**Version 15**

**Updated on 7 July 2023**

**Practical guidance for applicants on the submission of applications on food additives, food enzymes and food flavourings**

**Disclaimer:**

**This guidance is intended to assist applicants in the submission of applications subject to Regulation (EC) No 1331/2008. It provides information of factual and technical nature. It is not aimed at providing interpretations and is not legally binding. It was prepared by DG SANTE services and does not commit the European Commission. It will be updated, when necessary. Therefore, applicants are advised to check DG SANTE website regularly for updates.**

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# Introduction

On 16 December 2008 a legislative package of four Regulations was adopted by the European Parliament and Council. The package is consisting of three sectoral food Regulations on so-called "food improvement agents" (Regulation (EC) No 1333/2008 on food additives[[1]](#footnote-2), Regulation (EC) No 1332/2008 on food enzymes[[2]](#footnote-3) amended by Regulation (EU) No 1056/2012[[3]](#footnote-4), and Regulation (EC) No 1334/2008 on food flavourings and certain food ingredients with flavouring properties[[4]](#footnote-5)) and a common procedure for the assessment and authorisation of these substances (Regulation (EC) No 1331/2008[[5]](#footnote-6)).

Following the requirements of Article 9 of Regulation (EC) No 1331/2008, the Commission adopted Regulation (EU) No 234/2011[[6]](#footnote-7) implementing Regulation (EC) No 1331/2008. This Regulation concerns the content, drafting and presentation of applications to update the Union lists of food additives, food enzymes and food flavourings, the arrangements for checking the validity of applications and the type of information that must be included in the opinion of the European Food Safety Authority (‘the Authority’ or ‘EFSA’). In the context of food enzymes, Regulation (EU) No 234/2011 has been amended by Regulation (EU) No 562/2012[[7]](#footnote-8) in relation to the derogation from submitting toxicological data in some specific cases and the possibility of grouping food enzymes under one application under certain conditions.

As of 27 March 2021, Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain[[8]](#footnote-9) amended Regulation (EC) No 1331/2008 and Regulation (EC) No 178/2002[[9]](#footnote-10). As regards the placing on the market of food additives, food enzymes and flavourings and ingredients with flavouring properties for use in and on foods, the amendments to Regulation (EC) No 178/2002 introduced new provisions concerning, amongst other issues: general pre-submission advice by the staff of the Authority at the request of a potential applicant and the obligation to notify studies commissioned or carried out by business operators to support an application and the consequences of non-compliance with that obligation. Regulation (EU) 2019/1381 also introduced provisions on the public disclosure, by the Authority, of all scientific data, studies and other information supporting applications with the exception of confidential information, early on in the risk assessment process, followed up by a consultation of third parties. The amendments also set out specific procedural requirements for the submission of confidentiality requests and the assessment thereof by the Authority in relation to the information submitted by an applicant, where the Commission requests the opinion of the Authority. Regulation (EC) No 1331/2008 was also amended to ensure consistency with the adaptations of Regulation (EC) No 178/2002 and to take sectoral specificities with respect to confidential information into account. Regulation (EU) No 234/2011 was also subsequently amended by Commission Implementing Regulation (EU) 2020/1823[[10]](#footnote-11) in order to take into account the above changes.

Article 3 of Regulation (EU) No 234/2011 requires the applicant to take into account the present practical guidance on the submission of applications made available by the Commission on Directorate General for Health and Food Safety website.

### Purpose

The objective of this guidance is to provide applicants with practical information which aims at facilitating the preparation and submission of applications for updating (adding or removing a substance, adding, removing or changing conditions, specifications or restrictions) the Union lists falling under the sectoral food Regulations. This guidance is intended to assist applicants in the submission of applications subject to Regulation (EC) No 1331/2008.

This guidance further clarifies the type of requested information and data that are to be included in an application file (referred to as “dossier”) and it lists a number of documents (EU legislation, EFSA practical arrangements and guidance, etc.) which are relevant when preparing the dossier (see Annex II - References). It provides also a brief description of the various stages of the authorisation procedure.

EFSA also issued an [administrative guidance for the preparation of applications on food improvement agents](https://www.efsa.europa.eu/en/supporting/pub/en-6509)[[11]](#footnote-12) (food enzymes, food additives and food flavourings), which provides guidance to applicants submitting applications on food enzymes, food additives or food flavourings, which are to be evaluated by EFSA[[12]](#footnote-13).

provides guidance to applicants submitting applications on food enzymes, food additives

or food flavourings, which are to be evaluated by EFSA.

### Scope

The guidance concerns applications falling under the scope of Regulations (EC) No 1332/2008, 1333/2008 and 1334/2008 (it does not concern smoke flavourings which are subject to Regulation (EC) No 2065/2003[[13]](#footnote-14)).

### Particularities of the sectoral food law

This guidance contains separate subchapters on additives, enzymes and flavourings since for some aspects the specific characteristics of different substances have to be taken into consideration in order to verify that the use of the substances complies with the conditions as provided in the respective sectoral food laws.

# Pre-submission advice

In accordance with Article 32a of Regulation (EC) No 178/2002, potential applicants may request advice from the Authority on the rules applicable to and the content required for an application, prior to its submission.

The Authority has laid down [practical arrangements in respect of this provision](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf) and requests for pre-submission advice should be submitted to the Authority in accordance with these practical arrangements (see Annex II - References).

Potential applicants will receive a pre-application identification which links all pre-submission activities undertaken by a potential applicant to support a future application on a specific product. The pre-application identification must be indicated when submitting the application, in accordance with EFSA’s practical arrangements.

