

Information on the procedure for the renewal of existing authorisations for smoke flavourings

About the Regulation

[Regulation \(EC\) No 2065/2003](#) establishes a procedure for the safety assessment and the authorisation of smoke flavouring primary products with a view to ensuring a high level of protection of human health and the interests of consumers and the effective functioning of the internal market.

The Regulation provides that smoke flavourings or food containing them may not be placed on the market if a smoke flavouring that is not an authorised primary product is present.

[Commission Implementing Regulation \(EU\) No 1321/2013](#) authorised 10 smoke flavouring primary products **for a 10-year period**, due to expire on 1 January 2024.

As per Article 12(1) of Regulation (EC) No 2065/2003, **authorisation holders wishing to renew the authorisations must submit applications at the latest 18 months before the expiry date of the authorisation.**

The applications shall be submitted through the [E-submission Food Chain platform](#).

In light of the upcoming deadline for requesting such renewals, the Commission services wish to provide authorisation holders and other interested parties with the following information in respect of this process.

Authorisation holder

In accordance with Article 12(1) of Regulation (EC) No 2065/2003, **only the actual authorisation holders** may request the said renewal of authorisation.

Insofar as the ownership of an authorisation would have changed or if changes would be intended in the near future, it is important that authorisation holders take this element into account, so as not to compromise a possible application for renewal of an existing authorisation.

The change of authorisation holder can be requested by means of an application for modification of the existing authorisation by the authorisation holder itself.

Requirements arising from Regulation (EU) 2019/1381

The provisions of [Regulation \(EU\) 2019/1381](#) apply to all applications under Union Food law submitted on or after 27 March 2021 (see Article 10) and that this Regulation amended in particular the [General Food Law](#) and Regulation (EC) No 2065/2003 as regards certain provisions that are relevant for the applications for renewal of authorisations of smoke flavouring primary products. In particular:

- Article 32a of the General Food Law, which allows potential applicants to request the European Food Safety Authority ('the Authority') for advice on the rules applicable to, and the content required for, an application for which Union law foresees the delivery of a scientific output by the Authority.
- Article 32b of the General Food Law, which requires business operators and laboratories and other testing facilities located in the Union to notify the Authority of the title and scope of any study commissioned or carried out to support an application. Non-compliance with these requirements may lead to procedural consequences for the application, including its possible inadmissibility or invalidity, as set out by Article 32b(4) and (5) of the General Food Law.
- Article 32c(1) of the General Food Law, which allows potential applicants for renewal of authorisations to notify the Authority of intended studies with a view to obtaining the Authority's advice on the content of the intended renewal application, as well as on the design of the studies.
- Articles 14 and 15 of Regulation (EC) No 2065/2003, which in turn refer to the proactive disclosure and confidentiality requirements set out respectively in Articles 38 and 39 to 39e of the General Food Law. As a result, information, studies and data supporting applications submitted on, or as of, 27 March 2021 to the Authority are made publicly available by it unless a confidentiality request has been submitted pursuant to the Authority's Practical Arrangements concerning Transparency and Confidentiality.
- Article 32c(2) of the General Food Law also provides for a consultation of the public and of stakeholders on the basis of the non-confidential version of the application, immediately after it is made public in accordance with Articles 38 to 39e of the General Food Law.

Applicants are invited to refer to the [General Food Law](#) and [Regulation \(EC\) No 2065/2003](#) as well as to the [Authority's Practical Arrangements](#).

Procedure for the renewal of authorisations

Deadline for applications for the renewal of authorisations

Authorisation holders must request the renewal of authorisations for smoke flavouring primary products **at the latest 18 months before the expiry date of the authorisation**.

This deadline is applicable in respect of the authorisations that are presently included in the Union list of authorised smoke flavouring primary products and which are due to expire on 1 January 2024.

Handling of applications for the renewal of authorisations

In accordance with Article 8(3)(a) of Regulation (EC) No 2065/2003, the Authority shall verify that the application is valid in the sense that it contains the information referred to in Article 7(3) of the

Regulation, which refers to Annex II, listing the information necessary for the scientific evaluation of primary products, including point 6 concerning toxicological data.

This information should be compiled in accordance with [Scientific Guidance for the preparation of applications on smoke flavouring primary products](#) and the [Administrative guidance for the preparation of applications on smoke flavouring primary products](#).

Applicants may deviate from the Authority's guidance documents and submit alternative toxicological studies to the ones recommended by the Authority, provided that they can justify their strategy and that the submitted alternative data could address the safety endpoints as indicated in the guidance, allowing to assess the safety of the smoke flavouring primary product under the proposed conditions of use.

