TECHNICAL REPORT

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Administrative guidance on the submission of applications for authorisation of a novel food pursuant to Article 10 of Regulation (EU) 2015/2283

European Food Safety Authority

Abstract

This document provides guidance on the submission of applications for authorisation of a novel food in the European Union within the scope of Article 10 of Regulation (EU) 2015/2283 and according to Commission Implementing Regulation (EU) 2017/2469. The guidance is currently composed of a completeness checklist which reflects the data requirements for applications on novel foods, as outlined in the EFSA 'Guidance on the preparation and presentation of an authorisation of a novel food in the context of Regulation (EU) 2015/2283' and four tables on the scientific studies provided in the technical dossier. EFSA recommends applicants to use the completeness checklist and the summary tables during the preparation of a technical dossier on novel foods to ensure that the criteria for the completeness of the data for risk assessment are met. The information contained in this document only applies to applications submitted under Article 10 of Regulation (EU) 2015/2283.

Key words: Application, submission, completeness check, novel foods, Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2469

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Table of contents

Introduction

Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods constitutes the legal basis for the authorisation of novel foods in the European Union (EU). It lays down specific measures as regards the presentation of applications and the type of information that should be included in the opinion of the European Food Safety Authority (EFSA). The implementing measures concerning the content, drafting and presentation of an application, arrangements for verifying the validity of an application and the type of information that should be included in the opinion of EFSA are laid down in Commission Implementing Regulation (EU) 2017/2469.

This document applies to applications for authorisation of a novel food falling under the scope of Article 10 of Regulation (EU) 2015/2283 and Commission Implementing Regulation (EU) 2017/2469. This guidance is to be read in conjunction with the above mentioned Regulations. In case of discrepancy between the content of this document and a provision of an applicable legal act, the latter prevails.

With the introduction of Regulation (EU) 2015/2283 on novel food as of 1st January 2018, several documents have been published to assist applicants in the preparation of an application.

- EFSA has issued the 'Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283'[1] to assist applicants in the preparation of the scientific data for the risk assessment of novel foods.
- The European Commission (EC) has developed an e-submission platform and a user guide[2] to help applicants submitting applications through the EC e-submission system.

To complement these documents and to better support applicants in the preparation of applications on novel foods, EFSA has developed this administrative guidance, currently composed of:

- a completeness checklist -Appendix A- that the applicant should use 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.
- four summary tables -Appendix B- that the applicant is encouraged to use 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 presented in Appendix B will facilitate EFSA to carry out the risk assessment.

EFSA strongly recommends applicants to use both the completeness checklist and the summary tables when preparing an application for novel food and to upload Appendices A and B as other relevant information through the EC e-submission system.

The publication of this document occurs in the context of the EFSA project on a customer-oriented approach for regulated products[3] aiming at supporting applicants and other stakeholders during the whole life-cycle of the applications for regulated products[4].

For the purpose of this document, an "applicant" shall mean any legal or natural person (e.g. individuals, food business operators, industry associations, consultancy companies, etc.), no matter whether situated within or outside the EU, which has submitted an application in the context of the above mentioned regulations.

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

[1] http://www.efsa.europa.eu/en/efsajournal/pub/4594
[2] https://ec.europa.eu/food/safety/novel_food/e-submission_en
[3] EFSA REPRO Customer oriented approach mandate:
http://registerofquestions.efsa.europa.eu/roqFrontend/mandateLoader?mandate=M-2014-0106
[4] https://www.efsa.europa.eu/en/supporting/pub/1025e

Appendices

Appendix A - Completeness checklist

The completeness checklist should be submitted through the EC e-submission system using a common word processing format (e.g. MS Word).[5]

The completeness checklist is meant to support applicants in the building up of applications for the authorisation of a novel food according to Regulation (EU) 2015/2283. The completeness checklist follows the sections, headings and numbering detailed in Part 2: Characterisation of the novel food, technical and scientific data included in the 'Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283'[6]. It does not substitute the requirements of the 'Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283'. The completeness checklist will be used by EFSA to verify the completeness of the data for risk assessment presented in the technical dossier.

