TECHNICAL REPORT

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Administrative guidance for the preparation of applications on food improvement agents (food enzymes, food additives and food flavourings)

European Food Safety Authority (EFSA)

Abstract

This document provides guidance to applicants submitting applications on food enzymes, food additives or food flavourings, which are to be evaluated by EFSA. It describes the administrative requirements for the preparation and online submission of the dossier to support an application for a new authorisation or for the modification of an existing authorisation of food enzymes, food additives or food flavourings for applications submitted to the European Commission as of 27 March 2021.

The Transparency Regulation amended the General Food Law by introducing new provisions in the pre-submission phase and in the application procedure: general pre-submission advice, notification of information related to studies commissioned or carried out to support an application, public disclosure of non-confidential version of all information submitted in support of the application and related confidentiality decision-making process, public consultation on submitted applications. These new requirements, as implemented by the Practical Arrangements laid down by EFSA, are reflected in this guidance.

The guidance describes the procedure and the associated timelines for handling applications on food enzymes, food additives and food flavourings, the different possibilities to interact with EFSA and the support initiatives available from the preparation of the application (pre-submission phase) to the adoption and publication of EFSA's scientific opinion.

Key words: Application, e-submission, food enzyme, food flavouring, food additive, Regulation (EC) No 1331/2008, Commission Regulation (EU) No 234/2011.

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Summary

This document provides guidance to applicants preparing applications for a new authorisation or for the modification of an existing authorisation of food enzymes, food additives or food flavourings in the European Union within the scope of Regulation (EC) No 1331/2008 and Commission Regulation (EU) No 234/2011. It takes into account the new provisions introduced in Regulation (EC) No 178/2002 (i.e. the General Food Law) and in Regulation (EC) No 1331/2008 by Regulation (EU) 2019/1381 (i.e. the Transparency Regulation).

This guidance applies to all applications submitted to the European Commission as of 27 March 2021 and should be used for the preparation of applications intended to be submitted from that date onwards.

The present guidance document consists of three chapters:

- Chapter 1. *Background and Terms of Reference* provides the context for the publication of this guidance document;
- Chapter 2. *Guidance* describes the procedure, the associated timelines and the documentation to be provided for an application submitted for the authorisation of a food improvement agent and for the modification of an existing authorisation of food enzymes, food additives and food flavourings;
- Chapter 3. *Interaction with EFSA staff* provides information on the different possibilities to interact with EFSA staff during the life-cycle of the application, from the preparation of the application (pre-submission phase) to the adoption and publication of EFSA's scientific opinion;

For all applications submitted as of 27 March 2021, this administrative guidance (version 2021) supersedes the following documents:

- the entire 'Administrative guidance to applicants on the suitability check of applications for authorisation of food enzymes' including its Appendix 1 (EFSA, 2014); the chapter 'Submission of an application', the sub-chapters 'Summary on dossier submission' and 'Administrative data' within the 'Guidance on the Submission of a Dossier on Food Enzymes for Safety Evaluation' (EFSA CEF Panel, 2009);
- the sections 'Administrative requirements' and 'Procedure' in Appendix B of the 'Guidance for submission for food additive evaluations' (EFSA ANS Panel, 2012);
- the chapter 'Submission of an application' of the 'Guidance on the data required for the risk assessment of flavourings to be used in or on foods' (EFSA CEF Panel, 2010).

For all applications submitted before 27 March 2021, the documents listed above continue to apply.

This administrative guidance will be updated, if needed, in accordance with relevant changes of the sectoral legislation and/or guidance documents.

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1. Background and Terms of Reference as provided by EFSA

Since 2014, EFSA implemented dedicated services and initiatives to support applicants and other stakeholders during the whole life-cycle of applications for regulated products.

In this context, EFSA prepared this administrative guidance on food enzymes, food additives and food flavourings (hereinafter also referred to as 'food improvement agents'), in order to provide applicants with updated and detailed information as regards the procedure for the preparation and the online submission of an application, the format of the dossier and the handling of the application by EFSA. It aims at improving the understanding of the requirements for applications and the services in place in EFSA during the life-cycle of the applications, from preparation of the application (pre-submission phase) to adoption and publication of EFSA's scientific opinion.

The scope of this administrative guidance document relates to Regulation (EC) No 1331/2008[1] read jointly with Commission Regulation (EU) No 234/20112, as amended by Commission Regulation (EU) 2020/1823[3],regarding applications for authorisation of a new food improvement agent i.e. addition of a substance to the Community list, and for modification of an existing authorisation i.e. for adding, removing or changing conditions, specifications or restrictions associated with the presence of the substance on the Community list.

It is to be read in conjunction with the above-mentioned Regulations, as well as with Regulation (EU) 2019/1381[4] (hereinafter 'Transparency Regulation') amending *inter alia* Regulation (EC) No 178/2002[5] (i.e. the General Food Law, hereinafter 'GFL Regulation') and Regulation (EC) No 1331/2008, and with EFSA's Practical Arrangements[6] implementing the Transparency Regulation. In case of discrepancy between the content of this document and applicable legal acts, or EFSA's Practical Arrangements, the legal acts and the latter prevail.

This guidance applies to all applications submitted to the European Commission (EC) as of **27 March 2021** and should be used for the preparation of applications intended to be submitted from that date onwards. For applications submitted before 27 March 2021:

- the entire 'Administrative guidance to applicants on the suitability check of applications for authorisation of food enzymes' including its Appendix 1 (EFSA, 2014); the chapter 'Submission of an application', the sub-chapters 'Summary on dossier submission' and 'Administrative data' within the 'Guidance on the Submission of a Dossier on Food Enzymes for Safety Evaluation' (EFSA CEF Panel, 2009) continue to apply for food enzymes;
- the sections 'Administrative requirements' and 'Procedure' in Appendix B of the 'Guidance for submission for food additive evaluations' (EFSA ANS Panel, 2012) continue to apply for food additives;

[1] Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings. OJ L 354, 31.12.2008, p. 1–6.
[2] Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings. OJ L 64, 11.3.2011, p. 15–24.
[3] Commission Implementing Regulation (EU) 2020/1823 of 2 December 2020 amending Regulation (EU) No 234/2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings. C/2020/8358. OJ L 406, 3.12.2020, p. 43–50.
[4] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, PE/41/2019/REV/1. OJ L 231, 6.9.2019, p. 1–28.
[5] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, as amended by Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, PE/41/2019/REV/1. OJ L 231, 6.9.2019, p. 1–28.
[6] EFSA's Practical Arrangements are available online at: https://www.efsa.europa.eu/en/corporate/pub/tr-practical-arrangements

- the chapter 'Submission of an application' of the 'Guidance on the data required for the risk assessment of flavourings to be used in or on foods' (EFSA CEF Panel, 2010) continues to apply for food flavourings.

Smoke flavouring primary products are outside the scope of this document. For guidance on the preparation of applications on smoke flavouring primary products, applicant should follow the indications provided in the dedicated guidance available on EFSA's website.

For the purpose of this guidance document, an 'applicant' means any legal or natural person (e.g. individuals, business operators, industry associations, consultancy companies), no matter whether situated within or outside the European Union (EU), who has submitted an application under Regulation (EC) No 1331/2008.

EFSA will update this document, if needed, in line with relevant changes of the legislation and/or guidance documents and according to the experience gained in the handling and assessment of applications on food improvement agents. Therefore, applicants are advised to always consult the latest published version of this document available on EFSA's website.[7]

[7] https://www.efsa.europa.eu/en/applications/food-improvement-agents/regulationsandguidance

2. Guidance

This guidance applies to all applications submitted to the European Commission as of 27 March 2021 and should be used for the preparation of applications intended to be submitted from that date onwards.

For all applications submitted as of 27 March 2021, this administrative guidance (version 2021) supersedes the following documents:

- the entire 'Administrative guidance to applicants on the suitability check of applications for authorisation of food enzymes' including its Appendix 1 (EFSA, 2014); the chapter 'Submission of an application', the sub-chapters 'Summary on dossier submission' and 'Administrative data' within the 'Guidance on the Submission of a Dossier on Food Enzymes for Safety Evaluation' (EFSA CEF Panel, 2009) which has been republished without the administrative information (EFSA CEF Panel, 2009, updated in 2021);
- the sections 'Administrative requirements' and 'Procedure' in Appendix B of the 'Guidance for submission for food additive evaluations' (EFSA ANS Panel, 2012); this guidance has been republished without the administrative information (EFSA ANS Panel, 2012, updated in 2021);
- the chapter 'Submission of an application' of the 'Guidance on the data required for the risk assessment of flavourings to be used in or on foods' (EFSA CEF Panel, 2010) this guidance has been republished without the administrative information (EFSA CEF Panel, 2010, updated in 2021).

For all applications submitted before 27 March 2021, the documents EFSA, 2014; EFSA CEF Panel, 2009; EFSA ANS Panel, 2012; EFSA CEF Panel, 2010 continue to apply.

Food improvement agents are subject to a regulatory authorisation before entering the EU market. Prior to their authorisation, EFSA is tasked to perform a comprehensive and science-based risk assessment of the food improvement agent in the context of its intended uses.