# Notification of studies

In accordance with Article 32b of Regulation (EC) No 178/2002, business operators, as well as laboratories and other testing facilities located in the Union or in third countries insofar as set out in relevant agreements and arrangements with those countries, must notify the title, scope, starting and planned completion dates of any study commissioned or carried out as of 27 March 2021 to support an application as well as the laboratory or testing facility carrying out that study.

The Authority has laid down [practical arrangements in respect of this provision](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf) and studies should be notified in the database of study notifications available on the Authority’s website[[14]](#footnote-15), in accordance with those practical arrangements (see Annex II - References).

The non-compliance with the obligations of notification of studies may have important procedural consequences[[15]](#footnote-16), including applications being considered not valid in certain cases of non-compliance.

# Authorisation procedure

The procedural aspects concerning authorisation procedure are laid down in Regulation (EC) No 1331/2008 and further elaborated in Regulation (EU) No 234/2011. The time limits established in Regulation (EC) No 1331/2008 for various stages of the common Union assessment and authorisation procedure apply at present time for food additives and food flavourings. Regarding food enzymes, these time limits do not apply to the Authority’s adoption of its opinion for applications received before 11 March 2015. These are listed in a Register and the Commission will adopt the Union list for the first time after the Authority has delivered its opinion on all the food enzymes listed in that Register[[16]](#footnote-17).

The above mentioned Regulations as well as with other documents listed in Annex II - References of this guidance may be relevant in the preparation of applications.

## Application

Applications should be submitted through the electronic submission system provided by the Commission: [**e-**submission food chain platform](https://webgate.ec.europa.eu/esfc/) (ESFC)[[17]](#footnote-18).

An application (“dossier”) must contain[[18]](#footnote-19):

* an accompanying letter;
* a technical dossier;
* a detailed summary of the dossier and a public summary of the dossier (non-confidential).

The above-mentioned elements should be submitted in the electronic submission system provided by the Commission. In that system, the information is structured under the following headings: Administrative data, Public Summary and Technical dossier.

Documents submitted as part of the application must be downloadable, printable and searchable. After the adoption of standard data formats pursuant to Article 39f of Regulation (EC) No 178/2002, documents must be submitted in accordance with those standard data formats[[19]](#footnote-20).

Note that where the Authority is requested by the Commission to deliver a scientific output, it will proactively disclose all scientific data, studies and other information supporting any application with the exception of duly justified confidential data, in accordance with Article 38(1)(c) of Regulation (EC) No 178/2002, Article 11 of Regulation (EC) No 1331/2008 and the [Authority’s practical arrangements](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf) (See below 4.2.3 Risk assessment).

In accordance with EFSA’s practical arrangements, applicants must indicate the pre-application identification associated with the pre-submission activities carried out in relation to the specific regulated product subject to the application submitted.

### Accompanying letter

The accompanying letter must be drafted in accordance with the model provided in the Annex to Regulation (EU) No 234/2011[[20]](#footnote-21). Different model letters are provided for an application for food additives, food enzymes and food flavourings. It should summarise in a few sentences the request of an applicant. It should be addressed to Directorate-General Health and Food Safety, Directorate Food safety, sustainability, and innovation, Unit E2 Food processing technologies and novel foods.

The letter should be submitted in the electronic submission system provided by the Commission under the heading Administrative Data.

### Technical Dossier

The dossier consists of the administrative data, the data required for risk assessment and the data required for risk management[[21]](#footnote-22).

In case of an application to add a new substance to the Union list, a full package of data (administrative, risk assessment, risk management data) should be submitted. However, in application of Article 12(6) of Regulation (EU) No 234/2011, an application may be considered as valid even if it does not contain all data required provided the applicant submits an appropriate justification for each missing element.

In case of an application for modification of the conditions of use of an already authorised substance, certain data may not be necessary, in accordance with Article 2(4) of Regulation (EC) No 234/2011. However, the applicant must submit a verifiable justification why the proposed changes do not affect the results of the existing risk assessment[[22]](#footnote-23).

In case of an application for modification of the specifications of an already authorised substance, the data may be limited to the justification of the request, the description of the proposed changes and a verifiable justification that the changes do not affect the results of the existing risk assessment, in accordance with Article 2(5) of Regulation (EC) No 234/2011.

#### Administrative data

Applicants must comply with the requirements of Article 4 of Regulation (EU) No 234/2011.

#### Risk assessment data

All applications must follow the requirements of Article 5 of Regulation (EU) No 234/2011. In addition, applicants must take into account the latest guidance documents adopted or endorsed by the Authority[[23]](#footnote-24) available at the time of the submission of the application[[24]](#footnote-25) .

The Authority has issued a number of scientific cross-cutting guidance documents[[25]](#footnote-26) on broad assessment principles (e.g. genotoxicity assessment, risk assessment of substances present in food intended for infants below 16 weeks of age, statistical reporting etc.) that apply to the EFSA's scientific assessments including to applications on food additives, food enzymes and food flavourings.

Specific data required for risk assessment concern:

* *Food additives applications*following the requirements of Article 6 of Regulation (EU) No 234/2011.

As regards the dietary exposure assessment requested for both risk assessment as well as risk management (see the checklist for food additive applications –sections 2.2.8 and 2.3.7), the applicants are advised to use the [‘Food additives intake model’ (FAIM)](https://www.efsa.europa.eu/it/applications/food-improvement-agents/tools). This is a screening exposure assessment tool specifically developed by the Authority, to support the calculation by applicants of estimates of exposure to the food additive (see Annex II - References).