For each section, applicants can identify which information has been provided or not provided and if not provided, a justification should be included. The definitions of the different options are detailed below:

- **Information provided:** the section/subsection/paragraph is required by the relevant guidelines/guidance and the information is provided by the applicant in the appropriate section/subsection/paragraph of the technical dossier.
- **Not provided (to be justified):** the section/subsection/paragraph is required by the relevant guidelines/guidance but the information is not provided by the applicant in the appropriate section/subsection/paragraph of the technical dossier. A proper justification for the omission of that data needs to be provided in the appropriate section/subsection/paragraph of the technical dossier.

At the end of each section, applicant can add comments in the designated "Comments" box.

All the fields in blue are reserved for EFSA's use.

[5] The word document Appendix A can be downloaded from the section 'Supporting information'
[6] http://www.efsa.europa.eu/en/efsajournal/pub/4594

Appendix A COMPLETENESS CHECKLIST

Name of the substance:

EC application number: NF 201X/0YYY

	PROVIDED	NOT PROVIDED	EFSA AGREES	EFSA COMMENTS
2.1 Introduction				
▪ Description of purpose of the novel food	☐	☐	☐	
▪ Intended use of the novel food	☐	☐	☐	
Comments				

	PROVIDED	NOT PROVIDED	EFSA AGREES	EFSA COMMENTS
2.2 Identity of the novel food (select and fill the relevant of the following novel food classes - all the others to be ignored)				
2.2.1 Chemical substances				
▪ Chemical name (IUPAC)	☐	☐	☐	
▪ CAS number and/or other identification numbers	☐	☐	☐	
▪ Synonyms, trade names, abbreviations	☐	☐	☐	
▪ Molecular and structural formulae, stereochemistry	☐	☐	☐	
▪ Molecular mass (Da)	☐	☐	☐	
2.2.2 Polymers				
▪ Structural formulae of monomers and starting materials	☐	☐	☐	
▪ Reagents involved in the polymerisation	☐	☐	☐	
▪ Structure of the polymer	☐	☐	☐	
▪ Number average molecular weight	☐	☐	☐	
▪ Weight average molecular weight	☐	☐	☐	
▪ Nature and degree of modification of the polymer	☐	☐	☐	
▪ Particle size, shape, distribution	☐	☐	☐	
2.2.3 Foods consisting of, isolated from or produced from microorganisms, fungi or algae				
▪ Scientific (Latin) name (family, genus, species, strain) according to the international codes of nomenclature	☐	☐	☐	
▪ Synonyms that may be used interchangeably with the preferred scientific name	☐	☐	☐	
▪ For algae and fungi, verification of the identity according to internationally recognised databases and methodology	☐	☐	☐	
▪ For bacteria and yeasts (unicellular organisms), verification of the species and strain identity according to internationally accepted methods.	☐	☐	☐	
▪ Origin of the organism	☐	☐	☐	
▪ Deposition in an officially recognised culture collection	☐	☐	☐	