In this framework, the applicant can submit applications for updating the Community list as per Article 2 of Regulation (EC) No 1331/2008:

- **Applications for the authorisation of a new food improvement agent**;
- **Applications for the modification of the existing authorisation of a food improvement agent**.

The life-cycle of an application encompasses various steps and activities:

- **Pre-submission phase**: this covers the preparation of the application and all pre-submission activities;
- **Submission phase and suitability check**: through the e-submission system, the applicant submits the application to the European Commission. EFSA checks that the application is complete and suitable for risk assessment;
- **Risk assessment phase**: following the validation of the application, EFSA launches a public consultation on the information contained in the application (non-confidential version of the application dossier) and performs the risk assessment leading to the adoption of EFSA's scientific opinion by the EFSA CEP Panel (in case of food enzyme applications) or by the EFSA FAF Panel (in case of food additive or food flavouring applications);
- **Post-adoption phase**: EFSA's scientific opinion, which provides scientific advice to support decision-making by risk managers, is published on the EFSA Journal. After EFSA has forwarded its opinion to the European Commission (EC), the Member States and the applicant, the European Commission prepares, where appropriate, a draft regulation updating the Community list.[8]

Confidentiality decision-making and proactive disclosure by EFSA of information contained in the application (non-confidential version) take place at different moments during the application life-cycle.

[8] In accordance with Article 7 of Regulation (EC) No 1331/2008.

The tools that applicants are expected to use in the preparation of the application and subsequent phases (e.g. EFSA's portal supporting pre-submission activities, database of study notifications, e-submission system, as detailed below) are available on EFSA's website[9], together with a brief description of each tool, how to access it, and dedicated user guide where available.

Overview of the main preliminary actions for preparing an application for food improvement agents

Before starting to prepare an application for a food enzyme, a food additive or a food flavouring, EFSA strongly advises applicants to check the list below concerning the preliminary actions to be considered in order to correctly prepare and submit an application.

- ✓ Consult the 'Food Improvement Agents' section on European Commission's website for information on the regulatory framework and the authorisation process for food enzymes, food additives and food flavourings: https://ec.europa.eu/food/safety/food_improvement_agents_en
- ✓ If an application for a food improvement agent is to be submitted, besides this administrative guidance, consult EFSA's scientific guidance documents on food enzymes, food additives or food flavourings for information on how to prepare the dossier supporting the application: https://www.efsa.europa.eu/en/applications/foodingredients/regulationsandguidance
- ✓ Consult EFSA's Practical Arrangements on pre-submission phase and public consultations (EFSA, 2021a) and EFSA's Practical Arrangements concerning transparency and confidentiality (EFSA, 2021b): https://www.efsa.europa.eu/en/corporate/pub/tr-practical-arrangements
- ✓ Consult the Administrative guidance for the processing of applications for regulated products (EFSA, 2021c) for the general principles and harmonised way followed to process applications for regulated products in EFSA: https://www.efsa.europa.eu/en/supporting/pub/en-6471
- ✓ In case of doubts on the requirements for an application, ask for clarification to EFSA using the webform: https://connect.efsa.europa.eu/RM/s/new-ask-efsa-request
- ✓ Notify EFSA of information related to all studies commissioned or carried out in support of the application as of 27 March 2021, using the database of study notifications established by EFSA: https://www.efsa.europa.eu/en/applications/toolkit
- ✓ Request general pre-submission advice (GPSA), if needed (optional), using the dedicated GPSA form available on EFSA's website: https://www.efsa.europa.eu/en/applications/toolkit
- ✓ For questions that EFSA cannot answer by means of GPSA, contact the European Commission: SANTE-E2-ENZYMES@ec.europa.eu; SANTE-E2-Additives@ec.europa.eu; SANTE-E2-FLAVOURINGS@ec.europa.eu
- ✓ Consult EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products (EFSA, 2021d) for an overview of the support initiatives provided by EFSA to applicants: https://www.efsa.europa.eu/en/supporting/pub/en-6472

Specific indications on how to prepare and submit the application are provided in the following sections of the guidance document.

[9] https://www.efsa.europa.eu/en/applications/toolkit

Pre-submission phase

Before submitting an application for a food improvement agent, a potential applicant should first register in EFSA's portal supporting pre-submission activities available on EFSA's website.[10] The registration is needed only if at least one of the pre-submission activities is carried out.

Upon request addressed to EFSA, potential applicants are given a reference i.e. pre-application identification 'ID' (EFSA-ID-YYYY-NNNNNN[11]), valid for a specific regulated product and a given regulated product area, to be used for any activity related to the pre-submission phase (see Sections 2.1 and 2.2), as introduced by the GFL Regulation:

- possibility to request general pre-submission advice from EFSA (optional, applicable to all types of applications);

- notification of information related to studies commissioned or carried out (mandatory, applicable to all types of applications).

The pre-application ID(s), if any, must be provided when submitting the application (see Sections 2.3 and 2.11).[12]

The sections below provide an overview to applicants of the procedure governing the pre-submission phase. They are to be read in conjunction with binding Union legal acts, in particular with the GFL Regulation and with EFSA's Practical Arrangements on pre-submission phase and public consultations[13] (EFSA, 2021a), which provide comprehensive information and instructions on that matter.

2.1. General pre-submission advice

In accordance with Article 32a(1) of the GFL Regulation, potential applicants may request general pre-submission advice (GPSA) from EFSA at any time before submitting the corresponding envisaged application with respect to both intended applications for new authorisations or modification of existing authorisations. The GPSA is optional for the potential applicant. Within the framework of GPSA, EFSA provides advice on the rules applicable to, and the content required for, an application prior to its submission.

In particular, the following items are considered outside of the scope of the GPSA:

- design of the studies to be submitted and questions related to hypotheses to be tested, unless the advice concerns guidance documents developed by EFSA in which study design is addressed;
- risk management questions;
- any aspects going beyond the information available in the legislation, rules, guidance documents or guidelines applicable to applications.

For questions outside the scope of the GPSA, applicants should contact the European Commission.

EFSA recommends submitting the request for GPSA at least six months before the envisaged submission date of the application.

Requests for general pre-submission advice must be submitted to EFSA by filling in the dedicated general pre-submission advice online form ('GPSA form') available on EFSA's website.[14]

Following an administrative check EFSA will provide its feedback on whether the submitted request is accepted or rejected within 15 working days from the receipt of the GPSA form. For accepted requests, the advice is notified to the potential applicant. A summary of the advice is drawn up and stored by

[10] https://www.efsa.europa.eu/en/applications/toolkit
[11] YYYY corresponds to the year and NNNNNN is a progressive number.
[12] In accordance with Article 5 of Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission phase and public consultations (EFSA, 2021a).
[13] See Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission phase and public consultations
[14] https://www.efsa.europa.eu/en/applications/toolkit

EFSA. It is sent to the potential applicant for information purposes. For a comprehensive description of applicable procedures and provisions, please refer to EFSA's Practical Arrangements on pre-submission phase and public consultations (EFSA, 2021a).

The summary of the advice is made public together with the non-confidential version of the application dossier, as soon as the application is declared valid. On applicable transparency and confidentiality requirements, please see Section 2.6.

2.2. Notification of studies

In accordance with Article 32b of the GFL Regulation, potential applicants commissioning or carrying out studies as of 27 March 2021 to support an application concerning a food improvement agent (new authorisation, modification of an existing authorisation) have the obligation to notify EFSA without delay of the following information[15] related to those studies:

- title and scope of the study;
- laboratory or testing facility carrying out the study;
- starting and planned completion dates of the study.

The same obligation applies to the laboratories and other testing facilities located in the EU[16] for studies commissioned by potential applicants and carried out by such laboratories and other testing facilities. Therefore, both potential applicants and laboratories/testing facilities have the obligation to notify information about all studies commissioned or carried out to support an application.

Study notifications must be submitted in the database of study notifications available on EFSA's website[17] without delay before the starting date of the study. The database will assign a unique study identification 'ID' to each study notification (i.e. study ID: EFSA-YYYY-NNNNNNNN[18]).

For any study notification submitted after the starting date of the study, the applicant must provide justifications for the delay when submitting the application.

The obligations of notification of studies apply to any additional studies provided after the submission of the application either during the suitability check or in relation to the risk assessment, or as part of a spontaneous submission of information, if such studies are commissioned or carried out as of 27 March 2021.

Applicants should be aware that non-compliance with the notifications of study obligations may result in the non-validity of the application or in delays in the risk assessment process (see Sections 2.5 and 2.8).

Studies submitted to support an application are not subject to the study notification obligations if they were commissioned or carried out before 27 March 2021.

For a comprehensive description of applicable procedures and provisions, please refer to EFSA's Practical Arrangements on pre-submission phase and public consultations (EFSA, 2021a).

[15] The full list of information to be notified for each study is provided in Annex II to Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission phase and public consultations (EFSA, 2021a).