Account may be given to the fact that it might not have been feasible to complete the Extended One Generation Reproductive Toxicity study (EOGRTS), conducted according to OECD TG 443 as recommended by the Authority in the scientific guidance, or an alternative toxicological study to the EOGRTS, during the period between the publication of the Authority's guidance documents and the deadline for applying for the renewal of the existing of authorisations for smoke flavouring primary products.

In this context, the Authority could confirm validity of the renewal applications without the complete data required in the Authority's scientific guidance provided the application contains:

- Complete dataset, regarding the characterisation of the smoke flavouring primary product, its genotoxicity and exposure data;
- Information demonstrating that the EOGRTS (or an alternative toxicological study to the EOGRTS) is ongoing by providing:
 - a statement from the applicant detailing the reasons for not providing the EOGRTS (or the alternative toxicological study) and a declaration that the study has been already commissioned to a contract research laboratory (CRO);
 - a notification of the EOGRTS (or the alternative toxicological study) in the Authority's database for study notifications, referred to in Article 32b of Regulation (EC) No 178/2002, i.e. the Transparency Regulation. The notification of the study has to be performed by the applicant after the commissioning of the study and before its starting date. Moreover, this notification must be carried out before submitting the renewal application to the Commission.

Upon validation, the Authority will make publicly available the non-confidential version of the application as submitted by the applicant.

A second, non-confidential version of the application dossier implementing the Authority's confidentiality decision may be disclosed by the Authority later during the safety assessment in case the Authority disagrees with one or more of the confidentiality requests submitted by the applicant.

The Authority will first evaluate the available full dataset submitted at the time of application (chemical characterisation, genotoxicity data, dietary exposure) with the aim of ruling out potential concern with respect to genotoxicity by the end of September 2023.

Second, provided that the genotoxic concern can be ruled out, the Authority will proceed to complete the rest of the safety assessment, in particular after receiving the submission of the final EOGRTS (or the alternative toxicological study) for the concerned applications for the renewal of authorisations for smoke flavouring primary product.

Procedure in case of delays of the renewal procedure for reasons beyond the control of the authorisation holder

In accordance with Article 12(4) of Regulation (EC) No 2065/2003, **where no decision is taken on the concerned application for reasons beyond the control of the authorisation holder, the period of authorisation of products for which a procedure of renewal is ongoing would be extended by six months.**

Where this provision is applied, the Commission would inform the authorisation holder and the Member States about the delay.

This provision seeks to ensure that the procedure for the renewal of authorised smoke flavouring primary products can be completed without leading to disruptions on this regulated market.

Taking this into account as well as the need to ensure that time-pressure would not prevent the Authority and the Commission to carry out the thorough safety assessment and the risk management decisions that are necessary to protect human health and the interests of consumers, the Commission considers that, as long as the conditions of Article 12(4) would be complied with, multiple extensions may occur for a given application for renewal.

The application of this provision is subject to the condition that it can be established that the absence of a decision on the renewal of an authorisation is due to 'reasons beyond the control of the authorisation holder'.

To ensure that the conditions for the extension provided for in Article 12(4) are met, the applicants are invited to report to the Commission every 6 months on the situation of their application and on the status of the data being generated.

Such reporting should be carried out by the end of the months of May and November and addressed to the Commission services at the following address: SANTE-SMOKE-FLAVOURINGS@ec.europa.eu including the Authority's address in copy: FDP@efsa.europa.eu.

Six-month extension of the authorisation of smoke flavourings SF-001, SF-002, SF-003, SF-004, SF-005, SF-006, SF-008 and SF-009 (Update)

In June 2022, the Directorate-General for Health and Food Safety received applications for the renewal of the authorisation of SF-001, SF-002, SF-003, SF-004, SF-005, SF-006, SF-008 and SF-009 as smoke flavouring primary products according to Article 12 of Regulation (EC) No 2065/2003.

The Commission requested EFSA to perform the safety assessment of the above smoke flavouring primary products, in line with Regulation (EC) No 2065/2003. As a first step, EFSA carried out the evaluations of the submitted data related to the chemical characterisation, genotoxicity and dietary exposure of each smoke flavouring primary products. The outcomes of these assessments were published by EFSA on 16 November 2023.