with access number (if available)				
2.2.4 Foods consisting of, isolated from or produced from material of mineral origin				
▪ Chemical name (IUPAC)	☐	☐	☐	
▪ CAS number and/or other identification numbers	☐	☐	☐	
▪ Synonyms, trade names, abbreviations	☐	☐	☐	
▪ Molecular and structural formulae	☐	☐	☐	
▪ Molecular mass (Da)	☐	☐	☐	
▪ Particle size, shape, distribution, crystal form	☐	☐	☐	
2.2.5 Foods consisting of, isolated from or produced from plants or their parts				
▪ Scientific (Latin) name (botanical family, genus, species, subspecies, variety with author's name, chemotype, if applicable) according to the international codes of nomenclature	☐	☐	☐	
▪ Synonyms (botanical name) that may be used interchangeably with the preferred scientific name	☐	☐	☐	
▪ For plants, verification of the identity according to internationally recognised databases and methodology	☐	☐	☐	
▪ Common names (if a trivial or a common name is used, it should be linked to the scientific name and part used)	☐	☐	☐	
▪ Part(s) used (e.g. root, leaf, seed, etc.)	☐	☐	☐	
▪ Geographical origin (continent, country, region)	☐	☐	☐	
2.2.6 Foods consisting of, isolated from or produced from animals or their parts				
▪ Scientific (Latin) name (zoological family, genus, species, subspecies, breed, if applicable)	☐	☐	☐	
▪ Synonyms that may be used interchangeably with the preferred scientific name	☐	☐	☐	
▪ Common names (if a trivial or a common name is used, it should be linked to the scientific name and part used)	☐	☐	☐	
▪ Part(s) used	☐	☐	☐	
▪ Geographical origin (continent, country, region)	☐	☐	☐	
2.2.7 Foods consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, fungi or algae				
▪ Biological source (taxonomic information on family, genus, species, subspecies, variety) according to the international codes of nomenclature	☐	☐	☐	
▪ For plants, algae and fungi, verification of the identity according to internationally recognised databases and methodology	☐	☐	☐	
▪ Organ and tissue or part of the organism sourced	☐	☐	☐	
▪ Laboratory or culture collection sourced	☐	☐	☐	
▪ Information on the identity of cells	☐	☐	☐	

▪ Cell or tissue substrate used as a novel food	☐	☐	☐	
▪ Type of cultures	☐	☐	☐	
2.2.8 Foods consisting of "engineered nanomaterials"				
▪ The applicant is requested to comply with the requirements related to the characterisation of engineered nanomaterials outlined in the "Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain"	☐	☐	☐	

Comments

	PROVIDED	NOT PROVIDED	EFSA AGREES	EFSA COMMENTS
2.3 Production process				
2.3.1 Detailed description of the production process				
▪ Production flow chart (including quality and safety control checks)	☐	☐	☐	
▪ Description of key steps and parameters of the production process -including information on potential by-products, impurities, contaminants, operational limits, measures for production control and quality and safety assurance (e.g. HACCP, GMP, ISO) and standardisation criteria (e.g. chemical markers for the novel food)	☐	☐	☐	
▪ In case a novel process is used, i.e. not used for food production within the Union before 15th May 1997, a detailed characterisation of the novel aspects of the process	☐	☐	☐	
▪ Information on the handling of the sources, e.g. propagation growth, harvesting conditions for plants and fungi (e.g. wild or cultivated, cultivation practices, time of harvest in relation to both season and stage of the plant growth), farm animals (breeding, rearing, feeding, farming conditions), wild living animals (hunting, catching, collecting, killing), culture conditions for microorganisms and algae, cell culture or tissue culture from plants and animals, use of pesticides, antimicrobials and antiparasetic agents (cultivation/rearing)	☐	☐	☐	
▪ Description of post harvesting handling of unprocessed foods and the raw materials for further processing, and the preparation intended for a food product, e.g. transport, drying techniques, storage conditions (duration, light, moisture, temperature)	☐	☐	☐	
▪ Substances used in the manufacturing process, e.g. identity of the extraction solvents, ratio of the extraction solvent to the material, reagents, residues remaining in the final product	☐	☐	☐	
▪ The part of organism used as a raw material and other starting substances or materials	☐	☐	☐	

▪ For novel foods consisting of, isolated from or produced from plant, animal or microbiological sources: a detailed description of the conversion of the raw material to an ingredient or a preparation intended for a food product (e.g. heat treatment, extraction, distillation, squeezing, fractionation, purification, concentration, fermentation, extraction solvents, reagents, residues)	☐	☐	☐	
▪ For novel foods consisting of, isolated from or produced from plants: specific considerations and complementary information should be provided according to the requirements on the description of the manufacturing process outlined in the EFSA "Guidance on safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements"	☐	☐	☐	
▪ For novel foods obtained via chemical synthesis: description of chemical synthesis (reaction sequence, side reactions, purification steps), information on reaction conditions (e.g. reagents, temperature, duration of the reaction, catalyst), information on chemical or physical purification methods (e.g. solvent extraction and crystallisation)	☐	☐	☐	
▪ For novel foods consisting of, isolated from or produced from cell culture or tissue culture: Growth medium and culture conditions	☐	☐	☐	
▪ For novel foods derived from genetically modified microorganisms (GMMs), the applicant is requested to comply with the requirements related to the production process outlined in the EFSA "Scientific opinion on guidance on the risk assessment of GMMs and their products intended for food and feed use"	☐	☐	☐	
2.3.2 Non-confidential description of the production process				
▪ Non-confidential summary of the production process	☐	☐	☐	