In July 2012, the Authority issued a *guidance for submission for food additive evaluation*, which provides a detailed description of the data requirements and their context, and also a description of the risk assessment paradigm applied (see Annex II - References).

The manufacturing process should be described in detail.

In case of food additives produced with genetically modified microorganisms, more details are given in the *Scientific guidance for the submission of dossiers on food enzymes* (see Annex II - References).

In case of use of nanotechnologies, the applicant should consult the Authority’s scientific opinion on *Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain* and the *Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles* (see Annex II - References).

* *Food enzymes applications* following the requirements of Article 8 of Regulation (EU) No 234/2011 as amended.

More details are given in the *Scientific guidance for the submission of dossiers on food enzymes* (see Annex II – References).

*EFSA Scientific Guidance for the submission of dossiers on food enzymes* (see Annex II - References).

As regards the dietary exposure assessment requested for risk assessment as well as for risk management, the applicants are advised to use the [‘Food enzyme intake model’ (FEIM).](https://www.efsa.europa.eu/it/applications/food-improvement-agents/tools) This is a screening exposure assessment tool specifically developed by the Authority, to support the calculation by applicants of estimates of exposure to the food enzymes (see Annex II - References).

* *Food flavourings applications*following the requirements of Article 10 of Regulation (EU) No 234/2011.

More details are given in the EFSA scientificg*uidance on the data required for the risk assessment of flavourings* (see Annex II - References). The scientific opinion elaborates on information to be supplied with an application for the authorisation of different types of flavourings for which an evaluation and an approval is required according to Regulation 1334/2008.

Different principles are followed and different risk assessment data are required depending on the type of flavouring (flavouring substance, flavouring preparations, thermal process flavourings, flavour precursors, other flavourings and source material), depending on the level of exposure, etc. Therefore, it is essential that applicants are familiar with the Authority’s guidance document.

In case of flavourings produced with genetically modified microorganisms, more details are given in EFSA’s *Scientific guidance for the submission of dossiers on food enzymes* (see Annex II - References).

In case of use of material in which small particles, including nanoparticles, are present, the applicant should consult the Authority’s scientific opinion on *Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain* and the *Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles* (see Annex II - References).

#### Risk management data

* *Food additives applications*must follow the requirements of Article 7 of Regulation (EU) No 234/2011
* *Food enzymes applications*must follow the requirements of Article 9 of Regulation (EU) No 234/2011

The guidance document on criteria for categorisation of food enzymes (see Annex II - References) provides criteria for determining the status of a food enzyme either as an ingredient or as a processing aid in a given context of use. This guidance may help applicants to complete the risk management data in the food enzyme applications.

* *Food flavourings applications*must follow the requirements of Article 11 of Regulation (EU) No 234/2011.

In the context of Article 11, it is important to highlight the following:

*Article 11 (a) the identity*: special attention should be paid to information on the configuration of the flavouring substance (stereoisomerism).

*Article 11 (b) organoleptic properties*:

* organoleptic properties of the substance should be demonstrated by providing a sensory profile of the substance in question
* description should be provided if the substance has flavour modifying properties (see Annex II - References)

### Detailed summary of the dossier

The detailed summary should follow the structure of the technical dossier. It should include details of each part of the documents submitted to support the application and address all the different parts with reference to the relevant sections and pages of the dossier.

In accordance with Article 2(6) of Regulation (EU) No 234/2011, it must include also a reasoned statement that the use of the product complies with the conditions of the relevant sectoral food law, i.e.:

* Articles 6, 7 and 8 of Regulation (EC) No 1333/2008 (*food additives applications*)
* Article 6 of Regulation (EC) No 1332/2008 (*food enzymes applications*)
* Article 4 of Regulation (EC) No 1334/2008 (*food flavourings applications*)

The applicant should also reiterate information on an overall conclusion on the safety of the proposed uses of the substance. The overall evaluation of potential risk to human health must be made in the context of known or likely human exposure[[26]](#footnote-27).

The detailed summary of the dossier should be submitted in the electronic submission system provided by the Commission under the heading Technical Dossier.

### Public summary of the dossier (non-confidential)

The target group of a public summary is a non-professional audience. The structure and content of the public summary should be elaborated accordingly. The document should be less extensive compared to the *detailed summary of the dossier* and should indicate what added value brings the authorisation for consumers. A scientific/professional terminology should be avoided if possible.

The public summary will be published and should not therefore contain any information subject to a request for confidential treatment, in line with Article 2(6) of Regulation (EU) No 234/2011.

Note that where the Authority is requested by the Commission to deliver a scientific output, it will proactively disclose all scientific data, studies and other information supporting any application with the exception of duly justified confidential data, in accordance with Article 38(1)(c) of Regulation (EC) No 178/2002, Article 11 of Regulation (EC) No 1331/2008 and the Authority’s [practical arrangements.](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf) Such disclosure is therefore not limited to the above-mentioned public summary of the dossier (See below 4.2.3 Risk assessment).

### List of parts of the dossier requested to be treated as confidential

Applicants may request confidential treatment of certain parts of the information submitted in their application. They must indicate which sections and data they wish to be treated as confidential and give verifiable justification for each part for which a confidential treatment is required following the provisions on confidentiality as laid down in Article 12 of Regulation (EC) No 1331/2008 and Articles 39 to 39e of Regulation (EC) No 178/2002.

Note that confidential treatment may only be granted by the Commission or EFSA with respect to the items of information listed in Article 39 of Regulation (EC) No 178/2002 and Article 13 of Regulation (EC) No 1331/2008.

