TECHNICAL REPORT

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Administrative guidance for the processing of applications for regulated products (update 2021)

European Food Safety Authority (EFSA)

Abstract

EFSA is continuously striving to enhance its support initiatives in the area of regulated products, enhancing a customer-oriented approach, supporting applicants during the applications for regulated products life-cycle. EFSA is registering around 500 mandates on applications for regulated products on a yearly basis governed by more than 34 different EU Directives and Regulations and following 39 workflows. In this context, EFSA developed this administrative guidance on the principles followed to process applications for regulated products in order to enhance transparency and understanding, and to ensure that a coherent, sound, systematic and efficient process is carried out, in compliance with each sectoral legislation.

This administrative guidance for the processing of applications for regulated products describes the general workflow of applications, the key steps of the scientific risk assessment process, the mechanism of suspension/extension of the scientific assessment, its restart, the conclusion of the scientific risk assessment process, the publication of the scientific output, as well as the new requirements introduced by the General Food Law in the pre-submission and submission application procedure: general pre-submission advice by EFSA, specific aspects for intended applications for renewal (notification of intended studies, including their design, public consultation on the intended studies, renewal pre-submission advice by EFSA), notification of commissioned or carried out studies, 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 applicable as of 27 March 2021.

This administrative guidance applies to all areas of regulated products, with the exception of pesticides and the re-evaluation of food additives. The document includes an Annex listing the indicative timelines for submitting additional/supplementary information to EFSA during the risk assessment.[1]

Key words: Applicants, applications, mandates, regulated products, sectoral legislation, scientific assessment, scientific outputs, workflows.

Requestor: European Food Safety Authority

Question number: EFSA-Q-2020-00364

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[1] The annex applies to all areas of regulated products. For pesticides it includes only the timelines for requesting additional studies on endocrine properties.

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1. Introduction

1.1. Background and Terms of Reference as provided by EFSA

The European Food Safety Authority (EFSA) provides independent scientific advice on risk assessment of substances, products and processes intended to be used in the food chain as well as on the substantiation of claims made on foods. EFSA is also responsible for developing guidance documents and providing advice on emerging safety issues related to products already authorised within the European Union. EFSA adheres to a number of principles and practices which aim at ensuring the excellence of its work, including the development of a comprehensive body of good risk assessment practices to guide the Scientific Committee and Panel experts.[2]

EFSA is registering around 500 mandates on applications for regulated products on a yearly basis. Such mandates are governed by more than 34 different relevant EU Directives and Regulations and follow 39 different workflows. EFSA's work on regulated products applications produces around 500 scientific outputs on applications for regulated products annually.

EFSA is continuously striving to enhance the provision of support initiatives to applicants submitting applications on regulated products. Since 2014, EFSA implemented dedicated services and initiatives to support applicants and other stakeholders during the entire life-cycle of applications for regulated products. In this context, EFSA publishes this 'Administrative guidance for the processing of applications for regulated products' with the aim to enhance transparency and understanding and to ensure that a coherent, sound, systematic and efficient process is carried out, without prejudice to sectoral legislation.

The guidance also includes reference to the provisions introduced by Regulation (EU) 2019/1381[3], hereinafter 'the Transparency Regulation' amending *inter alia* Regulations (EC) 178/2002[4] (i.e. the General Food Law, hereinafter 'GFL Regulation'), (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. It is to be read in conjunction with the sectoral Regulations pertaining to each scientific area, as well as with EFSA's Practical Arrangements[5] implementing the Transparency Regulation and, where available, EFSA's and European Commission's guidance for applicants. 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. In case multiple interpretations are compatible with the content of this document, the interpretation most in line with the applicable legal acts prevails.

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

1.2. Scope

The administrative guidance for the processing of applications for regulated products presently applies to applications for authorisation of substances used in feed and food (such as additives, enzymes, flavourings, nutrient sources, infant formulae[6]), food contact materials (plastic food contact materials substances, recycling processes, active and intelligent materials and substances), novel foods, genetically modified organisms, processing aids (e.g. decontamination substances), health claims, alternative methods for animal-by products, under the GFL Regulation. The guidance does not apply to pesticides processes (except for the indicative timelines for submitting additional information to EFSA

[2] http://www.efsa.europa.eu/en/about/howwework

[3] 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.

[4] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January2002 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.

[5] EFSA's Practical arrangements are available online at: https://www.efsa.europa.eu/en/corporate/pub/tr-practical-arrangements

[6] Infant formulae are considered in the scope of this document as they are processed by EFSA to the extent possible similarly to applications.

following a request for additional studies on endocrine properties, see Annex A – to this guidance) nor to the re-evaluation of food additives.

For the purpose of this guidance, an 'applicant' means any legal or natural person (e.g. individuals, food business operators, industry associations, consultancy companies) irrespective of his/her residence, who has submitted an application for the authorisation or a notification of a product, substance, claim, organism or process in the European Union which may lead to a scientific evaluation by EFSA.