[16] The same obligation applies to laboratories and testing facilities located in third countries insofar as set out in relevant agreements and arrangements with those third countries, including as referred to in Article 49 of the GFL Regulation.

[17] https://www.efsa.europa.eu/en/applications/toolkit

[18] YYYY corresponds to the year and NNNNNNNN is a progressive number.

From submission of the application to adoption of EFSA's scientific opinion

2.3. Submission of an application

Applicants must submit the application to the European Commission.[19] The submission of the application must be done by using the electronic tool, i.e. the **e-submission system,** accessible through European Commission's website or EFSA's website.[20]

The system allows applicants to submit and follow-up on applications through an online web interface from the start to the end of the authorisation process. Detailed instructions for accessing and using the e-submission system are provided in the dedicated user guide.[21]

A detailed description of the content of the dossier to prepare in support of the application is given in Section 2.11 of this Administrative guidance.

Regarding the study notification obligations of Article 32b(2) and (3) of the GFL Regulation, when submitting an application, the applicant must provide the following information:

- **pre-application ID(s)** related to the food improvement agent which is the subject matter of the submitted application provided to the applicant at pre-submission phase, in case pre-submission advice was requested and/or or new studies have been notified;
- **study ID** generated by EFSA's database of study notifications for each study submitted in the application;
- if necessary, **justifications** explaining the divergences between the information notified in accordance with Section 2.2 and the studies included in the application, linked, where applicable, to the study ID.

For a comprehensive description of the information to be provided when submitting applications to allow verification of compliance with study notification obligations, please refer to EFSA's Practical Arrangements on pre-submission phase and public consultations (EFSA, 2021a).

At the moment a draft application is created, the e-submission system assigns a unique reference number i.e. application 'ID' (AAA YYYY/NNNNN[22]) that persists even after submission. Once the submission is completed, the applicant receives a confirmation.

2.4. Receipt of the application by EFSA

Once an application is submitted through the e-submission system, the European Commission verifies the validity of the application. It may request EFSA to verify whether the data provided in the application are suitable for the risk assessment ('suitability check'). The applicant is notified accordingly.

At the receipt of the application by EFSA, a unique reference number is assigned to the application and communicated to the applicant. This unique number (i.e. EFSA question number: EFSA-Q-YYYY-NNNNN[23]) should be used in any communication related to the application.

The status of the application is automatically updated in the e-submission system. Each step is registered and can be monitored by the applicant.

Information on all applications received by EFSA is available to the public in the OpenEFSA portal.[24]

Applicants should note that information and documents uploaded as part of the initial submission of the dossier, later during suitability check or in the scientific evaluation process are subject to the provisions on confidentiality and proactive disclosure of the information, as detailed in Sections 2.6 and 2.7.

[19] In accordance with Article 3 of Regulation (EC) No 1331/2008.
[20] https://www.efsa.europa.eu/en/applications/toolkit
[21] https://www.efsa.europa.eu/en/applications/toolkit
[22] AAA corresponds to a three letter code of the regulatory domain, YYYY corresponds to the year the draft is created and NNNNN is a progressive number.
[23] YYYY corresponds to the year and NNNNN is a progressive number.
[24] https://open.efsa.europa.eu

2.5. Suitability check of data for risk assessment and validation of the application

During the suitability check phase, the application is handled by the EFSA Applications Desk (APDESK) Unit.

EFSA checks the suitability of the data for risk assessment in accordance with the legal requirements, including those on notification of studies[25], and the requirements set in EFSA's guidance documents on food enzymes, food additives or food flavourings.

The starting date of the suitability check is the date of receipt by EFSA of both the dossier supporting the application and the European Commission's request to perform the suitability check.

At this stage, the status of the application in the e-submission system shows that the application is acknowledged and that EFSA's suitability check has started.

EFSA endeavours to finalise the outcome of the suitability check and inform the European Commission on the suitability/non suitability of the data for risk assessment and on the compliance with study notification obligations within 30 working days[26] from the receipt date of the application.

In case certain parts of the dossier need modification or completion, in order to be considered suitable, the applicant receives a request for missing information.

The applicant should insert the response in the e-submission system within 30 days from the receipt of the request for missing information. When this is not possible, the applicant should indicate the date by which the response is expected, including an appropriate justification.

After receiving a request for missing information or clarifications and before submitting the response, the applicant can ask EFSA to organise a teleconference to clarify the questions raised.[27]

When responding to the requests, the applicant should upload an updated version of documents that were subject to completion or modification, and any missing files (e.g. studies, annexes, references) directly to the e-submission system in the corresponding sections. Applicants are reminded that the provisions on confidentiality and proactive disclosure of the information, as detailed in Sections 2.6 and 2.7, apply to all information, documents or information uploaded as part of the initial submission, or later during suitability check or in the scientific evaluation process. Therefore, should the documents include elements that are claimed to be confidential, the applicant is expected to upload a version with these elements blackened (non-confidential version, also called 'public version', see details in Section 2.6.1) and a version including the elements claimed confidential, where the confidential information is boxed or earmarked (confidential version, not for public disclosure).

Applicants should note that if new studies are submitted following a request during the suitability check, these studies are subject to the study notification obligations if commissioned or carried out as of 27 March 2021. In this case, the relevant information must be notified in EFSA's database of study notifications in accordance with EFSA's Practical Arrangements on pre-submission phase and public consultations (EFSA, 2021a).

Once the requested information is uploaded to the e-submission system, EFSA checks the content of the submission to see if it is complete and the application can be declared as suitable, or if further revision is required. EFSA endeavours to inform the European Commission within 15 working days from the upload of the missing information to the e-submission system.

Applicants are reminded that notified studies and the justifications provided to prove compliance with notification of studies obligations (see Sections 2.2) are also subject to suitability check.

[25] See Chapter IV Chapter IV on Notification of Studies of Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission phase and public consultations (EFSA, 2021a).

[26] In accordance with Article 12(2) of Commission Regulation (EU) No 234/2011, as amended by Commission Implementing Regulation (EU) 2020/1823.

[27] See Section 2.2.2 of EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products (EFSA, 2021d).

EFSA interrupts the suitability check and informs the European Commission, which declares the application as non-valid[28], if during the suitability check EFSA concludes that:

- a submitted study was not previously notified in EFSA's database of study notifications or was notified after the starting date of the study (i.e. non-notification regulated by Article 32b(4) of the GFL Regulation) and the applicant has provided no valid justification; and/or
- a study previously notified in EFSA's database was not included in the application and the applicant has provided no valid justification (i.e. non-inclusion of a study regulated by Article 32b(5) of the GFL Regulation); and/or
- a notification of a study was withdrawn and the applicant has provided no valid justification (Article 23(2)(c) of EFSA's Practical Arrangements on pre-submission phase and public consultations (EFSA, 2021a)).

The applicant may re-submit the application, provided that:

- it notifies in the database the studies that were not previously notified; and/or
- it submits all the studies which were previously notified in the database or, in case of unjustified withdrawal of a notification of a study, the data delivered by the relevant laboratory or testing facility even without the study having been completed.

To this end, the applicant should insert in the e-submission system a completely new application. When re-submitting the application, the applicant should contextually provide the unique number of the application (i.e. EFSA's question number: EFSA-Q-YYYY-NNNNN) which was previously not considered valid. The suitability check of the new application will commence six months after the re-submission of the application.

For a comprehensive description of applicable procedures and provisions, please consult EFSA's Practical Arrangements on pre-submission phase and public consultations (EFSA, 2021a).

Once the suitability check is completed and the application has been deemed as being 'suitable', the European Commission validates the application[29] and mandates EFSA to carry out the risk assessment.

At this stage, the e-submission system shows that the suitability check is concluded and the validity/non-validity is confirmed.

Upon validation, EFSA proactively discloses the non-confidential version of the dossier as provided by the applicant[30] on the OpenEFSA portal. The non-confidential version published on the OpenEFSA portal will be replaced by the one sanitised by EFSA pursuant to its confidentiality decision, in case one or more confidentiality requests submitted by the applicant are rejected by EFSA (see Section 2.6).

The starting date for the scientific risk assessment of the application and for the assessment of the confidentiality requests contained therein is the date when the European Commission receives by EFSA the notification of the suitability of the application.[31]

2.6. Transparency and confidentiality requirements

This section aims at giving an overview to applicants on the procedure implementing transparency and confidentiality requirements, in accordance with relevant provisions of the GFL Regulation and Articles 11 and 12 of Regulation (EC) No 1331/2008, as amended by the Transparency Regulation, and with EFSA's Practical Arrangements concerning transparency and confidentiality[32] (EFSA, 2021b). It is to be read in conjunction with Union law[33] and case law, as well as with EFSA's Practical Arrangements

[28] In accordance with Article 32b(4) and (5) of the GFL Regulation.
[29] In accordance with Article 12 of Commission Regulation (EU) No 234/2011, as amended by Commission Implementing Regulation (EU) 2020/1823.
[30] In accordance with Article 11 of Regulation (EC) No 1331/2008 as amended by the Transparency Regulation, and with Article 38 of the GFL Regulation.
[31] In accordance with Article 12(3) of Commission Regulation (EU) No 234/2011, as amended by Commission Implementing Regulation (EU) 2020/1823.
[32] See Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements concerning transparency and confidentiality
[33] Relevant provisions of the GFL Regulation and Articles 11 and 12 of Regulation (EC) No 1331/2008.

concerning transparency and confidentiality (EFSA, 2021b), which provide a comprehensive description of applicable procedures and provisions.