If an applicant requests that some parts of the dossier are to be treated as confidential then these parts have to be listed with the accompanying verifiable justification demonstrating how the disclosure of such information would potentially harm the interests of the applicant to a significant degree. In that electronic submission system provided by the Commission, information concerning the confidentiality of certain information is to be submitted for each piece of information, together with the verifiable justification demonstrating how disclosure of the concerned information would potentially harm the applicant’s interests to a significant degree.

In case EFSA is asked to deliver a scientific opinion, EFSA’s [practical arrangements concerning transparency and confidentiality](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf) apply (see Annex II - References).

Furthermore, where the applicant submits a confidentiality request, it must provide a non-confidential and a confidential version of the information[[27]](#footnote-28).

### List of studies submitted to support the application and information demonstrating compliance with the obligation to notify studies

See above under 3 Notification of studies.

When submitting their application, applicants are required to include a list of the studies submitted to support the application, including information demonstrating compliance with this requirement[[28]](#footnote-29). In the electronic submission system provided by the Commission, and in accordance with [EFSA practical arrangements on pre-submission phase and public consultations](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf), this must be done by indicating the study notifications submitted in the EFSA database in support of the applications and/or the justification in the event of deviations.

The non-compliance with the obligations of notification of studies may have important procedural consequences[[29]](#footnote-30), including applications being considered not valid in certain cases of non-compliance.

### Checklist

Applicants may use the model checklist provided in Annex I - Checklists to this guidance in order to verify that the dossier is complete. They may also submit the checklist as part of their application.

TO BE NOTED: As from 7 July 2023 (i.e. in the guidance version No 15), the checklists do not contain anymore the part related to the risk assessment data. The checklists for the risk assessment data are newly included in the updated EFSA administrative guidance for the preparation of applications on food improvement agents[[30]](#footnote-31). Please check the EFSA guidance as regards the data for the risk assessment.

### Submission of an application

Applications must be submitted through the electronic submission system provided by the Commission: [**e-submission food chain platform**](https://webgate.ec.europa.eu/esfc/)[[31]](#footnote-32) **(ESFC)**.

In case of specific enquiries applicants can contact the Commission also via:

Email: sante-e2-additives@ec.europa.eu

 sante-e2-flavourings@ec.europa.eu

sante-e2-enzymes@ec.europa.eu

## What happens after an application has been submitted?

### Acknowledgement of receipt

The Commission acknowledges receipt of the application immediately after it has been submitted through the ESFC.[[32]](#footnote-33).

### Validity check[[33]](#footnote-34)

The Commission must, without delay, verify whether the application falls within the scope of the appropriate sectoral food law, whether the application contains all the elements required and whether it fulfils the requirements concerning the notification of studies.

Where necessary, the Commission may request the Authority to verify the suitability of the data for risk assessment and compliance with the requirements concerning the notification of studies. The Authority must provide the Commission with its views within 30 working days.

Where necessary, the Commission may request additional information from the applicant on matters regarding the validity of the application and inform the applicant of the period within which that information must be provided. In the context of applications for food enzymes included in the Register the Commission determines that period together with the applicant.

When the application does not fall within the appropriate sectoral food law, does not contain all the elements required under Chapter II, does not comply with Article 32b of Regulation (EC) No 178/2002 or, where the Authority considers that the data for risk assessment are not suitable, the application must be considered not valid. In such a case the Commission must inform the applicant indicating the reasons why the application is considered not valid[[34]](#footnote-35). Where the application is considered not valid pursuant to Article 32b (4) or (5) of Regulation (EC) No 178/2002, the Commission would also inform the applicant about any applicable procedural consequences in relation to these provisions.

### Risk assessment

When the Commission requests the Authority to carry out risk assessment, the Authority must give its opinion within 9 months of receipt of a valid application[[35]](#footnote-36). However, this deadline does not apply to food enzymes included in the Register[[36]](#footnote-37).

In accordance with Article 6 of Regulation (EC) No 1331/2008, this period may be extended in duly justified cases where the Authority requests additional information from applicants.

Moreover, in exceptional circumstances the time limits for both risk assessment and risk management may be extended if the nature of the matter in question so justifies[[37]](#footnote-38).

In accordance with Article 38(1)(c) of Regulation (EC) No 178/2002, Article 11 of Regulation (EC) No 1331/2008 and the [Authority’s practical arrangements](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf), the Authority will proactively disclose all scientific data, studies and other information supporting any application for which a scientific output is to be delivered by the Authority, with the exception of duly justified confidential data. Such disclosure applies to the entire dossier. Subsequently, EFSA will disclose a redacted version of the non-confidential version of the dossier in case it disagrees with one or more of the confidentiality requests submitted, pursuant to Articles 39 to 39e of Regulation (EC) No 178/2002. The applicant must ensure that terms and conditions asserted by any rights-holder 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 (e.g. studies published in scientific journals upon payment of fees) 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, and (b) these relevant bibliographic references/citations where these publications are available to the public for public dissemination.

In accordance with Article 32c(2) of Regulation (EC) No 178/2002 and [EFSA practical arrangements concerning transparency and confidentiality](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf), in particular Article 27 thereof, the Authority will also consult stakeholders and the public on non-confidential version of the application in order to identify whether other relevant scientific data or studies are available on the subject matter concerned by the application.

### Risk management and updating the Union list

Either within 9 months of the Authority giving its opinion or within 9 months of the date the Commission receives a valid application (in those cases where an opinion of the Authority has not been requested) the Commission must submit to the Standing Committee on Plants, Animals Food and Feed a draft regulation updating the Union list, taking account of the Authority’s opinion, any relevant provisions of Union law and any legitimate factors relevant to the matter under consideration[[38]](#footnote-39). By way of derogation, the Commission will only adopt the Union list on food enzyme after the Authority has delivered its opinion on all the food enzymes listed in the Register[[39]](#footnote-40).