Smoke flavourings: [Q&A with Wim Mennes, EFSA's working group chair on flavourings](#) | EFSA (europa.eu)

It has not been possible for the European Commission to finalise decisions on the renewal of authorisation of the mentioned products at least a month before the expiry date of the current authorisations (31 December 2023) as prescribed by Article 12(4) of Regulation (EC) No 2065/2003.

Pursuant to the same Article 12(4) of Regulation (EC) No 2065/2003, when for reasons beyond the control of the authorisation holder no decision is taken on the renewal of an authorisation until one month before its expiry date, the period of authorisation of the products is automatically extended by six months. Therefore, the authorisations of smoke flavourings SF-001, SF-002, SF-003, SF-004, SF-005, SF-006, SF-008, SF-009 as smoke flavouring primary products are extended until 30 June 2024, in accordance with the provision of Article 12(4) of Regulation (EC) No 2065/2003. During this period, the Commission will nevertheless follow-up on the EFSA opinions and put forward the regulatory measures as necessary.

As no applications have been submitted for the renewal of the authorisations of SF-007 and SF-010, the authorisations of these smoke flavouring primary products expire on 31 December 2023. According to the provisions of Article 4(2) of Regulation (EC) 2065/2003 no products containing SF-007 or SF-010 should be placed on the market after the 31st December 2023. Foods containing SF-007 or SF-010 that were placed on the market prior to 1st January 2024 may remain on the market until their date of minimum durability or 'use by' date."

UPDATE (24 June 2024): Pending the adoption of the legal acts in relation to smoke flavourings that received a favourable opinion of the Standing Committee on Plants, Animals, Food and Feed, section Novel Food and Toxicological Safety, at the meeting of 24 April 2024, Article 12(4) of Regulation (EC) No 2065/2003 applies, meaning that currently the authorisations of the SFPPs (SF-001, SF-002, SF-003, SF-004, SF-005, SF-006, SF-008 and SF-009) should be considered automatically extended by another six months."

No renewal of the authorisation of smoke flavourings SF-001, SF-002, SF-003, SF-004, SF-005, SF-006, SF-008 and SF-009 and phase out measures (Update 01/08/2024)

Based on the outcomes of the assessments by EFSA that were published on 16 November 2023, the European Commission drafted the relevant legal acts that were endorsed by the Member States in the Standing Committee on Plants, Animals, Food and Feed, section Novel Food and Toxicological Safety of the Food Chain on 24 April 2024 and adopted by the Commission on 31 July 2024.

The 8 Commission Implementing Decisions and the related Commission Implementing Regulation can be found here:

- **SF-001:** [Commission Implementing Decision 2024/2071](#)
- **SF-002:** [Commission Implementing Decision 2024/2066](#)
- **SF-003:** [Commission Implementing Decision 2024/2073](#)
- **SF-004:** [Commission Implementing Decision 2024/2072](#)
- **SF-005:** [Commission Implementing Decision 2024/2079](#)
- **SF-006:** [Commission Implementing Decision 2024/2078](#)

- **SF-008:** [Commission Implementing Decision 2024/2069](#)
- **SF-009:** [Commission Implementing Decision 2024/2077](#)

[Commission Implementing Regulation \(EU\) 2024/2067](#) of 31 July 2024 amending Implementing Regulation (EU) No 1321/2013 as regards the deletion of entries SF-001 to SF-010 from the Union list of authorised smoke flavouring primary products.

The legal acts, in addition to the no renewal of the authorisation of the eight smoke flavourings, also describe the relevant phase-out measures as follows:

- The smoke flavourings SF-001, SF-002, SF-003, SF-004, SF-005, SF-006, SF-008 and SF-009 may continue to be placed on the market until 1 July 2029.
- Foods containing smoke flavouring primary products SF-001, SF-002, SF-003, SF-004, SF-005, SF-006, SF-008 or SF-009 that comply with the provisions laid down for those smoke flavouring primary products in the Union list before 21 August 2024 may continue to be placed on the market and remain on the market until their date of minimum durability or use by date if they are placed on the market until the following dates:
 - (a) 1 July 2029 for food categories 1.7 (cheese and cheese products), 8 (meat), 9.2 (processed fish and fishery products including crustaceans and molluscs), 9.3 (Fish roe) and their corresponding sub-categories.
 - (b) 1 July 2026 for all other food categories.

Please see the [schematic representation](#) and [examples](#) of the phase out measures.

Kindly note that this information is intended to assist authorisation holders in the application of Regulation (EC) No 2065/2003 as regards possible applications for renewal of authorisations for smoke flavouring primary products but that only the Court of Justice of the European Union is competent to authoritatively interpret Union law.