Comments

	PROVIDED	NOT PROVIDED	EFSA AGREES	EFSA COMMENTS
2.4 Compositional data				
▪ Overview table, as indicated in Appendix B.1.	☐	☐	☐	
▪ Overview table, as indicated in Appendix B.2.	☐	☐	☐	
2.4.1 General Requirements - Applicable to all novel foods				
▪ Qualitative and quantitative data on the composition	☐	☐	☐	
▪ Information on the identities and the quantities of impurities or by products, residues and chemical and microbiological contaminants (e.g. heavy metals, mycotoxins, PCBs/dioxins, pesticides)	☐	☐	☐	
▪ Analyses on preferably at least 5, representative, independently produced batches of the novel food for	☐	☐	☐	

each proposed production process				
▪ Certificate for each analysis	☐	☐	☐	
▪ For each analytical methods, full description, references, LOD, LOQ	☐	☐	☐	
▪ Justification for implementing in-house methods, if any	☐	☐	☐	
▪ Accreditation documents for test facility	☐	☐	☐	
2.4.2 Single substances and simple mixtures thereof				
▪ Mass balance	☐	☐	☐	
▪ Information on the identity and the relevant ratios of all components	☐	☐	☐	
▪ Identity tests (e.g. UV-VIS, IR, NMR, GC–MS, LC–MS)	☐	☐	☐	
▪ Particle size, shape, distribution	☐	☐	☐	
▪ Minimum purity value	☐	☐	☐	
▪ Density and/or viscosity for liquid preparations	☐	☐	☐	
▪ In case of single substances and their mixtures produced with genetically modified microorganisms, the applicant is requested to comply with the requirements outlined in the "Scientific opinion on guidance on the risk assessment of genetically modified microorganisms and their products intended for food and feed use"	☐	☐	☐	
2.4.3 Complex mixtures and whole foods				
▪ Qualitative and quantitative analysis of the main constituents and of the naturally or chemically derived components that characterise the nature of the novel food (e.g. peptided, phospholipids, carotenoids, phenolics, steroids)	☐	☐	☐	
▪ For whole foods, the proximate analysis (e.g. ash, moisture, protein, fat, carbohydrates)	☐	☐	☐	
▪ Calculation of mass balance, including the amount of unidentified compounds	☐	☐	☐	
▪ Qualitative and quantitative data on nutritionally relevant inherent constituents (e.g. micronutrients)	☐	☐	☐	
▪ Qualitative and quantitative data on inherent substances of possible concern to human health (e.g. toxic, addictive, psychotropic, allergenic)	☐	☐	☐	
▪ Literature search performed according to the methodology developed by EFSA ("Application of systematic review methodology to food and feed safety assessment to support decision making") to retrieve published compositional data for the source and the parts used in/as novel food, including keywords and applied inclusion/exclusion criteria for the literature search	☐	☐	☐	