This period may be extended where the Commission requests additional information from applicants on matters concerning risk management, in accordance with Article 8 of Regulation (EC) No 1331/2008.

Also, in exceptional circumstances the time limits for both risk assessment and risk management may be extended if the nature of the matter in question so justifies[[40]](#footnote-41).

The Commission may end the authorisation procedure and decide not to proceed with a planned update, at any stage of the procedure, if it judges that such an update is not justified, taking account of the Authority’s opinion, the views of the Member States, any relevant provisions of Union law and any legitimate factors relevant to the matter under consideration. In such cases, the Commission will inform the applicant indicating in its letter the reasons for not considering the update justified[[41]](#footnote-42).

# Annexes

## Checklists

Checklists give an overview of the information to be submitted so that the applicant can check the completeness of the dossier even before uploading the files through the electronic submission system. The checklists below do not contain the part related to the risk assessment data. Specific checklists for the risk assessment data are available in [*the EFSA administrative guidance*](https://www.efsa.europa.eu/en/supporting/pub/en-6509) *for the preparation of applications on food improvement agents*.

### Checklist for food additive applications

| No | Type of information / document  | Information / document provided? | *Do NOT fill the boxes below* |
| --- | --- | --- | --- |
| **1** | **Accompanying letter - see Annex to Regulation EU (No) 234/2011** |  | [ ]  |
| **2** | **Technical dossier** |
| **2.1** | **Administrative data**  |  | [ ]  |
| 2.1.1 | Name, address and contact details of the applicant |  | [ ]  |
| 2.1.2 | Name, address and contact details of the manufacturer |  | [ ]  |
| 2.1.3 | Name, address and contact details of the person responsible for the dossier |  | [ ]  |
| 2.1.4 | Date of submission (automatically generated by the ESFC |  | [ ]  |
| 2.1.5 | Type of application indicated: i.e. new food additive; modification of the conditions of use of an already authorised food additive; modification of the specifications of an already authorised food additive |  | [ ]  |
| 2.1.6 | Identification of the substance (e.g. chemical name, E-number, INS-number, CAS registry number) |  | [ ]  |
| 2.1.7 | Information on authorisation falling under Regulation (EC) No 1829/2003 on genetically modified food and feed |  | [ ]  |
| 2.1.8  | Table of content of the dossier |  | [ ]  |
| 2.1.9 | References - list of documents – the number and titles of volumes of documents submitted in support of the application; a detailed index with a reference to volumes and pages |  | [ ]  |
| 2.1.10 | List of the parts to be treated as confidential, accompanied by verifiable justification demonstrating how the disclosure of such information would potentially harm the interests of the applicant to a significant degree |  | [ ]  |
| 2.1.11 | List of the studies submitted to support the application, including information demonstrating compliance with Article 32b of Regulation (EC) No 178/2002 |  | [ ]  |
| **2.2** | **Risk assessment data***Please see the checklist in the EFSA administrative guidance for the preparation of applications on food improvement agents available at* [*https://www.efsa.europa.eu/en/supporting/pub/en-6509*](https://www.efsa.europa.eu/en/supporting/pub/en-6509) |
| **2.3** | **Risk management data** |
| 2.3.1 | Identity of the food additive, including reference to the existing specifications |  | [ ]  |
| 2.3.2 | Function and technological need for the level proposed in each food category for which authorisation is requested and an explanation why this can not be reasonably achieved by other economically and technologically practical means |  | [ ]  |
| 2.3.3 | Investigations on the efficacy of the food additive for the intended effect at the use level proposed |  | [ ]  |
| 2.3.4 | Advantages and benefits for the consumer according to the requirements laid down in Article 6 (2) of Regulation (EC) No 1333/2008 |  | [ ]  |
| 2.3.5 | Information why the use would not mislead the consumer |  | [ ]  |
| 2.3.6 | Proposed normal and maximum use levels in the food categories mentioned in Annex II to Regulation (EC) No 1333/2008, or in a newly proposed food category, or in a more specific foodstuff belonging to one of these categories |  | [ ]  |
| 2.3.7 | Exposure assessment based on normal and maximum use levels for each of the categories or products concerned |  | [ ]  |
| 2.3.8 | Amount of the food additive present in the final food as consumed by the consumer |  | [ ]  |
| 2.3.9 | Analytical methods allowing the identification and quantification of the additive or its residues in food |  | [ ]  |
| 2.3.10 | Compliance with specific conditions for sweeteners as laid down in Article 7 of Regulation (EC) No 1333/2008 |  | [ ]  |
| 2.3.11 | Compliance with specific conditions for colours as laid down in Article 8 of Regulation (EC) No 1333/2008 |  | [ ]  |
| **3** | **Verifiable justification for each missing element of data required** |  | [ ]  |
| **4** | **Detailed summary of the dossier** |  | [ ]  |
| **5** | **Public summary of the dossier** |  | [ ]  |
| **6** | **If confidential treatment is required also the following has to be included:** |
| **6.1** | A non-confidential version of the information |  | [ ]  |