EFSA will update this document, if needed, in line with amendments to the legislation, the evolving case-law of the Union courts, relevant changes to guidance documents and/or approaches, according to the experience gained in handling and assessing applications. Therefore, applicants are advised to always consult the latest published version of this document available on EFSA's website.[7]

[7] http://www.efsa.europa.eu/en/applications

2. Guidance

2.1. General procedure for processing applications for regulated products

Before the EU risk managers (European Commission, competent authority in Member States) can authorise a regulated product/process or a health claim, an application has to be evaluated by EFSA (Figure 1). The procedures for submitting an application and the information to be included in the technical dossier vary widely for each area, according to the specific legislation and applicable guidance documents. EFSA continuously develops guidance documents (explanatory documents that describe the requirements to be considered in the preparation of an application) to support the preparation of applications in the various scientific areas. An overview of the relevant regulatory framework, administrative and scientific guidance documents per regulated product area is available and regularly updated on EFSA's website.[8]

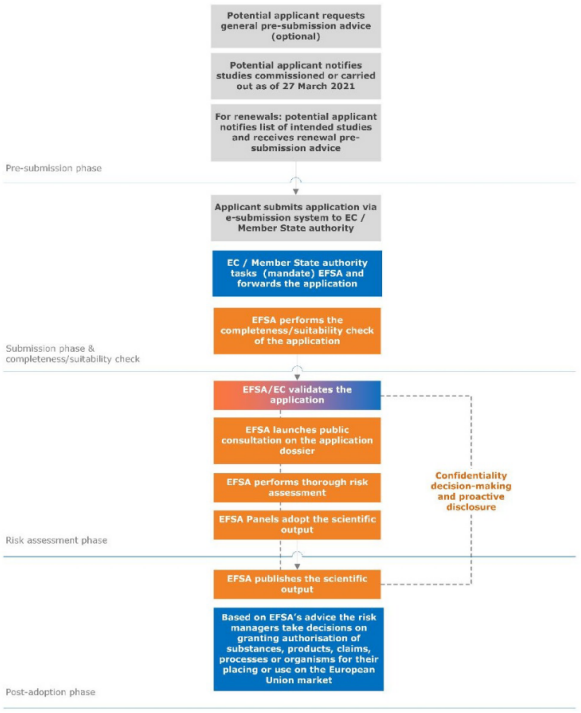

Figure 1: General procedure for processing applications for regulated products. This figure has been drafted by EFSA based on the common elements which are applicable to several evaluation procedures in which EFSA is involved. Specific procedures for each regulated product area include further details and variations to the flow.

[8] https://www.efsa.europa.eu/en/applications/regulatedproducts

2.2. General principles for processing applications for regulated products

When processing applications for regulated products, EFSA follows the below general principles:

- EFSA ensures compliance with the principle of **equal treatment** and of **non-discrimination of identical or largely comparable situations**;
- EFSA exercises exclusively the **powers** attributed to it by the legislators, or by acts adopted by the competent institutions and bodies pursuant to the Treaties, or those implicit in the powers explicitly entrusted to EFSA;
- EFSA takes its scientific and administrative decisions **timely, carefully, objectively, consistently and impartially**[9], ensuring the absence of conflict of interests with the servants and experts contributing to its decision-making processes and therefore also the impartiality of the evaluation performed;
- In relation to the evaluation of applications, EFSA ensures **compliance with the deadlines** stipulated in the relevant legal acts or, as appropriate, agreed with the requestor;
- In adopting new EFSA policies, decisions, approaches, or scientific methodologies that affect the assessment of an application for regulated products, EFSA ensures that a reasonable **transitional period** is granted and that the date of implementation is clearly specified. Account is given to the time required to comply with the new requirement(s). In case of safety concerns, new EFSA policies, decisions, approaches, or scientific methodologies are immediately implemented and the date of implementation is clearly specified;
- EFSA ensures that any request to the applicants (whether of a scientific or administrative nature) is **proportionate** to the aim to be pursued and is limited to what is necessary to perform and finalise the scientific risk assessment. EFSA also ensures that the request does not exceed the legitimate requirements and that it corresponds to what is considered necessary in order to reach conclusions on the risk assessment;
- EFSA ensures **transparency** of its interactions with the applicant/requestor on data requirements during the risk assessment by publishing its correspondence on the OpenEFSA portal[10];
- EFSA maintains a **dialogue** with the relevant applicant and with the requestor (e.g. applicant, European Commission, competent authorities in the Member States), keeping all actors involved in the evaluation procedure regularly informed on the achievement of key milestones (e.g. reception of application, validity/suitability of application, request for additional information, publication of EFSA's scientific output);
- EFSA respects the principles on the protection of natural persons laid down in Regulation (EC) No 2018/1725[11] with regards to the processing of **personal data** by the Union institutions, bodies, offices and agencies and on and the free movement of such data;
- EFSA complies with applicable provisions on **transparency** and **confidentiality** as outlined in the Transparency Regulation amending *inter alia* the GFL Regulation and in each relevant legislation, including on the obligations to make publicly available the data and information on which its opinions are based;
- EFSA complies with applicable provisions on **regulatory data protection** as outlined in the applicable legislation.

[9] As derived from the EFSA Code of Good Administrative Behaviour http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/admincode.pdf

[10] https://open.efsa.europa.eu

[11] 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.

EFSA provides support to applicants in all regulated products areas on the basis of the information included in **EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products** (EFSA, 2021a).

