

INFO SHEET

HOW TO SUBMIT AN APPLICATION UNDER THE NOVEL FOOD AUTHORISATION PROCEDURE

✚ [REGULATION \(EU\) 2015/2283 OF 25 NOVEMBER 2015](#) sets out the requirements for the placing of ‘novel food’ products on the EU market: notably these requirements concern the content of the application for authorisation which applicants must conform with and the procedural steps to be followed by the EC, the EU Member States and the EFSA in the authorisation process.

✚ The different steps of the authorisation procedure are laid down in **chapter III of Regulation (EU) 2015/2283**.

1. WHO CAN SUBMIT AN APPLICATION FOR THE AUTHORISATION OF AN EDIBLE INSECT NOVEL FOOD?

✚ The definition of ‘placing on the market in the ‘General Food Law’ (i.e. [REGULATION \(EC\) NO 178/2002 OF 28 JANUARY 2002](#)), provides ‘indications’ on those actors whom the legislator sees as responsible for applying for authorisation, namely the first food business operator that places a novel food on the EU market (i.e., the first actor in the supply chain). Consequently, the main responsibility of submitting applications will generally lie on the insect primary producers (breeders and primary processors), as they determine the composition / intrinsic characteristics of the product that forms the subject matter of the application.

- ✚ The actors who have submitted applications so far are mostly insect primary producers/insect breeders who sell insects as ‘ingredients’ (e.g. whole insects or insect meal) to a subsequent processor (operators involved in the preparation of insect-based ingredients or end-consumer products) and/or directly to consumers through an intermediary or distributor. However, several applications were also submitted by national associations.

2. OPERATORS’ RESPONSIBILITIES FOR SUBMITTING AN APPLICATION FOR AUTHORISATION OR INITIATING A NOTIFICATION UNDER REGULATION 2015/2283

- ✚ The responsibility for submitting a novel food application or initiating a Notification Procedure primarily lies on actors ‘placing the novel food on the market’.
- ✚ The definition of ‘placing on the market’ provides indications on those actors on whom the responsibility for applying for authorisation mainly lies. The first food business operator that places a novel food on the EU market is required to initiate the appropriate steps towards approval of that product, irrespective of whether the product is intended to be reused, incorporated into a final product, or further processed by a subsequent food business operator further down the supply chain.

3. “INSTITUTIONAL” APPLICANTS

- ✚ The definition under Article 3(2)(d) of Regulation (EU) 2015/2283 entails that EU Member States authorities may assist companies that are active in the production of the same species, to prepare and submit an application on their behalf. This type of approach could be envisaged for example where insect products originating from several different insect producers are concerned, provided that these products originate from the same insect species and have similar intrinsic characteristics. This approach would then lead to a joint application.

- ✚ In practice, this option of a joint application led by an authority however seems more relevant in the case of a third country seeking authorisation through the notification procedure (as per Article 14 of Regulation (EU) 2015/2283). Indeed, national authorities in those countries where insects are traditionally consumed (e.g. South East Asia, African countries, Mexico) are sometimes ‘better placed’ than operators themselves - who very often are ‘micro scale’ farmers - to gather, collect, aggregate and analyse the data required for the compilation of the notification dossier.
- ✚ The European Commission has a right of initiative for the authorisation and update of authorisation of novel foods. For example, the Commission may deem it appropriate to amend a specific authorisation in consideration of public safety concerns. In such cases it is entitled to initiate a process towards amendments to the list of authorised Novel Food products.

4. ‘NON-INSTITUTIONAL’ APPLICANTS

- ✚ Any legal or natural person may be an applicant under Regulation (EU) 2015/2283. In particular, the regulation does not require that an applicant is established in the EU to the purpose of seeking an authorisation or submitting a notification. In practice, applicants may be food business operators, consultants, counsels, industry associations or any other natural or legal person.
- ✚ Applications can be filed by single applicants, or jointly by several applicants, e.g. a joint application could be submitted on behalf of several producers that are active in the production of the same product. The text of Regulation (EU) 2015/2283 leaves freedom for operators how to organise their collaboration. In practice, any form of ‘horizontal’ structure gathering several insect primary producers of the same species or ‘vertical’ forms of collaboration, congregating actors at different stages of the production chain (e.g. primary producers, processors, and retailers) is possible, and the choice of the legal form to use (e.g. joint venture, consortia, non-profit organisation or registered company) is also left to the interested parties’ discretion.