### Checklist for food enzyme applications

| No | Type of information / document  | Information / document provided? | *Do NOT fill the boxes below* |
| --- | --- | --- | --- |
| **1 Letters** |
| 1.1 | Accompanying letter- Annex to Regulation EU (No) 234/2011  |  | [ ]  |
| **2 Summaries of the Dossier** |
| 2.1 | Detailed summary of the dossier |  | [ ]  |
| 2.2 | Public summary of the dossier |  | [ ]  |
| **3 Technical dossier** |
| **3.1 Administrative data** |
| 3.1.1 | Name, address and contact details of the applicant |  | [ ]  |
| 3.1.2 | Name, address and contact details of the manufacturer if different than the above applicant |  | [ ]  |
| 3.1.3 | Name, address and contact details of the person responsible for the dossier |  | [ ]  |
| 3.1.4 | Date of submission (automatically generated by the ESFC) |  | [ ]  |
| 3.1.5 | Type of the application  |  | [ ]  |
| 3.1.6 | Where relevant, a reference to similar authorised food enzymes  |  | [ ]  |
| 3.1.7  | Table of contents of the dossier |  | [ ]  |
| 3.1.8 | References - list of documents – the number and titles of volumes of documents submitted in support of the application; a detailed index with a reference to volumes and pages |  | [ ]  |
| 3.1.9 | List of the parts to be treated as confidential, accompanied by verifiable justification demonstrating how the disclosure of such information would potentially harm the interests of the applicant to a significant degree |  | [ ]  |
| 3.1.10 | List of the studies submitted to support the application, including information demonstrating compliance with Article 32b of Regulation (EC) No 178/2002 |  | [ ]  |
| **3.2 Risk assessment data (as described by the Authority’s guidance)***Please see the checklist in the EFSA administrative guidance for the preparation of applications on food improvement agents available at* [*https://www.efsa.europa.eu/en/supporting/pub/en-6509*](https://www.efsa.europa.eu/en/supporting/pub/en-6509) |
| **3.3 Risk management data** |
| 3.3.1 | The identity of the food enzyme, including reference to the specifications, including the source material |  | [ ]  |
| 3.3.2 | The function and technological need, including a description of the typical process(es) in which the food enzyme may be applied |  | [ ]  |
| 3.3.3 | The effect of the food enzyme on the final food |  | [ ]  |
| 3.3.4 | Why the use would not mislead the consumer |  | [ ]  |
| 3.3.5 | The proposed normal and maximum use levels where applicable |  | [ ]  |
| 3.3.6 | The dietary exposure assessment |  | [ ]  |
| **4** | **If confidential treatment is required also the following has to be included:** |
| **4.1** | A non-confidential version of the information |  | [ ]  |

### Checklist for food flavouring applications

| No | Type of information / document  | Information / document provided? | *Do NOT fill the boxes below* |
| --- | --- | --- | --- |
| **1** | **Accompanying letter - see Annex to Regulation EU (No) 234/2011** |  | [ ]  |
| **2** | **Technical dossier** |
| **2.1** | **Administrative data**  |  | [ ]  |
| 2.1.1 | Name, address and contact details of the applicant |  | [ ]  |
| 2.1.2 | Name, address and contact details of the manufacturer |  | [ ]  |
| 2.1.3 | Name, address and contact details of the person responsible for the dossier |  | [ ]  |
| 2.1.4 | Date of submission (automatically generated by the ESFC) |  | [ ]  |
| 2.1.5 | Type of application - flavouring substance, flavouring preparation, flavouring precursor, thermal process flavouring, other flavouring |  | [ ]  |
| 2.1.6 | Identification of the substance (e.g. chemical name, FL-No, JECFA No, CoE No) |  | [ ]  |
| 2.1.7 | Information on authorisation falling under Regulation (EC) No 1829/2003 on genetically modified food and feed |  | [ ]  |
| 2.1.8  | Table of content of the dossier |  | [ ]  |
| 2.1.9 | References - list of documents – the number and titles of volumes of documents submitted in support of the application; a detailed index with a reference to volumes and pages |  | [ ]  |
| 2.1.10 | List of the parts to be treated as confidential, accompanied by verifiable justification demonstrating how the disclosure of such information would potentially harm the interests of the applicant to a significant degree |  | [ ]  |
| 2.1.11 | List of the studies submitted to support the application, including information demonstrating compliance with Article 32b of Regulation (EC) No 178/2002 |  | [ ]  |
| **2.2** | **Risk assessment data***Please see the checklist in the EFSA administrative guidance for the preparation of applications on food improvement agents available at* [*https://www.efsa.europa.eu/en/supporting/pub/en-6509*](https://www.efsa.europa.eu/en/supporting/pub/en-6509) |
| **2.3** | **Risk management data** |
| 2.3.1 | Identity of the flavouring, including reference to the existing specifications |  | [ ]  |
| 2.3.2 | Organoleptic properties of the substance |  | [ ]  |
| 2.3.3 | Proposed normal and maximum use levels in the food categories or in a more specific food |  | [ ]  |
| 2.3.4 | Exposure assessment based on normal and maximum use levels |  | [ ]  |
| **3** | **Classification and sensory profiles** (see Guidance notes on the classification of a flavouring substance with modifying properties and a flavour enhancer) |  | [ ]  |
| **4** | **Verifiable justification for each missing element of data required** |  | [ ]  |
| **5** | **Detailed summary of the dossier**  |  | [ ]  |
| **6** | **Public summary of the dossier** |  | [ ]  |
| **7** | **If confidential treatment is required also the following has to be included:** |
| **7.1** | A non-confidential version of the information |  | [ ]  |

## References

All applicants should familiarise themselves with documents under "general references" and according to the application with one of the sectoral references.