EFSA makes available on its website[12] 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), together with a brief description of each tool, how to access it, and dedicated user guide where available.

Pre-submission phase

Before submitting an application, a potential applicant should first register in the EFSA's portal supporting pre-submission activities available on EFSA's website.[13] 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'), 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 2.3, 2.4 and 112.5), as introduced by the GFL Regulation:

- possibility to request general pre-submission advice from EFSA (optional, applicable to all types of applications);
- in case of intended applications for renewal: notification of intended studies (mandatory if new studies are planned), including information on how the various studies are to be carried out (proposed study design), consultation of third parties and renewal pre-submission advice;
- notification of information related to studies commissioned or carried out (mandatory, applicable to all types of applications).

The pre-application ID, if any, must be provided by the applicant when submitting the application.[14]

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[15] (EFSA, 2021b) which provide comprehensive information and instructions on that matter.

2.3. General pre-submission advice

In accordance with Article 32a(1) of the GFL Regulation, potential applicants may request general pre-submission advice (GPSA) to EFSA at any time before submitting the corresponding envisaged application. 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 risk managers.

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

[12] https://www.efsa.europa.eu/en/applications/toolkit
[13] https://www.efsa.europa.eu/en/applications/toolkit
[14] 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, 2021b).
[15] See Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission phase and public consultations

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.[16]

For accepted requests, the advice is notified to the potential applicant. A summary of the advice is drawn up and stored by 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, 2021b).

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 2.8.

2.4. Provisions applicable to intended renewal applications

2.4.1. Notification of intended studies for renewals

In accordance with Article 32c(1) of the GFL Regulation, if new studies are planned for the purpose of the renewal, the potential applicant must submit a complete list of studies it intends to perform, including information on how the various studies are to be carried out to ensure compliance with regulatory requirements (study design).[17] EFSA recommends that the design of the studies is accompanied by the detailed proposed study protocols.

The notification of intended studies for renewal is mandatory and must be submitted in the system supporting the pre-submission activities available on EFSA's website.[18]

EFSA recommends that the intended studies for renewal are notified at least five months before the date of the intended commissioning of the studies in order to allow for the appropriate consultation to take place.

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

2.4.2. Public consultation on the intended studies for renewal

In accordance with Article 32c(1) of the GFL Regulation, upon notification to EFSA with the complete list of studies the applicant intends to perform for the purpose of the renewal, EFSA launches a public consultation on the intended studies for renewal, including on the proposed design of studies. The public consultation will be launched on a dedicated EFSA's webpage[19], after an administrative check of the information notified.

All comments received from third parties during the public consultation will be made public by EFSA without delay upon the closure of the public consultation. The results of the consultation of third parties (i.e. how the comments have been taken into account) will be inserted in the summary of the renewal pre-submission advice (see Section 2.4.3).[20]

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

2.4.3. Renewal pre-submission advice

In accordance with Article 32c(1) of the GFL Regulation, after the closure of the public consultation on the intended studies for renewal, EFSA reviews the comments received from third parties (see Section 2.4.2) and provides renewal pre-submission advice (RPSA) to the potential applicant, taking into account

[16] https://www.efsa.europa.eu/en/applications/toolkit
[17] The full list of information to be notified for each study is provided in Annex I 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, 2021b).
[18] https://www.efsa.europa.eu/en/applications/toolkit
[19] https://www.efsa.europa.eu/en/applications/toolkit
[20] 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 the Decision of the Executive Director of EFSA laying down the practical arrangements concerning transparency and confidentiality (EFSA, 2021c), respectively.

those comments which are relevant for the risk assessment of the intended renewal. The advice is notified to the potential applicant.

A summary of the RPSA is drawn up and stored by EFSA. The summary is sent to the potential applicant for information purposes and is published together with the non-confidential version of the application dossier, as soon as the application is declared valid. The RPSA summary will also include how the comments received during the public consultation have been taken into account by EFSA.

For a comprehensive description of applicable procedures and provisions on the renewal pre-submission advice (e.g. format, timing, outcome), please refer to EFSA's Practical Arrangements on pre-submission phase and public consultations (EFSA, 2021b).

2.5. Notification of studies

In accordance with Article 32b of the GFL Regulation, potential applicants commissioning or carrying out studies[21] as of 27 March 2021 to support an application have the obligation to notify EFSA without delay of certain information[22] related to those studies.

The same obligation applies to the laboratories and other testing facilities located in the EU[23] for studies commissioned by potential applicants and carried out by such laboratories and other testing facilities. Therefore, both potential applicant and laboratories/testing facilities located in the EU 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 available on EFSA's website[24] without delay before the starting date of the study. 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 completeness/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 the 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 2.7 and 2.10).

Studies submitted to support an application are not subject to the obligations of study notifications 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, 2021b).

[21] According to Article 2(c)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, 2021b), "study" means an experiment or set of experiments in which a test item is examined under laboratory conditions or in the environment to obtain data with respect to the properties and/or the safety of that test item, which is relevant for submission to appropriate regulatory authorities.

[22] 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, 2021b).

[23] 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.