2.6.1. Transparency requirements applicable to information shared by applicants with EFSA

The GFL Regulation as amended by the Transparency Regulation introduced a general principle of proactive disclosure and transparency of information, studies and data submitted to EFSA for scientific evaluation. In light of this principle, and of the related provisions, EFSA must proactively disseminate all information submitted by applicants for the purposes of EFSA's scientific evaluation of regulated products, including the information submitted during the assessment process at EFSA's explicit request.

Specifically, EFSA is to make publicly available[34] *inter alia* the following information[35]:

- all its scientific outputs;
- scientific data, studies and other information supporting applications, including additional information requested during an assessment, as well as other scientific data and information supporting requests from the European Commission and the Member States for a scientific output;
- the information on which its scientific outputs are based;
- a summary of the advice provided to potential applicants at pre-submission phase.

By derogation from the general principle of proactive disclosure and transparency, EFSA, when required to issue an opinion, may grant confidential status to certain elements of application dossiers, provided applicants submit a verifiable justification and EFSA accepts the confidentiality request. For this purpose, and for each document for which confidentiality is requested, applicants are required to upload to the e-submission system:

- **a request to treat certain item(s) as confidential**, specifying: the confidentiality ground(s) and conditions, justification, excerpt of the text, location in the file. These requests should be inserted in the e-submission system at the time of submission of the information. Multiple requests can be submitted per file, but only with regard to specific items as indicated in the relevant Union law (see Section 2.6.3);
- **a version of the concerned document with all information visible and no blackening applied**. In this version, all information claimed to be confidential by the applicant should be boxed or earmarked (confidential version, not for public disclosure);
- **a non-confidential version with all elements claimed to be confidential blackened** (public version). This version will be made publicly available in the OpenEFSA portal as soon as the application is declared valid (as mentioned in Section 2.5). This non-confidential version provided by the applicant and made available on the OpenEFSA portal will be replaced by the one sanitised by EFSA pursuant to its confidentiality decision, in case one or more confidentiality requests are rejected. Applicants should note that the public version should have all the names and addresses of individuals involved in testing on vertebrate animals or in obtaining toxicological information blackened as these elements must not be disclosed. Furthermore, the public version should also have all the personal data the applicants consider should not be disclosed pursuant to its confidentiality requests, equally blackened. For more information, see Section 2.6.3 as well as EFSA's Practical Arrangements concerning transparency and confidentiality (EFSA, 2021b).

[34] The proactive disclosure of the above information does not imply permission or licence for their re-use, reproduction, or exploitation in breach of the relevant existing rules concerning intellectual property rights or data exclusivity. EFSA cannot be held liable or responsible for any use of the disclosed data by third parties in breach of any existing intellectual property rights.

[35] For an exhaustive list of the types of information, documents or data which is made proactively available, please refer to Articles 5 and 6 of Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements concerning transparency and confidentiality (EFSA, 2021b).

2.6.2. How to submit a confidentiality request

Applicants are required to submit confidentiality requests via the e-submission system (see also Section 2.11.3) by providing reasoning supporting each request and addressing the requirements set out in Article 10 of EFSA's Practical Arrangement concerning transparency and confidentiality (EFSA, 2021b).

It is fundamental that applicants submit all relevant confidentiality requests at the time of submission of the related piece of information (e.g. technical dossier, information submitted following a request for missing or additional information, spontaneously submitted information, etc.). After submission, applicants may not modify confidentiality requests anymore, unless requested to do so by EFSA.

If EFSA requests the applicant to provide clarifications on the information initially provided to justify a confidentiality request, and the applicant does not react by the given timeline, EFSA will reject the confidentiality request.[36]

A comprehensive description of applicable procedures and provisions is available in EFSA's Practical Arrangements concerning transparency and confidentiality (EFSA, 2021b).

2.6.3. Parts of the application or information for which a confidentiality request can be submitted

Applicants may submit confidentiality requests only regarding the following items of the application or submissions, as indicated in the relevant Union law and specified in Annex of EFSA's Practical Arrangements concerning transparency and confidentiality (EFSA, 2021b):

- information provided in detailed descriptions of starting substances and starting preparations and on how they are used to manufacture the substance subject to the authorisation, and detailed information on the nature and composition of the materials or products in which the applicant intends to use the substance subject to the authorisation, except for information which is relevant to the assessment of safety[37];
- where applicable, detailed analytical information on the variability and stability of individual production batches of the substance subject to the authorisation, except for information which is relevant to the assessment of safety[38];
- the manufacturing or production process, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety[39];
- commercial links between a producer or importer and the applicant or the authorisation holder, where applicable[40];
- commercial information revealing sourcing, market shares or business strategy of the applicant[41];
- quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety[42].

Personal data are processed in accordance with Regulation (EU) 2018/1725[43]. The following personal data must by law be made proactively available by EFSA:

[36] In accordance with Article 9(5) of Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements concerning transparency and confidentiality (EFSA, 2021b).
[37] Article 12(3)(a) of Regulation (EC) No 1331/2008.
[38] Article 12(3)(b) of Regulation (EC) No 1331/2008.
[39] Article 12(3) of Regulation (EC) No 1331/2008.
[40] Article 12(3) of Regulation (EC) No 1331/2008.
[41] Article 12(3) of Regulation (EC) No 1331/2008.
[42] Article 12(3) of Regulation (EC) No 1331/2008.
[43] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ L 295, 21.11.2018, p. 39–98.

a. the name and address of the applicant;

b. the names of authors of published or publicly available studies supporting the application;

c. the names of all participants and observers in meetings of the Scientific Committee and the Scientific Panels, their working groups and any other ad hoc group meeting on the application.

In contrast, personal data (names and addresses) of individuals involved in testing on vertebrate animals or in obtaining toxicological information are not made publicly available by EFSA.[44]

2.6.4. Processing of confidentiality requests

EFSA will assess each confidentiality request, when requested to issue an opinion, by performing an individual examination of the information claimed as being confidential by the applicant and of the relevant justification provided.

Confidentiality requests are processed by EFSA in accordance with EFSA's Practical Arrangements concerning transparency and confidentiality (EFSA, 2021b).

The notification of the confidentiality decision or the decision itself will also inform the applicant of its right to ask for a review of its confidentiality decision (confirmatory application).[45]

A comprehensive description of applicable procedures and provisions is available in EFSA's Practical Arrangements concerning transparency and confidentiality (EFSA, 2021b).

2.6.5. Possibility of commenting on, or challenging, a negative decision on a confidentiality request

Applicants have several opportunities to participate in the decision-making process regarding confidentiality requests made on their dossiers and to put forward their views and observations.

Applicants have the opportunity to comment draft decisions on their confidentiality requests and challenge the decisions, once adopted:

a. **prior to the adoption of a decision rejecting the applicant's confidentiality request in part or in full,** by being consulted on the draft decision;

b. **after the adoption of a confidentiality decision,** by making use of the possibility of submitting a confirmatory application;

c. **after the adoption of a decision on a confirmatory application,** by having the possibility of bringing an action for annulment against the decision on the confirmatory application pursuant to Article 263 of the Treaty on the Functioning of the European Union.[46]

A comprehensive description of applicable procedures and provisions is available in EFSA's Practical Arrangements concerning transparency and confidentiality (EFSA, 2021b).

2.6.6. Implementation of EFSA's confidentiality decision

EFSA implements its confidentiality decisions without delay in accordance with its Practical Arrangements concerning transparency and confidentiality (EFSA, 2021b).

2.6.7. Implications of the award of confidential status to certain information

Information for which EFSA's decision on confidentiality is still pending or to which confidential status has been granted will not be made public. EFSA makes such information available to the European Commission and the Member States.

[44] Article 39(e)(2) of the GFL Regulation.
[45] In accordance with Article 39b(2) of the GFL Regulation.
[46] Consolidated version of the Treaty on the Functioning of the European Union. OJ C 326, 26.10.2012, p. 47–390.

All professionals having access to information for which EFSA's decision on confidentiality is still pending or to which confidential status has been granted are subject to the obligation of professional secrecy and bound to not disclose information to which confidential status has been granted. These obligations continue to apply even after their duties have ceased.

2.6.8. Proactive disclosure of information contained in the application

During the life-cycle of the application, EFSA will proactively disclose information contained in the application dossier. Specifically:

- The non-confidential version of the dossier is published once the application has been considered valid;
- If confidentiality requests are rejected, an updated non-confidential version of the dossier is published upon implementation of EFSA's confidentiality decision;
- Non-confidential version of information provided at EFSA's request for additional information, or as a result of spontaneous submission by the applicant, is published as soon as received;
- If confidentiality requests presented on the additional information are rejected, an updated non-confidential version of the information is published after implementation of EFSA's confidentiality decision, once EFSA's scientific opinion is adopted.