### General references

[Regulation (EC) No 178/2002 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](https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32002R0178)

[Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain and amending, amongst others Regulations (EC) No 178/2002 and (EC) No 1331/2008](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32019R1381)

[Regulation (EC) No 1331/2008 establishing a common authorisation procedure](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32008R1331)

[Regulation (EU) No 234/2011 implementing Regulation 1331/2008](https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32011R0234)

[Regulation (EU) No 562/2012 amending Commission Regulation (EU) No 234/2011](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32012R0562)

[Commission Implementing Regulation (EU) 2020/1823 amending Regulation (EU) No 234/2011](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32020R1823)

[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](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](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-transparency-and-confidentiality.pdf).

EFSA (European Food Safety Authority), 2021. Administrative guidance for the preparation of applications on food improvement agents (food enzymes, food additives and food flavourings), EFSA Journal 2021;18(18):EN-6509

<https://www.efsa.europa.eu/en/supporting/pub/en-6509>

EFSA cross-cutting guidance documents (accessible at [https://efsa.onlinelibrary.wiley.com/doi/toc/10.1002/(ISSN)1831-4732.GUIDANCE)](https://efsa.onlinelibrary.wiley.com/doi/toc/10.1002/%28ISSN%291831-4732.GUIDANCE%29)

In case of a substance produced with ***genetically modified microorganisms*** also:

EFSA: Guidance on the risk assessment of genetically modified microorganisms and their products intended for food and feed use, EFSA Journal 2011;9(6):2193.

EFSA: Evaluation of trial descriptions of strains of Bacillus licheniformis and Aspergillus niger genetically modified with alpha-amylase gene(s), EFSA Journal 2011;9(6):2284.

EFSA: Scientific guidance for the submission of dossiers on food enzymes, EFSA Journal 2021;19(10):6851.

In case of a substance produced with ***genetically modified plants or fungus*** also:

EFSA: Guidance for risk assessment of food and feed from genetically modified plants, EFSA Journal 2011; 9(5): 2150.

In case of use of ***nanotechnologies*** also:

EFSA: Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health, EFSA Journal 2021;19(8):6768. <https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2021.6768>

EFSA: Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles, EFSA Journal 2021;19(8):6769 https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2021.6769

### Food additives

[Regulation (EC) No 1333/2008 on food additives](https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32008R1333)

EFSA: Guidance for submission for food additive evaluations, EFSA Journal 2012;10(7):2760 (version republished in 2021)

EFSA: Food Additives Intake Model (FAIM) (accessible at <https://www.efsa.europa.eu/it/applications/food-improvement-agents/tools>)

### Food enzymes

[Regulation (EC) No 1332/2008 on food enzymes](https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32008R1332)

[Regulation (EU) No 1056/2012 amending Regulation (EC) No 1332/2008 on food enzymes](https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32012R1056)

[Guidance document on categorisation of food enzymes](https://ec.europa.eu/food/safety/food_improvement_agents/enzymes/eu_rules_en)

EFSA: Scientific guidance for the submission of dossiers on food enzymes, EFSA Journal 2021;19(10):6851.

https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2021.6851EFSA: Food Enzyme Intake Model (FEIM) (accessible at <https://www.efsa.europa.eu/en/applications/food-improvement-agents/tools>)

### Food flavourings

[Regulation EC (No) 1334/2008 on flavourings and certain food ingredients with flavouring properties](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32008R1334)

European Commission: [Guidance notes on the classification of a flavouring substance with modifying properties and a flavour enhancer](https://ec.europa.eu/food/safety/food_improvement_agents/flavourings/eu_lists_flavourings_en)

EFSA: Guidance on the data required for the risk assessment of flavourings to be used in or on foods, EFSA Journal 2022;20(12):7673, <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7673>

## The most common drawbacks of the applications received

If the application is incomplete or the data provided are not of a sufficient quality (i.e. not suitable for risk assessment/risk management) the application might be considered as not valid, in accordance with Article 12(5) of Commission Regulation (EU) No 234/2011.

In order to avoid such situation please find below the most common drawbacks of the food additive applications that have been received. Please take note that some items listed below may not be relevant for applications aimed at adding, removing or changing conditions, specifications or restrictions associated with the presence of a substance on the Community list.

* Full copies of the references (i.e. published papers and unpublished studies) are missing in the technical dossier[[42]](#footnote-43)
* Appropriate justification for each missing part of the application is not included[[43]](#footnote-44)
* Identity and characterisation of the proposed food additive is not sufficient - full set of specifications and analytical methods for substance’s characterisation and detection in food are missing[[44]](#footnote-45)
* Insufficient information on toxicological data not following the ‘EFSA guidance for submission for food additive evaluations’[[45]](#footnote-46)
* Missing description of the test material used in the toxicological studies[[46]](#footnote-47)
* Proposed use levels of the substance are not specified[[47]](#footnote-48)

## Changes introduced in the updated versions of the guidance

**Version 10**: administrative changes (name of the DG, Unit, contact person, contact details etc.); request that all electronic files should allow content copying and printing

**Version 11:** administrative changes (name of contact person, name of the unit and contact details)

**Version 12:** administrative changes (name of contact person and contact details)

**Version 13:** changes to allow the business continuity during the containment measures caused by COVID-19. The guidance was adjusted so that the applications are submitted via the online CIRCABC Sante-Cad-In Group system.

**Version 14**: changes reflecting the applicability of the new rules introduced by Regulation (EU) 2019/1381 (applicable from 27 March 2021) and the new electronic submission system. Update of the reference to scientific guidance documents.

**Version 15:** changes due to the update of the EFSA administrative guidance for the preparation of applications on food improvement agents that now newly includes the checklists for the risk assessment data. As a consequence, the risk assessment data were removed from the checklists in this guidance and as regards the risk assessment data the applicants are advised to see the EFSA checklists.