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

From receipt of applications to publication of adopted scientific outputs

2.6. Receiving applications

When the legislation requires to seek the opinion of EFSA, EFSA receives technical dossiers supporting applications, directly from the applicant or through the EU Risk managers (European Commission, competent authority in Member States), and the mandates[25] from EU risk managers. The submission of all applications for regulated products must be done by applicants using the electronic tool, i.e. the e-submission system accessible through EC's website or EFSA's website.[26] Through the e-submission system, the application is made available to EFSA automatically at submission or when forwarded by risk managers, according to the sectoral legislation.

EFSA examines each mandate received from the EU risk managers to ensure clarity of the scope and terms of reference and may ask the requestor to provide clarifications or revisions for the proposed terms of reference, deadlines or scientific information submitted with the request. The mandate is allocated to a Scientific Panel or Scientific Committee or respective Scientific Unit taking in due account Article 28 of the GFL Regulation. EFSA acknowledges receipt of the application when both mandate and technical dossier are received. Until receipt of the mandate, EFSA does not take any action on the technical dossier supporting the application.

In case the mandate is outside EFSA's remit, depending on the applicable sectoral legislations, EFSA rejects the mandate and notifies the European Commission or the Member State accordingly. Such rejection does not prevent the applicant and the institutional partner from submitting a new application under the most appropriate sectoral legislation.

At receipt, the application is given a unique reference number which is communicated to the applicant. During the life-cycle of the application, the status of the application is automatically updated every time the status of the application changes. In this way, the application can be directly monitored through the e-submission system.

Scientific and technical information provided throughout the lifecycle of the application is made available by EFSA to the public in the OpenEFSA portal.

2.7. Examination of applications

Upon receipt of an application, EFSA[27] performs the completeness/suitability check[28] of the data comprised in the application in accordance with the specific requirements laid down in the relevant sectoral legislation and in EFSA's guidance documents. It is to be noted that pending the adoption of standard data formats[29] pursuant to Article 39f of the GFL Regulation, the application must be submitted in an electronic format allowing for the downloading, printing and searching of documents, and wherever possible using existing structured templates. After the adoption of the standard data formats, the application and the dossier must be submitted in accordance with those standard data formats.

Without prejudice to existing timelines specified in applicable sectoral legal acts, within 30 working days, missing information or clarifications might be requested from the applicant before considering the application complete/suitable for risk assessment. This deadline may be extended, upon request and justification from the applicant.

Before answering to the missing information request, the applicant can also request a teleconference from EFSA to clarify the questions raised.[30] When responding to questions, the applicant should upload the missing information or clarifications directly on the e-submission system.

[25] For the purpose of this guidance, 'mandate' refers to any request received from the EU risk managers to assess applications for regulated products.
[26] https://www.efsa.europa.eu/en/applications/toolkit
[27] Namely, EFSA Applications Desk (APDESK). For the process of validation of health claim applications, please refer to the sectoral guidance.
[28] The suitability check is performed by EFSA upon request from the European Commission.
[29] See Article 4(3) of the Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements concerning transparency and confidentiality (EFSA, 2021c).
[30] See Section 2.2.2 of EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products (EFSA, 2021a).

Applicants should note that the provisions on notification of studies, confidentiality and proactive disclosure of the information, as detailed in Sections 2.5, 2.8 and 2.9, apply to all documents or information uploaded as part of the initial submission, or later during suitability/completeness check or in the scientific evaluation process.

Upon upload, EFSA assesses the submitted information within 15 working days.

- If the submitted information is complete, the application is considered valid for scientific risk assessment purposes and the application moves to the risk assessment phase. Where the responsibility of the validity lies with the European Commission, EFSA communicates to the Commission that the application is suitable for scientific risk assessment purposes and the Commission decides on its validity. This is without prejudice to the need for additional/supplementary information or clarifications that may be identified in the course of the risk assessment;
- If the submitted information is incomplete or unclear, the application is not considered valid/suitable for scientific risk assessment purposes, and the applicant receives a second request for missing information to be provided within a defined timeline (e.g. information and/or requirements specified in the legislative framework, in the implementing rules and/or recommended in EFSA's administrative and scientific guidance documents);
- If the requested information is not provided within the defined timeline, and in the absence of response and communication from the applicant despite EFSA's reminders, EFSA may either declare the application invalid (when the responsibility to decide on the validity lies exclusively with EFSA) or inform the European Commission of the lack/incomplete applicant's response[31] (where the responsibility of the validity lies with the Commission). The risk manager may withdraw the mandate/request accordingly. This decision does not prevent the applicant from submitting a new revised application.

When the application is considered invalid, the applicant is notified by the e-submission system and the status of the application is updated accordingly.

With respect to the obligations of study notifications laid down in Article 32b(2) and (3) of the GFL Regulation, applicants should note that the verification of compliance with study notification obligations, including the assessment of the justifications provided by the applicant, (see Section 2.5) is part of the verification of the validity/suitability of the application.

In this respect, the application is considered valid, provided that:

a. the application contains

(i) all studies that have been previously notified, unless a valid justification is provided; and

(ii) no additional studies apart from those previously notified, unless a valid justification is provided;

b. all other justifications provided by the applicant are valid.