Complex mixtures and whole foods derived from plants

The EFSA Compendium of Botanicals and the EFSA Chemical Database can help identifying the possible

substances of concern in a botanical material.				
▪ Classification according to their chemical structure for any substance of concern derived from plants	☐	☐	☐	
▪ Chemical fingerprinting of the botanical material (recommended)	☐	☐	☐	
▪ Information on possible presence of genotoxic and/or carcinogenic substances	☐	☐	☐	
Complex mixtures and whole foods produced with genetically modified microorganisms				
▪ The applicant is requested to comply with the requirements outlined in the "Scientific opinion on guidance on the risk assessment of genetically modified microorganisms and their products intended for food and feed use"	☐	☐	☐	
2.4.4 Stability				
▪ Stability test on preferably at least 5, representative, independently produced batches of the novel food. Test duration has to cover at least the end of the novel food shelf-life	☐	☐	☐	
▪ Characterisation of the nature of degradation products	☐	☐	☐	
▪ Information on normal storage conditions of the novel food	☐	☐	☐	
▪ Information on the storage conditions under which the stability test was performed	☐	☐	☐	
▪ Physicochemical stability of the novel food under normal conditions of storage	☐	☐	☐	
▪ Biochemical stability of the novel food under normal conditions of storage	☐	☐	☐	
▪ Microbiological stability of the novel food under normal conditions of storage	☐	☐	☐	
▪ If the novel food is used as an ingredient added to other foods, characterisation of the stability of the novel food in real food matrixes or in relevant model systems (e.g. effect of processing temperature, pH)	☐	☐	☐	
▪ Information on ingredients added to the novel food to improve stability, if relevant	☐	☐	☐	
Comments				

	PROVIDED	NOT PROVIDED	EFSA AGREES	EFSA COMMENTS
2.5 Specifications				
▪ A table with the specifications including: -the limits and information on the exact method for each of the selected parameters (i.e., as a minimum, the contents and/or limits for the parameters on the identity of the product, the minimal purity, limits acceptable for impurities and degradation products, in particular those of toxicological or nutritional relevance.	☐	☐	☐	

In the absence of legal requirements in the EU, it also includes maximum levels of contaminants) -the limits and information on nutritional or biologically active components or, when these are not known, on selected chemical markers -the limits and information on concentrations of the major group of constituents (e.g. amino acids, proteins, lipids, carbohydrates, inorganic ions, polyphenols, alkaloids, terpenes, alkenylbenzenes, lignin, saponins, chitin)				
▪ Rationale for the selected parameters	☐	☐	☐	

Comments

	PROVIDED	NOT PROVIDED	EFSA AGREES	EFSA COMMENTS
2.6 History of use of the novel food and/or of its source				
2.6.1 History of the source				
If relevant for the safety assessment, data on the composition, production and on the experience from use of the source or products from the source (other than the novel food itself).	☐	☐	☐	
2.6.2 History of the use of the novel food				
▪ Data on the use of the novel food as food in countries outside of the EU and on non-food uses (e.g. description of the extend of use as a food and/or for non-food purposes, the population group for which the food has been part of their diet, its role in the diet, handling of food, preparation of food and precautions on use)	☐	☐	☐	
▪ A comprehensive literature review of human studies reporting on relevant safety outcomes (including information on the search strategy, sources used to retrieve pertinent data, terms and limits used). Full study-reports should be provided, if available.	☐	☐	☐	
▪ If relevant for the safety assessment, a comprehensive literature review of studies with specific and safety-relevant components of the novel food and for studies with similar foods from the same or other closely related sources. Full study-reports to be provided, if available.	☐	☐	☐	

Comments

	PROVIDED	NOT PROVIDED	EFSA AGREES	EFSA COMMENTS
2.7 Proposed uses and use levels and anticipated intake				
2.7.1 Target population				
▪ Target population (e.g. age range, defined population subgroups), including a rationale, with cross-referencing to relevant safety data	☐	☐	☐	