2.7. Public consultation on information contained in the application

In accordance with Article 32c(2) of the GFL Regulation, in order to ensure that EFSA can have access to all relevant scientific data and studies available on the food improvement agent subject to the application, EFSA consults stakeholders and the public ('consultation of third parties') on the scientific data, studies and other information part of, or supporting, the submitted application to identify whether other relevant scientific data or studies are available.

Following the implementation of EFSA's confidentiality decision and upon publication by EFSA of the non-confidential version of the application dossier (see Section 2.6), EFSA launches a public consultation on its website.

The consultation of third parties remains open for a period of 3 calendar weeks. All comments received from third parties will be made public by EFSA upon the closure of the consultation of third parties. Relevant comments will be considered during the risk assessment phase. EFSA's scientific opinion will address the relevant comments received from the third parties.[47]

For a comprehensive description of applicable procedures and provisions, please refer to EFSA's Practical Arrangements on pre-submission phase and public consultations (EFSA, 2021a).

2.8. Risk assessment, adoption and publication of EFSA's scientific opinion

After validation of the application, EFSA performs the risk assessment of the application according to EFSA's standard procedures, which are published on EFSA's website.[48] At this stage, the status of the application in the e-submission system shows that the application is valid and that EFSA's risk assessment is ongoing.

During this phase, the application is handled by the EFSA Food Ingredients and Packaging (FIP) Unit.

The timeline to finalise the assessment of an application for food improvement agents by EFSA is nine months from the date when the application is considered valid (see Section 2.5).[49]

[47] The public disclosure of the results of the public consultation, as well as of the comments received, is done pursuant to Article 6(1), letter (d) and Article 5(2) letter (g) of Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements concerning transparency and confidentiality (EFSA, 2021b), respectively.

[48] https://www.efsa.europa.eu/en/corporate/pub/sops

[49] In accordance with Article 5(1) of Regulation (EC) No 1331/2008.

EFSA may extend the timeline to conclude the assessment for a maximum of seven weeks in case the results of the public consultation cannot be given proper consideration within the regulatory time limit allotted for delivering the opinion.[50]

During the risk assessment phase, EFSA may request the applicant to submit additional information.[51] In that case, the time limit to deliver an opinion by EFSA is extended accordingly and the scientific risk assessment process is put on hold ('stop-the-clock' procedure).

The request for additional information is inserted in the e-submission system and the applicant is notified of the request. At this stage, the status of the application in the e-submission system shows that the application is on hold and that additional information is requested.

The deadline for providing the additional information is specified by EFSA in the request.[52] This deadline may be extended at the request of the applicant. In that case, the applicant should contact EFSA requesting an extension of the deadline. In doing so, the applicant should provide detailed justification as to why an extension of the deadline to submit the additional information is needed. The justification should be accompanied by a detailed planning, which should be in any case proportional to the amount and type of information requested. EFSA will decide on the acceptability of the extension request on the basis of the justification given by the applicant and of the nature of the requested data.

After receiving a request for additional information or clarifications by EFSA and before submitting the response, the applicant can ask EFSA to organise a teleconference to clarify the questions raised by EFSA.[53]

When responding to EFSA's questions, the applicant should upload the additional information through the e-submission system.[54] Should the documents include elements that are claimed to be confidential pursuant to Section 2.6, the applicant is expected to upload a version with these elements blackened (non-confidential version, also called 'public version', see details in Section 2.6.1) and a version including also elements claimed confidential where the confidential information is boxed or earmarked (confidential version, not for public disclosure). In fact, additional information or data provided during the risk assessment phase are subject to the provisions on confidentiality and proactive disclosure of the information, as detailed in Sections 2.6 and 2.7.

Applicants should also note that if new studies are submitted following a request for additional information during the risk assessment, these studies are subject to the study notification obligations if commissioned or carried out as of 27 March 2021 (see Sections 2.2 and 2.3). In this case, the relevant information must be notified in EFSA's database of study notifications in accordance with EFSA's Practical Arrangements on pre-submission phase and public consultations (EFSA, 2021a).

In case the applicant does not provide the requested additional information or responds by providing inadequate information, EFSA will not reiterate already formulated requests nor will ask for the same information a second time. In this case, EFSA completes the risk assessment with the available information.[55]

After receipt of the additional information or clarifications, the scientific risk assessment is restarted ('re-start the clock' procedure[56]) and the status of the application in the e-submission system is updated accordingly.

[50] In accordance with Article 32c(2) of the GFL Regulation.
[51] In accordance with Article 6 of Regulation (EC) No 1331/2008.
[52] In line with the 'Indicative timelines for submitting additional or supplementary information to EFSA during the risk assessment process of regulated products' included in EFSA's Administrative guidance for the processing of applications for regulated products (EFSA, 2021c).
[53] See Section 2.3.1 of EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products (EFSA, 2021d).
[54] In case EFSA considers the submission incomplete, the applicant is asked to provide clarifications and the clock remains on hold.
[55] In accordance with Article 6 of Regulation (EC) No 1331/2008.
[56] See Section 2.12 of EFSA's Administrative guidance for the processing of applications for regulated products (EFSA, 2021c) for details.

In case EFSA needs further clarifications on an application or on the submitted additional information, EFSA may decide to invite the applicant for an applicant's hearing.[57] In such case, the applicant is invited to attend the corresponding agenda item of EFSA's working group or Panel meeting to answer questions and to clarify outstanding issues about the submitted information.

Applicants are reminded of the specific obligations of notification of studies commissioned or carried out to support the application (see Sections 2.2 and 2.3).[58] If, following a more extensive verification of the data submitted by the applicant, it is detected that the studies previously notified in accordance with Article 32b(2) and (3) of the GFL Regulation are not included in full in the submitted application, EFSA requests the applicant to provide justifications regarding any missing data.

The applicant is informed that the time limit within which EFSA is required to deliver its scientific opinion is suspended, pending the provision of valid justifications for the absence of certain data of studies previously notified. EFSA assesses the justifications provided by the applicant.

If the justifications are considered valid, the risk assessment process re-starts and the applicant is informed accordingly.

If the justifications provided by the applicant are not considered valid, the applicant is requested to submit the missing data of the notified study/ies. The applicant is also informed that the risk assessment process will remain suspended for six months after the submission of any missing data relating to any supporting studies.[59]

For details on implications and duration of the suspension, please consult EFSA's Practical Arrangements on pre-submission phase and public consultations (EFSA, 2021a).

The draft scientific opinion is presented to the EFSA CEP Panel (in case of food enzyme applications) or to the EFSA FAF Panel (in case of food additive or food flavouring applications), for adoption at a plenary meeting. In case of adoption, the applicant is notified.[60]

Following the adoption of the scientific opinion by the Panel, the process of publication starts, and the scientific opinion is checked for editorial review. The applicant is pre-notified[61] at least 36 hours prior to publication. The scientific opinion is then published[62] in the EFSA Journal,[63] implementing the decision of EFSA on the confidentiality (see Section 2.6), as outlined in EFSA's Practical Arrangements concerning transparency and confidentiality (EFSA, 2021b).

Should the opinion identify foreseeable effects regarding public health, animal health or the environment, and should these effects regard items that were granted confidential status pursuant to EFSA's Practical Arrangements above, EFSA will have to review its initial confidentiality decision in accordance with Article 39c of the GFL Regulation.

When the opinion is published, the status of the application in the e-submission system shows that the risk assessment is finalised.

2.9. Spontaneous submission of information during the life-cycle of an application

The applicant is expected to submit a complete application, including all relevant information available at the time of submission of an application. The spontaneous submission of information by an applicant on its own initiative and without a formal request for information by EFSA is possible but limited to:

- newly produced data; and/or

[57] See Section 2.3.3 of EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products (EFSA, 2021d).
[58] In accordance with Article 32b(2) and (3) of the GFL Regulation.
[59] In accordance with Article 32b(6) of the GFL Regulation.
[60] See Section 2.3.4 of EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products (EFSA, 2021d).
[61] See Section 2.3.5 of EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products (EFSA, 2021d).
[62] https://www.efsa.europa.eu/en/corporate/pub/sops
[63] EFSA Journal: https://www.efsa.europa.eu/en/publications

- information which was not available to the applicant at the time of the submission of the application; and/or
- information not previously requested by EFSA.

Spontaneous information[64] should be submitted as early as possible during the risk assessment process, and the applicant should explain how it may influence the risk assessment.

The spontaneous information should be provided through the e-submission system exclusively following preliminary contact with the relevant EFSA unit[65] which will indicate the path to submit the spontaneous information.

The provisions on notification of studies (see Sections 2.2 and 2.3), as well as the provisions on confidentiality and proactive disclosure of the information, as detailed in Sections 2.6 and 2.7, apply to spontaneous submission of information.[66]

2.10. Withdrawal of an application

An applicant can withdraw its application at any time.[67] The request for withdrawal should be inserted directly in the e-submission system following the instruction provided in the e-submission system user guide.[68]

Once the intention to withdraw the application is confirmed in the e-submission system, all aspects related to the application process stop (e.g. risk assessment, assessment of confidentiality).