If the application is not considered valid, EFSA interrupts the completeness/suitability check and the application is declared as non-valid.[32] The application may be re-submitted, provided that:

a. the applicant notifies in the database the studies that were not previously notified; and/or

b. the applicant 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 file a completely new application. The completeness/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, 2021b).

[31] Depending on the applicable sectoral legislation.
[32] In accordance with Article 32b(4) and (5) of the GFL Regulation.

When the application is considered complete, the applicant is notified that EFSA has completed its completeness/suitability check, which form part of the assessment of the validity of the application. The status of the application is updated accordingly in the e-submission system and in the OpenEFSA portal.

2.8. Transparency and confidentiality requirements

This section aims at giving an initial overview on the procedure implementing transparency and confidentiality requirements, in accordance with relevant provisions of GFL Regulation and of the sectoral Regulations pertaining to each scientific area, and with EFSA's Practical Arrangements concerning transparency and confidentiality[33] (EFSA, 2021c). It is to be read in conjunction with Union law and case law, as well as with EFSA's Practical Arrangements concerning transparency and confidentiality (EFSA, 2021c), which provide a comprehensive description of applicable procedures and provisions.

2.8.1. 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/supplementary 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, the European Commission or the competent Member State, depending on the applicable legal framework, 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;
- 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

[33] See Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements concerning transparency and confidentiality

[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, 2021c).

application is declared valid. 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 EFSA's Practical Arrangements concerning transparency and confidentiality (EFSA, 2021c).

2.8.2. Processing of confidentiality requests

The actor responsible for taking the confidentiality decision (i.e. EFSA, European Commission or a Member State depending on the applicable legal framework) will assess each confidentiality request, 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, 2021c).

The notification of the confidentiality decision or the decision itself will also inform the applicant of its right to ask for a review of the confidentiality decision (confirmatory application).[36]

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

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

At different moments of the application life-cycle, applicants have several opportunities to participate in the decision-making process regarding their confidentiality requests 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**, EFSA will share the draft decision with the applicant, who may share its comments within 2 calendar weeks from the receipt of the draft decision. If comments are submitted by the set deadline, EFSA will assess them, modify the draft as appropriate, and adopt the decision. The applicant may withdraw the application in the same timeline, in which case the information for which confidentiality has been requested by the applicant will not be made public;

b. **after the adoption of a confidentiality decision**, the concerned applicant may withdraw the application for the regulated product, or submit a confirmatory application for the review of the confidentiality decision to the attention of the Executive Director;

c. **after the adoption of a decision on a confirmatory application**, the concerned applicant may bring an action challenging the legality of the confirmatory decision before the Court of Justice of the European Union or lodge a complaint to the European Ombudsman for alleged maladministration.

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

2.8.4. Implementation of EFSA's confidentiality decision

EFSA implements the confidentiality decisions without delay in accordance with its Practical Arrangements on transparency and confidentiality (EFSA, 2021c).

[36] In accordance with Article 39b(2) of the GFL Regulation.

2.8.5. 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 upon request, or proactively when explicitly prescribed by the law.

All professionals having access to information for which 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.

2.8.6. 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 confidentiality decision;
- Non-confidential version of information provided at request for additional/supplementary information, or as a result of spontaneous submission by the applicant, is published as soon as received;
- If confidentiality requests presented on the additional/supplementary information are rejected, an updated non-confidential version of the information is published after implementation of confidentiality decision, once EFSA's scientific output is adopted.

2.9. Public consultation on information contained in the application

In accordance with Article 32c of the GFL Regulation, in order to ensure that EFSA has access to all relevant scientific data and studies available on the subject matter of 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 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 (see Section 2.8), EFSA launches a public consultation on its website.

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. In case the results of the public consultation cannot be given proper consideration because of the time limit for delivering the scientific output, EFSA may extend the timeline to conclude the assessment for a maximum of seven weeks.[37] EFSA's scientific output will address the relevant comments received from the third parties.[38]

For detailed information, please refer to EFSA's Practical Arrangements on pre-submission phase and public consultations (EFSA, 2021b).

[37] In accordance with Article 32c(2) of the GFL Regulation.

[38] 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 the Decision of the Executive Director of EFSA laying down the practical arrangements concerning transparency and confidentiality (EFSA, 2021c), respectively.

2.10. Scientific risk assessment process

After having notified the applicant that the application is considered valid for the scientific risk assessment, the clock to perform the risk assessment starts in accordance with the specific timelines (between 3 to 12 months unless otherwise negotiated with the requestor as per specific regulatory framework), the procedures laid down in each sectoral legislation and EFSA's standard operating procedures, which are published on EFSA's website.[39] The Scientific Committee, Scientific Panel, its working groups, and scientific staff allocated to the application commence the scientific evaluation in accordance with the requirements of the sectoral legislations and relevant EFSA's guidance documents.

2.11. Suspending/extending[40] the scientific risk assessment process

EFSA, its Scientific Committee, Scientific Panel(s) and/or working groups assess all information and data provided in the application in line with the requirements defined in each sectoral legislation and in EFSA's guidance documents.