2.7.2 Proposed uses and use levels				
▪ Form of uses (e.g. as whole food, ingredient)	☐	☐	☐	
▪ Food categories in which the novel food (if an ingredient) is proposed to be used. Preferably refer to the EFSA Food classification system	☐	☐	☐	
▪ Information on whether the novel food is intended to replace another food	☐	☐	☐	
▪ Proposed maximum amounts in product(s) as consumed	☐	☐	☐	
▪ Proposed average and maximum daily intakes for different age/gender groups as appropriate	☐	☐	☐	
2.7.3 Anticipated intake of the novel food				
▪ Estimations of anticipated mean and high (at least 95th percentile) daily intakes of the novel food for each target group (per kg body weight and in absolute amounts). For the intake assessment the EFSA guidance on default values and rounding should be taken into account.	☐	☐	☐	
▪ Considerations regarding vulnerable groups (e.g. children, pregnant, lactating women)	☐	☐	☐	
▪ Description of methodological aspect of the intake assessment, which includes the sources of data used (summary statistics of the EFSA food consumption database, FAIM tool, individual data from national food consumption surveys), scientific principles and methods applied in particular with respect to model used for the calculation of high intake levels	☐	☐	☐	
▪ Where relevant, considerations and explanations why the novel food is intended to replace another food already existing in the market	☐	☐	☐	
2.7.4 Combined intake from the novel food and other sources				
▪ Mean and high daily intakes from natural sources (i.e. from the background diet)	☐	☐	☐	
▪ Daily intake from food fortification and supplements	☐	☐	☐	
▪ Daily intake from other uses	☐	☐	☐	
▪ Total daily intake of the constituent (mean and high anticipated intakes) from the intended uses as a novel food and from the background diet	☐	☐	☐	
2.7.5 Estimate of exposure to undesirable substances				
▪ Exposure estimates for relevant undesirable substances (e.g. potential secondary plant metabolites, residues, contaminants or degradation products)	☐	☐	☐	
2.7.6 Precautions and restrictions of use				
▪ Population (sub)groups (including population groups with certain physiological conditions) which should avoid consumption of the novel food, together with a rationale	☐	☐	☐	

Comments

	PROVIDED	NOT PROVIDED	EFSA AGREES	EFSA COMMENTS
2.8 Absorption, distribution, metabolism and excretion (ADME)				
▪ **For single substances and simple mixtures:** ADME of the novel food has been tested according to the requirements and tiered approach described in the EFSA "Guidance for submission for food additive evaluations"	☐	☐	☐	
▪ **For complex mixtures and whole foods:** ADME of toxicologically relevant constituents has been tested according to the requirements and tiered approach are described in the EFSA "Guidance for submission for food additive evaluations"	☐	☐	☐	
▪ **For novel foods consisting of "engineered nanomaterials":** The applicant is requested to comply with the specific requirements on ADME for engineered nanomaterials outlined in the "Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain"	☐	☐	☐	
▪ Available data on ADME of the novel food in humans	☐	☐	☐	

Comments

	PROVIDED	NOT PROVIDED	EFSA AGREES	EFSA COMMENTS
2.9 Nutritional information				
▪ Details of the nutrient composition of the novel food	☐	☐	☐	
▪ Description of the bioavailability of nutrients, taking into account influences of the production process, storage and further processing that may be required prior to consumption.	☐	☐	☐	
▪ Effects of processing/handling/preparation for the intended use (i.e. cooking to reduce or inactivate any anti-nutritional substances)	☐	☐	☐	
▪ Content and effect of antinutritional factors in the novel food and other known interactions with nutrients in the novel food. Estimation of the intake of potentially anti-nutritional substances from the novel food and comparison with health-based guidance (if available)	☐	☐	☐	
▪ If a novel food is intended to replace another food, demonstration that the novel food does not differ in a nutritionally disadvantageous way under the proposed conditions of use	☐	☐	☐	
▪ When a novel production process is applied to a food which is a relevant source for nutrients, demonstration that the novel food does not differ in a nutritionally disadvantageous way under the proposed conditions of	☐	☐	☐	