When an applicant withdraws its application prior to the adoption of a confidentiality decision (see Section 2.6 and EFSA, 2021b), EFSA, the European Commission and the Member States must not make public the information for which the confidential status had been requested.

In case an applicant withdraws its application after the adoption of a confidentiality decision, all actors having access to the relevant information must comply with the confidentiality decision.

For the effects of the withdrawal on information made publicly available on the OpenEFSA portal, please refer to EFSA's Practical Arrangements concerning transparency and confidentiality (EFSA, 2021b), which give a comprehensive overview of the applicable procedure.

The withdrawal of an application after the adoption of a scientific opinion has no effect on the adopted output, which will be in any case published, and remain published, on the EFSA Journal.

2.11. Preparation of the dossier

2.11.1. Language

In submitting an application under this guidance, please note that EFSA operates in accordance with its Decision on the Linguistic Regime[69], which recognises English as its working language. In order to facilitate the evaluation of the applications, scientific and technical documentation should be submitted in English. EFSA may ask the applicant to translate the parts of the dossier that would not be submitted in English.

2.11.2. Structure of the dossier

When entering the e-submission system, the respective regulated product area (i.e. Food Improvement Agents), authorisation list (e.g. Food additives, Food enzymes or Food flavourings) and type of application should be selected:

- Application for the authorisation of a new food additive/food enzyme/food flavouring

[64] See Section 2.13 of EFSA's Administrative guidance for the processing of applications for regulated products (EFSA, 2021c).
[65] During suitability check phase until validation, applicants should refer to the APDESK unit (see Section 2.5); during the risk assessment phase, applicants should contact the Food Ingredients and Packaging unit (see Section 2.8).
[66] Spontaneous submissions are proactively disseminated to the extent they are accepted by EFSA for use in the risk assessment.
[67] See Section 2.16 of EFSA's Administrative guidance for the processing of applications for regulated products (EFSA, 2021c).
[68] https://www.efsa.europa.eu/en/applications/toolkit
[69] See Decision of the Executive Director on the Linguistic Regime of EFSA, 20 April 2015, REF. EFSA/LRA/DEC/14046420/2015

- Application for a modification of an already authorised food additive/food enzyme/food flavouring

The e-submission system has a pre-filled table of content depending on the type of submission. The information required by the system for submitting a food enzyme, a food additive or a food flavouring application is detailed below:

- **Administrative data**
- **Public summary**
- **Technical dossier,** with the full information. Any information claimed to be confidential should be boxed or earmarked.

When applicable, applicants must also provide:

- A **non-confidential (i.e. public) version of documents** (with the elements claimed to be confidential blackened), for any document for which a confidentiality request is presented in accordance with Section 2.6.

2.11.2.1. Administrative data

The following information should be provided via the e-submission system:

- Applicant's contact details (name of applicant/company, email, phone, website, address, post-code, country);
- Person responsible for the dossier contact details (name of contact person/person responsible, name of entity, email, phone, website, address, post-code, country);
- Manufacturer's contact details (name of entity, email, address, post-code, phone, country, website);
- Subject of the request (name of the enzyme, additive or flavouring);
- Scope of the application (in case of applications for modification of the terms of the authorisation of a food improvement agent or for authorisation of a new food flavouring);
- Existing authorisations in non-EU countries (country, status, reference of the authorisation);
- Product falling within the scope of Regulation (EC) No 1829/2003 on genetically modified food and feed;
- Information on data sharing agreement in place, if any;
- Cover Letter, specifying the content of the submission.[70]

2.11.2.2. Public summary of the dossier

A short summary of the dossier must be provided.[71] This document will be made available to the public through the OpenEFSA portal once the application is considered valid. It should not contain any confidential information.

2.11.2.3. Technical dossier

The technical dossier included in an application for a food enzyme, food additive or food flavouring must comply with the applicable legal requirements of Commission Regulation (EU) No 234/2011 and the specific requirements of:

[70] According to Annex of Commission Regulation (EU) No 234/2011, as amended by Commission Implementing Regulation (EU) 2020/1823.
[71] In accordance with the requirements of Article 2(6) of Regulation (EU) No 234/2011, as amended by Commission Regulation (EU) 2020/1823.

- Regulation (EC) No 1332/2008[72] for food enzymes;
- Regulation (EC) No 1333/2008[73] for food additives;
- Regulation (EC) No 1334/2008[74] for food flavourings.

The technical dossier should also be compiled according to relevant EFSA's scientific guidance documents[75] and according to the format illustrated in this guidance document. As detailed in Sections 2.5 and 2.6, the technical dossier will also be made available to the public through the OpenEFSA portal except for information that will be claimed, and acknowledged by EFSA, as confidential.

The technical dossier should include detailed reports of all studies done and all the raw data of those experimental studies in a workable electronic format. Prior to submission of the application, applicants are advised to verify that all studies included in the technical dossier have been notified to EFSA by all parties involved as required by the GFL Regulation (see Sections 2.2 and 2.3).[76]

Applicants should summarise the principal information in a one stand-alone PDF document for each section as required by the e-submission system (see tables below).

Detailed reports of all studies performed in support of the application, e.g. full documentation of experiments, full description of analytical methods, raw data and bibliographic references should be provided as separate technical annexes and uploaded in the corresponding section (see Tables 1, 2 and 3).

A single file should be produced for each annex. When referring to a specific annex in the main text, a unique number should be used (e.g. Annex 2).

References and copies of all published scientific data relevant to the evaluation of the dossier should be included.

The applicant must ensure that terms and conditions asserted by any rightsholder of studies, information or data submitted to EFSA are fully satisfied. The applicant may consult with copyright licensing authorities (i.e. at national level) for guidance on purchasing the appropriate licenses to provide studies, information or data to EFSA, taking into account the proactive disclosure requirements as detailed above. For publications already available to the public upon payment of fees (e.g. studies published in scientific journals) for which the applicant does not have or cannot obtain intellectual property rights for the purposes of the proactive public disclosure requirements, the applicant must provide (a) a copy of the relevant publications along with the relevant bibliographic references/citations for scientific assessment purposes only, in the confidential version of its application and (b) these relevant bibliographic references/citations where these publications are available to the public in the non-confidential version of its application for public dissemination on the OpenEFSA portal.

Other documents which provide background information but have no direct relationship with the dossier and can help the Panel members to assess the safety of the food enzyme, food additive or food flavouring may be included in the appropriate sections.

All information requested to be treated as confidential should be boxed or earmarked in the main text of the sections and in the annexes of the technical dossier, as well as in all documents or information uploaded later during suitability check or in the risk assessment process. This information should appear blackened in the non-confidential version of the documents. To this end, a redaction software tool that blackens the relevant text and fully removes the underlying information from the document should be used.

[72] Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97. OJ L 354, 31.12.2008, p. 7–15.

[73] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008, p. 16–33.

[74] Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC. OJ L 354, 31.12.2008, p. 34–50.

[75] https://www.efsa.europa.eu/en/applications/foodingredients/regulationsandguidance

[76] In accordance with Article 32b of the GFL Regulation.

The information required in the technical dossier and the recommended format for food enzyme, food additive or food flavouring applications are presented below in Table 1, Table 2 and Table 3, respectively.

Applicants should note that the information provided under 'Risk management' section is not assessed by EFSA. This section is part of the information to be provided in the e-submission system and thus, it is included in the tables below for completeness. The information in this section is only for EC use, and should be provided following the indications of the EC guidance document on food enzyme, food additive or food flavouring applications[77] and according to Commission Regulation (EU) No 234/2011.[78]

Table 1: Information required in the technical dossier and recommended format for food enzyme applications

CONTENT OF THE TECHNICAL DOSSIER	INFORMATION TO BE PROVIDED	EXPECTED ACTION	FORMAT
Pre-application information	Pre-application ID(s)	Insert all relevant pre-application ID(s) received by EFSA in the pre-submission phase for the food enzyme which is the subject matter of the application.	Free text
	Information on studies that have been notified in EFSA's database of study notifications, but not submitted in the application	Insert study ID generated by EFSA's database of study notifications for each study notified, and justification for non-inclusion in the application, if relevant.	Free text
Detailed summary	Detailed summary of the dossier in accordance with Commission Regulation (EU) No 234/2011, as amended by Commission Regulation (EU) 2020/1823	Upload a file containing the main text of the section.	PDF
Identity, characterisation and specifications of the enzyme(s)	Characterisation of the food enzyme	Select the substance/organism from the list or insert manually the information on the substance and its identifiers.	Search box\drop-down list\free text\checkbox
	Identity and specifications of the food enzyme	Upload a file containing the main text of the section.	PDF
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
Risk assessment	Source of the food enzyme	Upload a file containing the main text of the section.	PDF
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
	Manufacturing process of the food enzyme	Upload a file containing the main text of the section.	PDF

[77] https://ec.europa.eu/food/safety/food_improvement_agents/common_auth_proc_guid_en
[78] See Articles 7, 9 and 11 of Commission Regulation (EU) No 234/2011.

