxicity study comprising OECD TG 408 and including assessments of neurotoxicity, effects on the endocrine system (annex B of OECD TG 408) and effects on the immune system based on investigation of the following parameters.

At term (at sacrifice):

- Histopathology, including bone marrow cellularity
- Weighing lymphoid organs

In blood:

- Immunoglobulin isotypes
- Complement assays: total serum haemolytic activity or individual components;
- C-reactive protein (CRP)
- Total and differential white blood cell count

In spleen:

- Phenotypic analysis of spleen cells (CD4 and CD8 T cells, regulatory T cells, B cells, natural killer (NK) cells, macrophages)
- Natural killer cell functional analysis
- Phagocytic activity
- Mitogen stimulation assays for B and T cells

b) A developmental toxicity test in rats according to OECD TG 414

Further details on the requirements for these studies can be found in Section 3.3.3 of the EFSA Guidance.

However, acknowledging the time constraints with regards to the timelines for the renewal of the smoke flavouring applications, applicants who choose not to utilise a NAMs strategy should alternatively provide evidence in their application that an EOGRT, or new 90-day study and developmental toxicity study in rats, has been commissioned and will be submitted once the study results are available.

Handling of applications for renewals

Some studies requested for the GB renewal process had not been completed by the end of June 2022, due to factors beyond the applicants' control. Therefore we accepted submissions for renewal if they included a complete dataset for the characterisation of the smoke flavouring primary product, exposure data and genotoxicity data. In addition, the dossier had to contain a statement from the applicant detailing why the NAMs, EOGRTs or the alternative toxicological studies were not included and a declaration that the studies had been commissioned.

As some studies were not included in the renewal application, Ministers will not be able to make a final decision on whether to approve the renewal applications before the authorisation end date of 1 January 2024. Accordingly, the current authorisation expiry dates will be extended as provided for in assimilated Regulation (EC) 2065/2003 until a decision has been made.

The FSA will update the GB register of smoke flavourings to reflect the revised new authorisation end dates.

Ongoing applications

If you submitted a smoke flavouring 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 regulated products application service. When completing the application form, you will be asked to provide your EFSA question number.

Existing authorisations

If your smoke flavouring has been authorised by the European Commission before 1 January 2021 and the necessary legislation applies, that authorisation will remain valid in Great Britain until its expiry date.

How long will my application take?

The law includes deadlines for key steps in the process:

- 6 months for the risk assessment
- 3 months for the development of risk management decisions

This could be longer if the clock is stopped as new information is requested.

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