- ✚ It is also advisable to restrict the ambit of the application to one single insect species. Furthermore, one of the practical challenges that these actors will need to address is the precise characterisation of the product(s) that form(s) the subject matter of their application.
- ✚ A particular attention will need to be reserved in that context for the production conditions and production processes used, as recorded in the product specifications. At the same time, these operators will need to demonstrate that their products have ‘similar characteristics’ and/or are produced under ‘similar conditions’.
- ✚ Other points of attention for operators intending to proceed with a joint application include - without limitation- the cost and profit sharing, confidentiality, regulatory data protection, and antitrust compliance.

5. CONTENT OF THE APPLICATION FOR AUTHORISATION (‘STANDARD’ PROCEDURE)

5.1. PRE-SUBMISSION ADVICE

- ✚ The [Transparency Regulation](#) inserted a new provision in [the General Food Law](#) (article 32a) concerning pre-submission advice. Since 27 March 2021, where EU law, such as the EU legislation on novel foods, contains provisions for the EFSA to provide a scientific output, potential applicants have the possibility to request general pre-submission advice (GPSA) from EFSA before submitting an application, but requesting GPSA is not mandatory. It should be noted that the scope of the GPSA is limited and mainly relates to the:
 - Applicable rules on the application procedure;
 - Required content for application. A GPSA can for example be used to seek clarifications as to the information requirements that need to be met by an application for authorisation related to an insect species or an insect-based ingredient as a novel food.

5.2. THE GPSA CAN HOWEVER NOT BE USED TO SEEK ADVICE REGARDING THE FOLLOWING:

- ✚ 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. Such advice provided by the staff of the EFSA is without prejudice and non-committal as to any subsequent assessment of applications by the Scientific Panels. This means that if insect operators request GPSA, this advice will not be binding, but it will rather have a guiding effect.
 - EFSA recommends that requests for GPSA are submitted at least six months prior to the envisaged submission date for the application.
 - Before submitting any GPSA request, applicants need to register through EFSA's website and obtain a pre-application ID which must be included in the application.
- Subsequently, the request must be submitted to EFSA by filling in a form that is available on the agency's website: <https://www.efsa.europa.eu/en/applications/toolkit>.
- For more information please refer to chapter 2.1. "General pre-submission advice" of EFSA's "Administrative guidance for the preparation of applications on novel foods pursuant to Article 10 of Regulation (EU) 2015/2283", which can be found here: <https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/sp.efsa.2021.EN-6488>

- Furthermore, Chapters II, III and IV of the Decision of the Executive Director of the EFSA laying down practical arrangements for the pre-submission phase and public consultations provide further guidance. This decision can be consulted here: https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAspre-submission-phase-and-public-consultations.pdf.

6. OVERALL STRUCTURE OF THE DOSSIER AND ADMINISTRATIVE REQUIREMENTS

- ✚ While article 10(2) of Regulation (EU) 2015/2283 sets out the main components of an application for authorisation, [“IMPLEMENTING REGULATION \(EU\) 2017/2470”](#) (more specifically, Articles 3 and 4 thereof) singles out more precisely the main elements to be included in the application.

Implementing Regulation (EU) 2017/2469 - Article 3 - Structure, content, and presentation of an application

1. An application shall be submitted electronically to the Commission and shall consist of the following:

- (a) a cover letter;
- (b) a technical dossier;
- (c) a summary of the dossier.

2. The cover letter referred to in paragraph 1

- (a) shall be drafted in accordance with the template provided in Annex I. 3.