1. 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. [↑](#footnote-ref-2)
2. 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. [↑](#footnote-ref-3)
3. Commission Regulation (EU) No 1056/2012 of 12 November 2012 amending Regulation (EC) No 1332/2008 of the European Parliament and of the Council on food enzymes with regard to transitional measures, OJ L 313, 13.11.2012, p. 9. [↑](#footnote-ref-4)
4. 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. [↑](#footnote-ref-5)
5. 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. [↑](#footnote-ref-6)
6. 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. [↑](#footnote-ref-7)
7. Commission Implementing Regulation (EU) No 562/2012 of 27 June 2012 amending Commission Regulation (EU) No 234/2011 with regard to specific data required for risk assessment of food enzymes, OJ L 168, 28.6.2012, p. 21. [↑](#footnote-ref-8)
8. Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and the 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 (OJ L 231, 6.9.2019, p. 1). [↑](#footnote-ref-9)
9. 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, OJ L 31, 1.2.2002. p. 1. [↑](#footnote-ref-10)
10. 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, OJ L 406, 3.12.2020, p. 43. [↑](#footnote-ref-11)
11. More information are also available at EFSA webpage: <https://www.efsa.europa.eu/en/applications/food-improvement-agents/regulationsandguidance> [↑](#footnote-ref-12)
12. The Commission may decide not to request the opinion of EFSA if the update of the Union list in question is not liable to have an effect on human health. [↑](#footnote-ref-13)
13. Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods, OJ L 309, 26.11.2003, p. 1. [↑](#footnote-ref-14)
14. <https://www.efsa.europa.eu/en/applications/toolkit> [↑](#footnote-ref-15)
15. Article 32b (4), (5), (6) of Regulation (EC) No 178/2002. [↑](#footnote-ref-16)
16. Article 17(4) of Regulation (EC) No 1332/2008. [↑](#footnote-ref-17)
17. <https://webgate.ec.europa.eu/esfc/> [↑](#footnote-ref-18)
18. Article 3(1) of Commission Regulation (EU) No 234/2011. [↑](#footnote-ref-19)
19. Article 3(1) of Commission Regulation (EU) No 234/2011. [↑](#footnote-ref-20)
20. Article 2(2) of Commission Regulation (EU) No 234/2011. [↑](#footnote-ref-21)
21. Article 2(3) of Commission Regulation (EU) No 234/2011. [↑](#footnote-ref-22)
22. Article 5(5) of Commission Regulation (EU) No 234/2011. [↑](#footnote-ref-23)
23. <https://www.efsa.europa.eu/en/methodology/guidance> ; <https://www.efsa.europa.eu/en/applications/food-improvement-agents/regulationsandguidance> [↑](#footnote-ref-24)
24. Article 5(3) of Commission Regulation (EU) No 234/2011. [↑](#footnote-ref-25)
25. [https://efsa.onlinelibrary.wiley.com/doi/toc/10.1002/(ISSN)1831-4732.GUIDANCE](https://efsa.onlinelibrary.wiley.com/doi/toc/10.1002/%28ISSN%291831-4732.GUIDANCE) [↑](#footnote-ref-26)
26. Article 5(8) of Commission Regulation (EU) No 234/2011. [↑](#footnote-ref-27)
27. Article 39a of Regulation (EC) No 178/2002. [↑](#footnote-ref-28)
28. Article 4(n) of Commission Regulation (EU) No 234/2011. [↑](#footnote-ref-29)
29. Article 32b (4), (5), (6) of Regulation (EC) No 178/2002. [↑](#footnote-ref-30)
30. <https://www.efsa.europa.eu/en/supporting/pub/en-6509> [↑](#footnote-ref-31)
31. <https://webgate.ec.europa.eu/esfc/> [↑](#footnote-ref-32)
32. Article 4(1)(a) of Regulation (EC) No 1331/2008. [↑](#footnote-ref-33)
33. Article 12 of Commission Regulation (EU) No 234/2011. [↑](#footnote-ref-34)
34. Article 12(5) of Regulation (EU) No 234/2011. [↑](#footnote-ref-35)
35. Article 5 of Regulation (EC) No 1331/2008. [↑](#footnote-ref-36)
36. Article 17(4) of Regulation (EC) No 1332/2008. [↑](#footnote-ref-37)
37. Article 10 of Regulation (EC) No 1331/2008 [↑](#footnote-ref-38)
38. Article 7(1) of Regulation (EC) No 1331/2008 [↑](#footnote-ref-39)
39. Article 17(4) of Regulation (EC) No 1332/2008. [↑](#footnote-ref-40)
40. Article 10 of Regulation (EC) No 1331/2008 [↑](#footnote-ref-41)
41. Article 3(4) of Regulation (EC) No 1331/2008. [↑](#footnote-ref-42)
42. Article 5(2) of Commission Regulation (EU) No 234/2011. [↑](#footnote-ref-43)
43. Article 12(6) of Commission Regulation (EU) No 234/2011. [↑](#footnote-ref-44)
44. Articles 6(1)(a), 7(2)(a), 9(2)(a), 11(a) of Commission Regulation (EU) No 234/2011. [↑](#footnote-ref-45)
45. Article 5(3) of Commission Regulation (EU) No 234/2011. [↑](#footnote-ref-46)
46. Article 5(7) of Commission Regulation (EU) No 234/2011. [↑](#footnote-ref-47)
47. Articles 6(1)(g), 7(2)(f), 8(1)(j), 9(2)(e), 10(1)(e), 11(c) of Commission Regulation (EU) No 234/2011. [↑](#footnote-ref-48)