During the risk assessment process, and when it is contemplated by the applicable legal framework, EFSA may request the applicant to supplement the information provided within a given time period specified by EFSA (request of additional/supplementary information). The indicative timelines for submitting additional/supplementary information to EFSA during the risk assessment are provided in Annex A – of this Administrative guidance. In such case, the scientific risk assessment process is put on hold ('stop-the-clock' procedure) until the requested additional/supplementary information is supplied by the applicant. The timeline to adopt the scientific output is postponed accordingly. Depending on each sectoral legislation, EFSA may extend the time limit for the scientific risk assessment, provided that an explanation for the delay has been supplied by the applicant and communicated to the European Commission and the Member States.

Annex A –on 'Indicative timelines for submitting additional or supplementary information to EFSA during the risk assessment process of regulated products (update 2021)' applies to all areas of regulated products[41] except re-evaluation of food additives.

To increase efficiency, when requesting additional/supplementary information, EFSA

- strives to group together requests for additional/supplementary information or clarifications regarding the same applications which are addressed to the same recipient;
- clearly formulates the questions and provides background explanation and justifications, the contact point responsible in EFSA for the application and the respective contact details;
- clearly specifies the deadline by which the applicant should provide the requested information to EFSA, including the consequences of the failure to such demand, and the means to object, or challenge EFSA's request;
- records (when applicable) the justification provided by the applicant in support to its request for extending the deadline to submit additional/supplementary information;
- when permitted under the applicable legal framework, accepts the request of extension of the deadline if duly justified and informs all relevant actors if the expected timeframe for completing the evaluation of the application is subject to change.

After receiving a request for additional/supplementary information or clarifications by EFSA and before submitting the response, the applicant can ask EFSA to organise a teleconference[42] to clarify the questions raised by EFSA.

[39] https://www.efsa.europa.eu/en/corporate/pub/sops
[40] For all specific regulatory framework, the deadline is extended. According to Article 10(2) of Regulation No (EC) 1935/2004, and Article 8(2) of Regulation (EC) No 2065/2003, the deadline is suspended.
[41] For pesticides it includes only the timelines for requesting additional studies on endocrine properties, in view of the new data requirements linked to the determination of endocrine disrupting properties under Regulation (EU) 2018/605.
[42] See Section 2.3.1 of EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products (EFSA, 2021a).

The provisions on notification of studies, (see Section 2.5) as well as the provisions on confidentiality and proactive disclosure of the information (see Sections 2.8 and 2.9) fully apply to the submission of additional/supplementary information requested during the risk assessment.

If during the risk assessment, 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-limits within which EFSA is required to deliver its scientific output is suspended, pending the provision of valid justifications.

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 until six months after the submission of any missing data relating to any supporting studies.[43]

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

2.12. Restarting the scientific risk assessment process

Upon upload of the additional/supplementary information or clarifications, the e-submission system notifies the upload of the information.

The scientific risk assessment re-starts ('re-start the clock') on:

- the date of the upload of the additional/supplementary information or clarifications. In case several questions were collected in one request, the clock re-starts only when all questions have been addressed and uploaded. The applicant is encouraged to upload all the requested information at the same time. EFSA aims to check compliance with the above criteria within 5 working days, before restarting the clock as of the date of upload of the additional/supplementary data[44]; or
- the date when EFSA receives notification by the applicant that the pending information will not be submitted; or
- the deadline given to the applicant to submit the requested information, in cases when it has not been provided and the applicant has not notified EFSA of intentions; or
- the deadline to re-start the clock specified in the sectoral legislation, when applicable.

Once the clock of the assessment is re-started, the scientific evaluation continues in accordance with the specific timelines and procedure. This is without prejudice to the need for further additional/supplementary information or clarifications that may be identified after the risk assessment restarts and during the scientific evaluation of the application and/or of the additional/supplementary information or clarifications provided.

In case the applicant does not provide the requested additional/supplementary information or clarifications or provides inadequate information, EFSA does not reiterate already formulated requests and does not ask for the same information a second time.

Once the clock is re-started, EFSA, its Scientific Committee, Scientific Panel and/or working groups complete the scientific risk assessment in a timely manner based on the information available. The status of the application is updated accordingly in the e-submission system and in the OpenEFSA portal.

[43] In accordance with Article 32b(6) of the GFL Regulation.

[44] In case EFSA considers the submission incomplete, 'questions for further clarifications' are posed to the applicant and the clock remains on hold.

In case the EFSA staff, Scientific Committee, Scientific Panel or its working groups need further clarifications on an application or on submitted additional/supplementary information, EFSA may decide to invite the applicant for an applicant's hearing.[45] 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 application.

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

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

The provisions on notification of studies, (see Section 2.5) as well as the provisions on confidentiality and proactive disclosure of the information (see Sections 2.8 and 2.9) fully apply to spontaneous submission of information.[46]

2.14. Audit of Good Laboratory Practices studies

EFSA implements a standard procedure[47] in the framework of its Quality system and selects on a yearly basis Good Laboratory Practices (GLP) studies submitted in new and on-going applications for regulated products for surveillance audits by the Monitoring Authorities in Member States of the European Union. Studies from all applications for regulated products are considered, independently of the legal requirements of the sectoral legislations. Two types of audit can be requested: a surveillance study audit[48] and a triggered study audit.[49]

2.15. Concluding the scientific risk assessment process

On the basis of the information available in the application and in the additional/supplementary information or clarifications provided by the applicant, and taking into account the relevant comments collected during public consultation with third parties, EFSA aims to finalise the scientific risk assessment of a regulated product application within the timeline specified by each sectoral legislation.