CONTENT OF THE TECHNICAL DOSSIER	INFORMATION TO BE PROVIDED	EXPECTED ACTION	FORMAT
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
	Chemical composition, properties and purity of the food enzyme	Upload a file containing the main text of the section.	PDF
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
	Methods of Analysis	Upload a file containing the main text of the section.	PDF
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
	Toxicological data	Upload a PDF document for each of the following information: – Genotoxicity – Subchronic toxicity – Other studies If relevant, upload a justification for not providing toxicological testing.	PDF
		In each subsection, upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
	Allergenicity	Upload a file containing the main text of the section.	PDF
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
	Documentation on the procedure followed when gathering literature data	Upload a file containing the main text of the section.	PDF
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
	Reaction and fate in foods to which the food enzyme is added	Upload a file containing the main text of the section.	PDF

CONTENT OF THE TECHNICAL DOSSIER	INFORMATION TO BE PROVIDED	EXPECTED ACTION	FORMAT
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
	Intended use(s) in food and use level(s) (Proposed normal and maximum use levels)	Upload a file containing the main text of the section.	PDF
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
	Dietary exposure assessment	Upload a file containing the main text of the section.	PDF
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
	Overall conclusion on the safety of the food enzyme	Upload a file containing the main text of the section.	PDF
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
Risk management (for EC use)	Information required by EC, as detailed in the EC guidance	See EC guidance	See EC guidance
List of annexes, references and checklist	List of annexes, list of references and checklist	Upload a list of all annexes submitted in support of the application, following the indications given below (see 'List of annexes').	PDF
		Upload a list of all references (published studies) submitted in support of the application, following the indications given below (see 'List of references').	PDF
		Upload checklist	See EC guidance

Table 2: Information required in the technical dossier and recommended format for food additives applications

CONTENT OF THE TECHNICAL DOSSIER	INFORMATION TO BE PROVIDED	EXPECTED ACTION	FORMAT
Pre-application information	Pre-application ID(s)	Insert all relevant pre-application ID(s) received by EFSA in the pre-submission phase for the food additive which is the subject matter of the application.	Free text
	Information on studies that have been notified in EFSA's database of study notifications, but not submitted in the application	Insert study ID generated by EFSA's database of study notifications for each study notified, and justification for non-inclusion in the application, if relevant.	Free text
Detailed summary	Detailed summary of the dossier in accordance with Commission Regulation (EU) No 234/2011, as amended by Commission Regulation (EU) 2020/1823	Upload a file containing the main text of the section.	PDF
Identity, characterisation and specifications of the additive(s)	Characterisation of the food additive	Select the substance/organism from the list or insert manually the information on the substance and its identifiers.	Search box\drop-down list\free text\checkbox
	Identity and specifications of the food additive	Upload a file containing the main text of the section.	PDF
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
Risk assessment	Proposed specification and methods of determination (including impurities and particle size)	Upload a file containing the main text of the section.	PDF
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
	Source material and manufacturing process	Upload a file containing the main text of the section.	PDF
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
	Methods of analysis in food	Upload a file containing the main text of the section.	PDF

CONTENT OF THE TECHNICAL DOSSIER	INFORMATION TO BE PROVIDED	EXPECTED ACTION	FORMAT
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
	Stability of the substance, reaction and fate in foods to which the additive is added	Upload a file containing the main text of the section.	PDF
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
	Use in food and use levels (Proposed normal and maximum use levels)	Upload a file containing the main text of the section.	PDF
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
	Dietary exposure assessment	Upload a file containing the main text of the section.	PDF
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
	Safety evaluation strategy and corresponding testing strategy	Upload a file containing the main text of the section.	PDF
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
	Biological and toxicological data	Upload a PDF document for each of the following information: – Toxicokinetic/Absorption, Distribution, Metabolism, Excretion – Genotoxicity – Subchronic toxicity – Chronic toxicity/Carcinogenicity – Reproductive and developmental toxicity – Other studies	PDF

CONTENT OF THE TECHNICAL DOSSIER	INFORMATION TO BE PROVIDED	EXPECTED ACTION	FORMAT
		In each subsection, upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
	Documentation on the procedure followed when gathering literature data	Upload a file containing the main text of the section.	PDF
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
	Overall conclusion on the safety of the proposed uses	Upload a file containing the main text of the section.	PDF
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
Risk management (for EC use)	Information required by EC, as detailed in the EC guidance	See EC guidance	See EC guidance
List of annexes, references and checklist	List of annexes, list of references and checklist	Upload a list of all annexes submitted in support of the application, following the indications given below (see 'List of annexes').	PDF
		Upload a list of all references (published studies) submitted in support of the application, following the indications given below (see 'List of references').	PDF
		Upload checklist	See EC guidance

Table 3: Information required in the technical dossier and recommended format for food flavouring applications

CONTENT OF THE TECHNICAL DOSSIER	INFORMATION TO BE PROVIDED	EXPECTED ACTION	FORMAT
Pre-application information	Pre-application ID(s)	Insert all relevant pre-application ID(s) received by EFSA in the pre-submission phase for the food flavouring which is the subject matter of the application.	Free text
	Information on studies that have been notified in EFSA's database of study notifications, but not submitted in the application	Insert study ID generated by EFSA's database of study notifications for each study notified, and justification for non-inclusion in the application, if relevant.	Free text
Detailed summary	Detailed summary of the dossier in accordance with Commission Regulation (EU) No 234/2011, as amended by Commission Regulation (EU) 2020/1823	Upload a file containing the main text of the section.	PDF
Identity, characterisation and specifications of the flavouring(s)	Characterisation of the food flavouring	Select the substance/organism from the list or insert manually the information on the substance and its identifiers.	Search box\drop-down list\free text\check box
	Identity and specifications of the food flavouring	Upload a file containing the main text of the section.	PDF
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
Risk assessment	Proposed specification and methods of determination (including impurities and particle size)	Upload a file containing the main text of the section.	PDF
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
	Source material and manufacturing process	Upload a file containing the main text of the section.	PDF
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
	Methods of analysis in food	Upload a file containing the main text of the section.	PDF
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
	Stability, decomposition products and interaction with food components	Upload a file containing the main text of the section.	PDF

CONTENT OF THE TECHNICAL DOSSIER	INFORMATION TO BE PROVIDED	EXPECTED ACTION	FORMAT
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
	Use in food and use levels (Proposed normal and maximum use levels)	Upload a file containing the main text of the section.	PDF
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
	Data on dietary and non-dietary sources	Upload a file containing the main text of the section.	PDF
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
	Dietary exposure assessment	Upload a file containing the main text of the section.	PDF
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
	Structural/metabolic similarity to flavouring substances present in existing flavouring group evaluations (FGEs)	Upload a file containing the main text of the section.	PDF
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
	Safety evaluation strategy and corresponding testing strategy	Upload a file containing the main text of the section.	PDF
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
	Biological and toxicological data	Upload a PDF document for each of the following information: – Toxicokinetic/Absorption, Distribution, Metabolism, Excretion – Genotoxicity – Subchronic toxicity – Reproductive and developmental toxicity – Chronic toxicity/Carcinogenicity – Other studies	PDF

CONTENT OF THE TECHNICAL DOSSIER	INFORMATION TO BE PROVIDED	EXPECTED ACTION	FORMAT
		In each subsection, Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
	Documentation on the procedure followed when gathering literature data	Upload a file containing the main text of the section.	PDF
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
	Overall conclusion on the safety of the proposed uses	Upload a file containing the main text of the section.	PDF
		Upload any related supporting information, study reports, certificates of analysis for each analysis performed, raw data, published studies, etc. as annexes.	PDF or Excel, one file for each annex
Risk management (for EC use)	Information required by EC, as detailed in the EC guidance	See EC guidance	See EC guidance
List of annexes, references and checklist	List of annexes, list of references and checklist	Upload a list of all annexes submitted in support of the application, following the indications given below (see 'List of annexes').	PDF
		Upload a list of all references (published studies) submitted in support of the application, following the indications given below (see 'List of references').	PDF
		Upload checklist	See EC guidance

Note on the preparation of the technical dossier for the modification of an existing authorisation of a food enzyme, a food additive or a food flavouring[79]

The applicant can apply to add, remove or change the conditions of use or the specifications of an existing food enzyme, food additive or food flavouring. [80]

In the preparation of the technical dossier the applicant should evaluate which information and relevant data need to be provided in order to support that the proposed modifications do not impact in the safety of the authorised food enzyme, food additive or food flavouring. It may not be necessary to provide all the data, where the applicant provides verifiable justification explaining that the proposed changes do not affect the results of the existing risk assessment.

The information provided in the application should support the request of changes following the requirements established in the applicable legislation and those defined in the relevant EFSA's guidance documents on food enzymes, food additives or food flavourings.[81]

[79] i.e. for adding, removing or changing conditions, specifications or restrictions associated with the presence of the substance on the Community list.
[80] In accordance with Article 2(4) of Commission Regulation (EU) 234/2011.
[81] https://www.efsa.europa.eu/en/applications/foodingredients/regulationsandguidance

List of annexes

A list of all the unpublished studies and documents submitted in support of the application should be uploaded under the section 'List of annexes, references and checklist' in the e-submission system.