The technical dossier referred to in paragraph 1(b) shall contain:

- (a) the administrative data as provided in Article 4;
- (b) the scientific data as provided in Article 5.

7. NOTIFICATION OF STUDIES

- ✚ The Transparency Regulation inserted a new article 32b in the General Food Law, that relates to the notification of studies. Potential applicants commissioning or carrying out studies as of 27 March 2021 to support an application covering insects or insect-based foods have an obligation to notify EFSA without delay before the starting date of such study.

7.1. THE FOLLOWING INFORMATION HAS TO BE NOTIFIED TO THE AGENCY:

- ✓ Title and scope of study
 - ✓ Laboratory or testing facility
 - ✓ Starting and planned completion dates of the study
- ✚ The same obligation applies to the laboratories and other testing facilities located in the EU for studies commissioned by potential applicants and carried out by such laboratories and other testing facilities.
- Notifications must be submitted in the database of study notifications available on the following website: www.efsa.europa.eu/en/applications/toolkit.
 - Applicants should be aware that non-compliance with the notifications of study obligations may result in the non-validity of the application or in delays in the risk assessment process.
 - For more information please refer to 2.2 (“Notification of studies”) of EFSA’s “Administrative guidance for the preparation of applications on novel foods pursuant to Article 10 of Regulation (EU) 2015/2283” (see: Administrative guidance for the preparation of applications on novel foods pursuant to Article 10 of Regulation (EU) 2015/2283).

- Further guidance can also be found in the Decision of the Executive Director of the EFSA laying down practical arrangements for the pre-submission phase and public consultations provide further guidance.
 - https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf

7.2. SCIENTIFIC DATA REQUIREMENTS

“IMPLEMENTING REGULATION (EU) 2017/2469”, Article 5, defines the scientific data requirements to be included in the application for authorisation:

- ✓ The dossier submitted in support of an application for the authorisation of a novel food shall enable a comprehensive risk assessment of the novel food. (...)
- ✓ The applicant shall provide a copy of the documentation on the procedure and strategy followed when gathering the data.
- ✓ The applicant shall provide a description of the safety evaluation strategy and the corresponding toxicological testing strategy and shall justify the inclusion or exclusion of specific studies or information.
- ✓ The applicant shall provide on request the raw data for the individual studies, published and unpublished, undertaken by the applicant, or on their behalf, to support their application. This information includes data used to generate the conclusions of the individual studies and the results of examinations.
- ✓ Where it cannot be excluded that a novel food intended for a particular group of the population would be also consumed by other groups of the population the safety data provided shall also cover those groups.

- ✓ For each biological or toxicological study, the applicant shall clarify whether the test material conforms to the proposed or existing specification. Where the test material differs from that specification, the applicant shall demonstrate the relevance of those data to the novel food under consideration.
 - i. Toxicological studies shall be conducted in facilities which comply with the requirements of Directive 2004/10/EC or, if they are carried out outside the territory of the Union, they shall follow the OECD Principles of Good Laboratory Practice.
 - ii. The applicant shall provide evidence of compliance with those requirements and shall justify any deviation from the standard protocols.
- 8. The applicant shall propose an overall conclusion on the safety of the proposed uses of the novel food.
- iii. The overall evaluation of potential risk to human health shall be made in the context of known or likely human exposure.

8. PROVISION OF EVIDENCE SUBSTANTIATING THE ABSENCE OF SAFETY RISKS

<u>Regulation (EU) 2015/2283 - Article 10(2), (c) and (e)</u>
<p>“2. The application for an authorisation shall include: [...]</p> <ul style="list-style-type: none">• (c) the description of the production process(es); [...]• (e) scientific evidence demonstrating that the novel food does not pose a safety risk to human health;”

8.1. THE PRODUCTION PROCESS(ES) USED TO PRODUCE THE NOVEL FOOD HAS/HAVE TO BE DESCRIBED

IN THE CASE OF INSECT PRODUCTS, ALL MEASURES IMPLEMENTED FOR PRODUCTION CONTROL AND QUALITY AND SAFETY ASSURANCE SHOULD BE DESCRIBED (E.G. HACCP, GMP, ISO):