EFSA aims to clearly indicate the sources of the information it relied on during the risk assessment and the conclusions reached by EFSA's experts. When concluding the evaluation process, EFSA addresses the terms of reference, clearly stating if EFSA identified a safety concern.

The draft scientific output is presented for possible adoption at relevant Scientific Committee or Panel plenary meeting. The draft agenda of the plenary meeting is published on EFSA's website before the starting date of the plenary.

After adoption of the scientific output, the applicant is notified.[50]

The status of the application is updated accordingly in the e-submission system and in the OpenEFSA portal, showing that the risk assessment is finalised.

[45] See Section 2.3.3 of EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products (EFSA, 2021a).
[46] Spontaneous submissions are proactively disseminated to the extent they are accepted by EFSA for use in the risk assessment.
[47] https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/SOP-022_S.pdf
[48] Surveillance study audit is an audit that is part of a planned routine GLP inspection.
[49] Triggered study audit is a special audit triggered by specific concerns identified upon submission of an application.
[50] See Section 2.3.4 of EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products (EFSA, 2021a).

2.16. Withdrawal of applications

In line with each sectoral legislation, an applicant may withdraw an application at any time. An application is considered withdrawn from the moment the authority that received the initial application (the competent authority of a Member State or the European Commission) is notified of the withdrawal. Without prejudice to the requirements of the relevant vertical legislation, once the request of withdrawal of the application is submitted, all relevant actors involved are notified.

When an applicant withdraws its application prior to the adoption of a confidentiality decision (see Section 2.8 and EFSA, 2021c) 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, 2021c), 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.

The status of the application is updated accordingly in the e-submission system and in the OpenEFSA portal.

2.17. Pre-publication notification of the adopted scientific output

At least 36 hours prior to publication, unless specified differently in the sectoral legislation, EFSA staff informs, under embargo, the applicant[51], the European Commission and other stakeholders of the upcoming publication of the scientific output adopted by EFSA's Panel.

EFSA also provides the (full) copy of the adopted scientific output and when applicable, the version of the scientific output not disclosing information to which confidential status was awarded by the European Commission, EFSA or the responsible Member State.

The pre-notification aims at informing in a timely manner the applicant, the European Commission and other selected stakeholders of the upcoming publication of the adopted scientific output on EFSA's website.

2.18. Publication of the scientific output

The scientific opinions, technical reports and other outputs related to the risk assessment of an application for regulated product, substance, claim, organism or process aim to be published within 28 working days after the adoption.

The outputs are published on EFSA's website or on its Scientific Journal in a version not disclosing the items to which confidential status was awarded by the European Commission, EFSA or the responsible Member State. Should the scientific output 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 concerning confidentiality and transparency (EFSA, 2021c), EFSA will have to review the initial confidentiality decision in accordance with Article 39c of the GFL Regulation.

2.19. EFSA's inconclusive scientific output

EFSA can adopt a scientific output which is inconclusive in relation to certain aspects of the risk assessment. The applicant may submit complementary information in order to complete the assessment and to allow the publication of an EFSA scientific output in relation to specific aspects the relevant Panel could not conclude on. In such case, the European Commission may mandate EFSA under the specific

[51] See Section 2.3.5 of EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products (EFSA, 2021a).

vertical legislation and/or under the GFL Regulation to issue a new scientific output based on the complementary information received.[52]

The mandate is allocated to a Scientific Panel or Scientific Committee and respective Scientific Unit taking in due account Article 28 of the GFL Regulation. The deadline is negotiated.

Once the risk assessment on the complementary information is finalised, EFSA issues a new scientific output in accordance with the terms of references defined in the request.

The provisions on notification of studies (see Section 2.5) as well as the provisions on confidentiality and proactive disclosure of the information (see Sections 2.8 and 2.9) fully apply to the submission of complementary information following an inconclusive EFSA scientific output.

[52] The legal basis for the request sent by the European Commission to EFSA in view of a new opinion based on the submitted complementary information is Article 29(1)(a) of the GFL Regulation.

References

EFSA (European Food Safety Authority), 2021a. EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products. EFSA Supporting Publication 2021:EN-6472. 36 pp. doi:10.2903/sp.efsa.2021.EN-6472

EFSA (European Food Safety Authority), 2021b. 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), 2021c. 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

Definitions

Additional/Supplementary information or clarifications: Information, including studies, that EFSA deems to be needed to be able to conclude on the evaluation of an application. This is in addition to the information initially submitted in the technical dossier. Such information, studies or clarifications have to be submitted in response to a formal request from EFSA to the applicant during the scientific assessment.

Applicant: any legal or natural person (e.g. individuals, food business operators, industry associations, consultancy companies) irrespective of his/her residence, who has submitted an application for the authorisation or a notification of a product, substance, claim, organism or process in the European Union which may lead to a scientific evaluation by EFSA.