use				

Comments

	PROVIDED	NOT PROVIDED	EFSA AGREES	EFSA COMMENTS
2.10 Toxicological information				
▪ Overview table, as indicated in Appendix B.1.	☐	☐	☐	
▪ Overview table, as indicated in Appendix B.3.	☐	☐	☐	
2.10.1 General considerations				
▪ Rationale for the toxicity testing strategy applied	☐	☐	☐	
2.10.2 Genotoxicity				
▪ The approach proposed by the "Scientific opinion on genotoxicity testing strategies applicable to food and feed safety assessment" has been followed	☐	☐	☐	
▪ Study report of the genotoxicity studies	☐	☐	☐	
▪ Certificate of analysis of the test material used in these studies	☐	☐	☐	
▪ If the studies have not been carried out with the novel food, a rationale to substantiate why the test material used in the study is appropriate for the safety assessment of the novel food	☐	☐	☐	
2.10.3 Subchronic toxicity				
▪ Study report of subchronic toxicity studies, carried out for at least 90 days	☐	☐	☐	
▪ Certificate of analysis of the test material used in these studies	☐	☐	☐	
▪ If the studies have not been carried out with the novel food, a rationale to substantiate why the test material used in the study is appropriate for the safety assessment of the novel food	☐	☐	☐	
2.10.4 Chronic toxicity and carcinogenicity				
▪ When needed (see triggers for such studies outlined in the guidance), chronic toxicity and carcinogenicity studies (study reports provided)	☐	☐	☐	
▪ Certificate of analysis of the test material used in these studies	☐	☐	☐	
▪ If the studies have not been carried out with the novel food, a rationale to substantiate why the test material used in the study is appropriate for the safety assessment of the novel food	☐	☐	☐	
2.10.5 Reproductive and developmental toxicity				
▪ When needed (see triggers for such studies outlined in the guidance), reproductive and developmental toxicity studies (study reports provided)	☐	☐	☐	
▪ Certificate of analysis of the test material used in	☐	☐	☐	

these studies				
▪ If the studies have not been carried out with the novel food, a rationale to substantiate why the test material used in the study is appropriate for the safety assessment of the novel food	☐	☐	☐	
2.10.6 Human data				
▪ Overview table, as indicated in Appendix B.4.	☐	☐	☐	
Available human studies relevant to the safety assessment	☐	☐	☐	
Other studies				
▪ In case there are indications that the novel food could trigger specific biological processes (e.g. immunotoxicity, hypersensitivity, food intolerance, neurotoxicity, endocrine activity) which have not been fully considered in the core areas for evaluation, additional studies addressing the endpoints have been conducted	☐	☐	☐	
2.10.7 Specific cases				
2.10.7.1 Insects				
▪ Considerations of the potential hazards related to the use of farmed insects as food identified in EFSA opinion on "Risk profile related to production and consumption of insects as food and feed"	☐	☐	☐	
2.10.7.2 Microorganisms				
▪ **If a Qualified Presumption of Safety (QPS) status assigned:** Considerations of how related criteria and qualifications are fulfilled and how the risk of antimicrobial resistance is addressed	☐	☐	☐	
▪ **If no QPS status assigned:** Consideration of the safety of the microorganism(s), based on unambiguous taxonomic classification at species level complete strain characterisation by whole genoma sequence to enable the detection of virulence-related genes, antibiotic resistances and their potential horizontal transfer, and other potentially adverse metabolic features. Phenotypic characterisation of the potential antimicrobial resistance carried out following EFSA recommendations set in "Guidance on the assessment of bacterial susceptibility to antimicrobials oh human and veterinary importance". Where appropriate, potentially adverse phenotypic features (e.g. potential toxin production, haemolytic activity, infectivity, adverse immune effects, etc.)	☐	☐	☐	
▪ Information on the numbers of viable microorganisms in the final product	☐	☐	☐	
2.10.7.3 Engineered nanomaterials				
▪ The applicant is requested to comply with the requirements on the toxicity testing of engineered	☐	☐	☐	

nanomaterials outlined in the "Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain"				

Comments

	PROVIDED	NOT PROVIDED	EFSA AGREES	EFSA COMMENTS
2.11 Allergenicity				
▪ Allergenic potential of the novel food, considering its composition, particularly its protein(s), its source (including taxonomic relationships), the production process, and available experimental and human data, including information on cross-reactivity. A comprehensive literature review in order to retrieve available information on sensitisation, case reports of allergic reactions, and/or allergenicity studies (in vitro, in animals, in humans) of the novel food and/or its source(s)	☐	☐	☐	
▪ Protein content in the novel food (including limit of detection and quantification) and accurate description of the methods used	☐	☐	☐	