- ✚ Notably, a production flow chart may be provided, including quality and safety control checks. Adherence to recognized professional guides of good hygiene practices are also a critical element to substantiate product food safety.
- ✚ The Scientific Opinion that EFSA published on 8 October 2015 on the risk profile related to production and consumption of insects as food and feed⁴ identified the production conditions, including inputs during production, as main determinant of potential hazards (e.g. biological and chemical contaminants) for the use and consumption of insects. An express reference to this Scientific Opinion is made in the EFSA Guidance on Applications for Authorisation, in the following terms:

“The EFSA Scientific Committee has identified potential hazards related to the use of farmed insects as food (EFSA Scientific Committee, 2015). These should be considered in applications for novel foods which consist of, are isolated from, or are produced from farmed insects, taking into account the species and substrate to be used, as well as methods for farming and processing. Insects collected from the wild may bear additional biological and chemical hazards which should be considered and addressed.”

- For more information, please consult the [‘IPIFF report on approaches to addressing data requirements for insects as novel food’](#).

9. CONDITIONS OF INTENDED USES, PRODUCT SPECIFICATIONS AND LABELLING REQUIREMENTS

- ✚ Besides the ‘scientific demonstration’ (see above), the novel food specifications or ‘conditions of intended use’ constitute another key element to be included in the application for authorisation. These specifications form a crucial component of the subsequent novel food authorisation and are specified in the Union list of novel foods.

Article 10(2)(g) of Regulation (EU) 2015/2283 sets out these elements:

“2. The application for an authorisation shall include: [...] g) a proposal for the conditions of intended use and for specific labelling requirements which do not mislead the consumer or a verifiable justification why those elements are not necessary.”

- ✓ Careful consideration should be given by the applicant to the framing of the conditions of intended uses in order to ensure that they are representative enough of the product to be placed on the European Union market and that they cover all intended uses of the product for which an authorisation is sought by the applicant.
- ✓ Any authorisation results in the inclusion of the authorised product in the Union list of novel foods, along with relevant product specifications that are listed in Table 2 of the Annex to Implementing Regulation (EU) 2017/2470.
- ✓ Based on the compositional data relating to the novel food, the specifications may notably include a description of the novel food and set out limits for relevant parameters.

9.1. IN THE CASE OF INSECT PRODUCTS, THESE SPECIFICATIONS ARE LIKELY TO INCLUDE:

- ✚ The concentrations of the main constituents in products (compositional requirements); • microbiological criteria (most likely in range values);
- ✚ Limits for impurities and degradation products (e.g., residues levels from chemical and biological contaminants that may originate from the substrate used or manufacturing practices) that may be present in the final product.
- ✚ However, according to current exchanges with the EC, no references to the production processes nor specific substrate use criterias would be included in the authorised product specifications.
- ✚ These may also include a precise description of good farming/production and hygiene practices to be followed by producers if the risk assessment concludes that these are necessary to achieve a high level of food safety for the final product.
- Compliance with the above conditions may notably be verified by Member States authorities in the context of official controls in relation to the applicant's product, but also in relation to products marketed by other operators relying on the same authorisation.

10. DESCRIPTION OF THE FOOD CATEGORIES FOR WHICH A NOVEL FOOD AUTHORISATION IS SOUGHT

- ✚ It is important to note that any applicant is required, both in the ordinary authorisation route and the Notification Procedure, to indicate the food categories for which the use is requested (hereafter, the “food uses”), along with a proposal for the conditions of the intended use of the novel food (See Articles 10(2)(g) and 14(f) of Regulation (EU) 2015/2283 and Annex I of Implementing Regulation (EU) 2017/2469 and Annexes I and II of Implementing Regulation (EU) 2017/2468). As regards the requested food uses, it is recommended to make use of the EFSA Food Classification system FoodEx2.
- ✚ Any novel food authorisation or notification will be valid only for the food uses requested by the applicant. This means that food uses that are not listed in the approved application or notification will not be covered by this application or notification. In case an operator seeks to commercialise a product for food use that is not covered it will need to obtain an extension of the existing.
- ✚ In practice, joint applications submitted on behalf of producers that are vertically integrated into the same structure (i.e., at different stages of production) are likely to offer valuable opportunities to tackle such situations, as insect users may anticipate and bring in food uses envisioned by insect users directly into the first, joint application.