All documents listed should be identified using a unique number (e.g. Annex 2). The corresponding file name should contain the number and a short description of the content (e.g. Annex 2_Effect on xx.pdf). Reference in the dossier to a specific document should be done using this unique number.

Every submission (i.e. submission of the dossier, information submitted following request for missing or additional information) should include an updated version of the List of annexes.

List of references

A list of all the published studies submitted in support of the application should be provided as an annex, and uploaded under the section 'List of annexes, references and checklist' in the e-submission system. Applicants are advised to list the references by section. The following standard format is recommended when listing the bibliographical references:

Authors [add names in the format: Surname followed by Initial(s), Surname followed by Initial(s) and Surname followed by Initial(s)], Year of publication. Title. Periodical Title, Volume(Issue), pp-pp.

See for example:

Alderman G and Stranks MH, 1967. The iodine content of bulk herd milk in summer in relation to estimated dietary iodine intake of cows. Journal of the Science of Food and Agriculture, 18(4), 151–153.

Every submission (i.e. submission of the dossier, information submitted following request for missing or additional information) should include an updated version of the List of references.

2.11.3. Metadata

For every file uploaded to the e-submission system, the applicant needs to fill in and/or define a set of metadata, i.e. additional information linked to that file:

- Document type: (e.g. main text, study report, raw data, certificate of analysis, etc.). The applicant should define the document type from a given list;
- If the file uploaded is an unpublished study report (hence: document type= 'Study report') then an additional set of metadata needs to be filled in (e.g. authors, study type, completion date, study ID generated by EFSA's database of study notifications, or justification if not previously notified in the database, or justification for any deviations from the study notification obligations, etc.).

Applicants may also insert confidentiality requests for certain elements included in the uploaded files (see Section 2.6.3 for the elements for which confidentiality can be requested) and define the different elements of their request: the confidentiality ground(s) and conditions (to select from given lists), justification, excerpt of the text, location in the file (free-text fields). Multiple confidentiality requests may be submitted per file.

Technical aspects on how the different metadata can be viewed/inserted, are described in the e-submission system user guide.[82]

2.11.4. File format and naming

It is mandatory that each document, including annexes (i.e. study reports, raw data, published studies and any other document in the technical dossier) be electronically **searchable** and accessible to allow downloading and printing of the file. This applies to **all documents or information** uploaded as part of the initial submission, or later during suitability check or in the risk assessment process.[83]

[82] https://www.efsa.europa.eu/en/applications/toolkit

[83] In accordance with Article 3 of Commission Regulation (EU) No 234/2011, as amended by Commission Regulation (EU) 2020/1823.

The recommended format for the majority of the electronic files is portable document format (PDF).

Submission of datasets (e.g. raw data) should be done using other appropriate common electronic formats (preferably Excel).

The electronic files should not include any security settings that may interfere with the process of assessment by the reviewers. For instance, if a document is protected with a password, this should be provided.

File names should not include special characters, such as: \ / : * ? \" < > | #.

2.11.5. Page numbering

All pages in the documents submitted as part of the technical dossier should be numbered, with progressive numbers. Numeration should restart at the beginning of each document.

2.11.6. Tables and figures

Applicants are encouraged, where possible, to present information in tabular form. Tables and figures should be inserted in their intended positions in the text where feasible and should be numbered with a unique identification number across the dossier. It is recommended to upload to the e-submission system also the respective Excel files containing data presented in tabular form.

It is better not to construct a table covering several pages. When this cannot be avoided, the header row should be repeated at the top of each page.

2.11.7. Standard units, terms and abbreviations

The International System of Units (SI)[84] should be used in reporting tests and studies. Other units may be used between parentheses if considered relevant.

Standard technical terms and abbreviations should be used. Acronyms and abbreviations should be defined when first mentioned. In addition, when acronyms and abbreviations are used in a document, a list of such acronyms/abbreviations should be included in the document uploaded through the e-submission system.

[84] https://www.bipm.org/en/publications/si-brochure/

3. Interaction with EFSA staff during the life-cycle of the application

EFSA has implemented several initiatives to support applicants in understanding the evaluation process of applications for regulated products and to engage with them during all phases of the life-cycle of applications (i.e. pre-submission phase, preparation and submission of the application, suitability check, risk assessment and adoption of EFSA's scientific opinion, post-adoption phase).

For the different possibilities of interaction with EFSA in the different phases of the application life-cycle, please consult EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products (EFSA, 2021d).

The Catalogue also describes the dedicated support EFSA offers to small and medium-sized enterprises (SMEs).

References

EFSA (European Food Safety Authority), 2014. Administrative Guidance to applicants on the suitability check of applications for authorisation of food enzymes submitted under Regulation (EC) No 1332/2008. *EFSA supporting publication* 2014:EN-638. 17 pp. doi:10.2903/sp.efsa.2014.EN- 638

EFSA (European Food Safety Authority), 2021a. Decision of the Executive Director of the European Food Safety Authority laying down the Practical Arrangements on pre-submission phase and public consultations. Available online: https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf

EFSA (European Food Safety Authority), 2021b. Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements concerning transparency and confidentiality. Available online: https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-transparency-and-confidentiality.pdf

EFSA (European Food Safety Authority), 2021c. Administrative guidance for the processing of applications for regulated products. *EFSA supporting publication* 2021:EN- 6471. doi:10.2903/sp.efsa.2021.EN- 6471

EFSA (European Food Safety Authority), 2021d. EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products. *EFSA supporting publication* 2021:EN-6472. doi:10.2903/sp.efsa.2021.EN-6472

EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), 2012. Guidance for submission for food additive evaluations. *EFSA Journal* 2012;10(7):2760. [60 pp.] doi:10.2903/j.efsa.2012.2760, updated in 2021

The previous version of this output (EFSA ANS Panel, 2012) is available online under 'Supporting Information' section at: https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2012.2760

EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2009. Guidance of EFSA prepared by the Scientific Panel of Food Contact Material, Enzymes, Flavourings and Processing Aids on the Submission of a Dossier on Food Enzymes. *The EFSA Journal* (2009) 1305, 1–26. doi:10.2903/j.efsa.2009.1305, updated in 2021

The previous version of this output (EFSA CEF Panel, 2009) is available online under 'Supporting Information' section at: https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2009.1305

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids, 2010. Draft Guidance on the data required for the risk assessment of flavourings. *EFSA Journal* 2010; 8(6):1623. [38pp.]. doi:10.2093/j.efsa.2010.1623, updated in 2021

The previous version of this output (EFSA CEF Panel, 2010) is available online under 'Supporting Information' section at: https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2010.1623

Useful links

- Applicant toolkit:
  https://www.efsa.europa.eu/en/applications/toolkit
- EFSA's Practical Arrangements:
  https://www.efsa.europa.eu/en/corporate/pub/tr-practical-arrangements
- EFSA Journal:
  https://www.efsa.europa.eu/en/publications
- Minutes of EFSA Food ingredients and packaging Working groups and composition of the Working groups:
  https://www.efsa.europa.eu/en/food-ingredients-and-packaging/working-groups
- Minutes of EFSA CEP Panel plenary meetings and composition of the CEP Panel:
  https://www.efsa.europa.eu/en/panels/cep
- Minutes of EFSA FAF Panel plenary meetings and composition of the FAF Panel:
  https://www.efsa.europa.eu/en/panels/faf
- APDESK section on food improvement agent applications:
  https://www.efsa.europa.eu/en/applications/food-improvement-agents
- Overview of regulations and guidance documents for food improvement agent applications:
  https://www.efsa.europa.eu/en/applications/food-improvement-agents/regulationsandguidance
- Frequently Asked Questions:
  https://connect.efsa.europa.eu/RM/s/faq
- Ask a question webform:
  https://connect.efsa.europa.eu/RM/s/new-ask-efsa-request
- Food enzymes topic:
  https://www.efsa.europa.eu/en/topics/topic/food-enzymes
- Food additives topic:
  https://www.efsa.europa.eu/en/topics/topic/food-additives
- Food flavourings topic:
  https://www.efsa.europa.eu/en/topics/topic/flavourings
- European Commission's website on food improvement agents:
  https://ec.europa.eu/food/safety/food_improvement_agents_en
- OpenEFSA portal:
  https://open.efsa.europa.eu

Abbreviations

ANS	Panel on Food Additives and Nutrient Sources added to Food (now replaced by the FAF Panel)
APDESK	Applications Desk
CEF	Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (now replaced by the CEP Panel)
CEP	Panel on Food Contact Materials, Enzymes and Processing Aids
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
FAF	Panel on Food Additives and Flavourings
FGE	Flavouring Group Evaluation
FIP	Food Ingredients and Packaging Unit
GFL	General Food Law
GPSA	General pre-submission advice
PDF	Portable Document Format
SI	International System of Units
SME	Small and Medium-sized Enterprise