Application: a formal request for authorisation of a regulated product submitted to the risk managers (European Commission or to a competent authority of a Member State depending on each sectoral legislation). Such request is supported by a technical dossier prepared by the applicant and evaluated by EFSA upon request from the risk managers.

Competent Authority: Any regulatory body in a Member State authorised by the European Member State government to monitor the compliance with regulations and carry out the tasks on behalf of the government in compliance with the relevant EU food law.

Completeness check: Verification of the completeness of the information in the submitted technical dossier performed by EFSA after the receipt of an application[53], under the relevant EU legislation.

Database of study notifications: EFSA's database of studies commissioned or carried out by business operators to support applications for regulated products in relation to which Union law contains provisions for EFSA to provide a scientific output, including a scientific opinion.

Mandate: Request for scientific advice, scientific or technical assistance addressed to EFSA.

Member State: for the purpose of this document, it is meant as a Member State of the European Union or a third country having signed an agreement pursuant to Article 49 of the GFL Regulation.

Missing information: Information missing from the submitted technical dossier as required in the sectoral legislation and guidance documents of EFSA. In the absence of such information (identified during the completeness or suitability check performed by EFSA) a technical dossier cannot be considered complete for the risk assessment.

Requestor: The European Commission, the European Parliament or a Member State of the European Union pursuant to Article 29(1) of the GFL Regulation.

E-submission system: The European Commission e-submission system used for the submission of the application as well as exchanges of information on applications for regulated products between EFSA, European Commission, Member States and applicants as of 27 March 2021 following entry into force of the Transparency Regulation.

Regulated products: regulated products include substances used in food and feed (such as additives, enzymes, flavourings, nutrient sources), novel foods, infant formulae, food contact materials and pesticides, genetically modified organisms, processing aids. EFSA's regulated products mandate also includes evaluating the scientific substantiation of nutrition and health claims.

Risk managers: Risk managers are the European Commission, Member State authorities and the European Parliament. They are responsible for making decisions or setting legislation about food safety.

Risk/scientific assessment process: Scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation, pursuant to Article 3(11) of the GFL Regulation.

[53] For applications on new food additives, food flavourings and food enzymes submitted under Regulation (EC) No 1331/2008 and for applications on novel foods submitted under Regulation (EU) 2015/2283, EFSA carries out a suitability check instead of a completeness check.

Spontaneous information: Information or data, including studies or clarifications, that are spontaneously submitted by the applicant or other interested parties without a request from the Authority.

Study: an experiment or set of experiments in which a test item is examined under laboratory conditions or in the environment to obtain data with respect to the properties and/or the safety of that test item, which is relevant for submission to appropriate regulatory authorities.

Suitability check: Verification of the suitability of the information in the submitted technical dossier performed by EFSA after the receipt of an application under Regulation (EC) 1331/2008 for new food additives, food flavourings, food enzymes and under Article 10 of Regulation (EU) 2015/2283 for applications on novel foods.

Technical dossier: Compilation of scientific information underpinning applications for regulated products, substances, claims, organisms and processes in accordance with the applicable sectoral legislation and guidance documents of EFSA.

Valid application: Application which after a completeness/suitability check is found complete and suitable for risk assessment, and following formal declaration by the European Commission or EFSA[54] enters the risk assessment phase.

[54] Depending on the applicable sectoral legislation.

Useful links

- EFSA scientific outputs:
  http://www.efsa.europa.eu/en/publications
- EFSA Journal:
  http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)1831-4732
- EFSA's Practical Arrangements:
  https://www.efsa.europa.eu/en/corporate/pub/tr-practical-arrangements
- Applicant toolkit:
  https://www.efsa.europa.eu/en/applications/toolkit
- EFSA webpage on scientific work:
  https://www.efsa.europa.eu/en/scientific-work
- EFSA webpage on Biological hazard applications:
  https://www.efsa.europa.eu/en/applications/biologicalhazard
- EFSA webpage on Feed additive applications:
  https://www.efsa.europa.eu/en/applications/feedadditives
- EFSA webpage on Food contact material applications:
  https://www.efsa.europa.eu/en/applications/foodcontactmaterials
- EFSA webpage on Food improvement agent applications:
  https://www.efsa.europa.eu/en/applications/food-improvement-agents
- EFSA webpage on Genetically modified organism applications:
  https://www.efsa.europa.eu/en/applications/gmo
- EFSA webpage on Nutrition applications:
  https://www.efsa.europa.eu/en/applications/nutrition
- EFSA Standard Operating Procedures:
  http://www.efsa.europa.eu/en/corporate/pub/sops
- EFSA Procedures:
  http://www.efsa.europa.eu/en/about/corporatedocs
- Working groups and networks:
  http://www.efsa.europa.eu/en/science/wgs-and-networks
- 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
- OpenEFSA portal:
  https://open.efsa.europa.eu

Abbreviations

APDESK	EFSA Applications Desk
MS	Member State
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
GFL	General Food Law
GLP	Good Laboratory Practices
GPSA	General pre-submission advice
RPSA	Renewal pre-submission advice

Annex A – Indicative timelines for submitting additional or supplementary information to EFSA during the risk assessment process of regulated products (updated in 2021)

Annex A can be found in the online version of this output under **'Supporting Information'** section: https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/sp.efsa.2021.EN-6471