11. EFSA ADMINISTRATIVE GUIDANCE FOR THE PREPARATION OF APPLICATIONS ON NOVEL FOODS

- ✚ The document provides administrative guidance on the preparation and submission of new applications or modifications of an existing authorisation of a novel food in the European Union. It applies to all applications submitted as of 27 March 2021. For applications submitted before that date, the previous version of the guidance applies.

- ✚ The document provides guidance to applicants submitting applications on novel foods in the European Union, which are to be evaluated by EFSA. It describes the administrative requirements for the preparation and online submission of the dossier to support an application pursuant to Article 10 of Regulation (EU) 2015/2283 such as timelines, language requirements, requirements on the structure of the dossier, etc. Annex A and B of the guidance furthermore contain a reference to the ‘completeness checklist’ and ‘summary tables’:
 - ✓ **Completeness checklist** - which refers to the data requirements for the application. The applicant should use the checklist to verify the completeness of the data for risk assessment in the technical dossier. It should be filled in and submitted using a common word processing format (e.g. MS Word). EFSA will use the completeness checklist provided by the applicant in its technical dossier to check the completeness of the data.

 - ✓ **Summary tables:** The applicants are encouraged to use the summary tables in order to summarise the results of the scientific studies provided in the technical dossier. These tables represent an example for the presentation of scientific data. The adherence to the common format will facilitate EFSA to carry out the risk assessment.

- ✓ EFSA strongly recommends the use of the completeness checklist and summary tables when preparing an application for novel food and to upload the two documents as other relevant information through the EC e -submission system. The documents can be accessed through this link: <https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/sp.efsa.2021.EN-6488> (under 'Supporting Information').

12. STAND-ALONE EVALUATION VS. GROUPED AUTHORISATION

- ✚ Article 2 of Implementing Regulation (EU) 2017/2468 and Article 2 of Implementing Regulation (EU) 2017/2469 define the concepts of 'notification' and of 'application'.

IMPLEMENTING REGULATION (EU) 2017/2469 - ARTICLE 2

“application’ means a stand-alone dossier containing the information and the scientific data submitted for the authorization of a novel food pursuant to Article 10(1) of Regulation (EU) 2015/2283.”

IMPLEMENTING REGULATION (EU) 2017/2468 - ARTICLE 2

“(a) ‘notification’ means a stand-alone dossier containing the information and the scientific data submitted in accordance with Article 14 of Regulation (EU) 2015/2283. (b) ‘application’ means a stand-alone dossier containing the information and the scientific data submitted in accordance with Article 16 of Regulation (EU) 2015/2283.”

- ✚ The fact that an application or, where relevant, a notification constitutes a stand-alone dossier, means that each scientific evaluation conducted by EFSA is specific to the concerned product, based on the information and scientific data provided in the corresponding dossier submitted in support of the notification or the application for authorisation.

- ✚ This article finds its relevance if two or more applications covering the same insect species are being examined at the same time. In that case, each application will be evaluated individually and separate decisions to authorise the product as novel food shall be taken based on the information and scientific evidence provided in each application.

- ✚ However, cross-references between applications may be considered when evaluating information and evidence that are equally relevant to all products being evaluated (generic published study substantiating the safety of insects for human consumption - e.g. nutritional information history of safe use, allergenicity). Such cross-references will however be possible only where the concerned information does not benefit from regulatory data protection.

- ✚ Furthermore, all products authorised and covering the same insect species may be recorded into one single entry within the Union list of novel foods. This entry would in such cases encompass common specifications applicable to all respective products authorised.