Comments

	PROVIDED	NOT PROVIDED	EFSA AGREES	EFSA COMMENTS
2.12 Concluding remarks				
▪ Overall considerations on how the information supports the safety of the novel food under the proposed conditions of use	☐	☐	☐	
▪ Considerations of the relevance of toxicologically relevant components (e.g. impurities, by-products, residues, chemical or microbiological contaminants) in relation to their estimated intakes, possible background exposure and their health-based guidance values (e.g. tolerable daily intakes), when applicable	☐	☐	☐	
▪ Considerations of the results of toxicity studies	☐	☐	☐	
▪ Considerations of any adverse effects identified through the human data	☐	☐	☐	
▪ Considerations of sources of uncertainties	☐	☐	☐	

Comments

Appendix B - Summary tables for scientific data

Appendices B.1. to B.4.[7] contain summary tables that the applicant is encouraged to include in the technical dossier through the EC e-submission system. Tables are meant to provide an overview of the studies submitted in the technical dossier. They will facilitate the risk assessment process by providing the assessors with an overview of the key information contained in the technical dossier. The risk assessment will be based on the content of the entire technical dossier and will not be restricted to the data reported in the tables.

As it is recognised that data in each application differs, these tables should be viewed as indicative templates. They are non-binding and other formats of these tables will be accepted, provided that the same aim is achieved. However the adherence to the common format presented in Appendix B will facilitate EFSA to carry out the risk assessment

Appendix B.1. Overview table of study reports provided in the novel food technical dossier

Appendix B.2. Compositional data of the novel food

Appendix B.3. Summary table of statistically significant observations in toxicity studies

Appendix B.4. Summary table of human studies on the novel food (or its constituents of potential safety concern)

[7] The four tables, Appendix B, can be downloaded from the section 'Supporting information'

Appendix B.1. Overview table of study reports provided in the novel food technical dossier

This table summarises the list of studies provided in the technical dossier. This table should be provided as a separate appendix of the technical dossier.

Appendix B.1. - Summary of study reports						
Title of the study report *(author, year, title of the study)*	**Section of the dossier the study relates to** *(e.g. 2.4.4 'stability'; 2.10.2 'genotoxicity')*	**Name of file** *(e.g. xxxx.pdf)*	**Guideline(s) followed** *(e.g. OECD, EMA, etc.)*	**Quality system(s) in place** *(e.g. GLP, GMP, GCP, etc.)*	**Facility where the study was carried out** *(name, country)*	**Accreditation of the facility** *(indicate the name of the file of the accreditation certificate)*

Appendix B.2. Compositional data of the novel food

This table summarises the compositional data of the novel food. This table should be provided as a separate appendix of the technical dossier.

Appendix B.2. – Compositional data of the novel food				
Parameter *(e.g. purity, heavy metals, residual solvents, etc.)*	**Analytical method used** *(indicate the name of the method and the relevant file e.g. xxxx.pdf)*	**Certificate of analysis** *(indicate the name of the file for the certificate of analysis e.g. xxxx.pdf)*	**Facility where the study was carried out** *(name, country)*	**Accreditation of the facility** *(indicate the name of the file of the accreditation certificate e.g. xxxx.pdf))*

Appendix B.3. Summary table of statistically significant observations in toxicity studies

This table summarises the statistically significant differences between controls and the novel food, which were observed in toxicity studies. This table should be provided as a separate appendix of the technical dossier for each study in which statistically significant differences were observed. When a statistically significant difference has been observed, the percentage of increase or decrease as compared to the control should be indicated as a footnote[8].

Appendix B.3. - Summary table of statistically significant observations in toxicity studies	
Title of the study report *(author, year, title)*	
Name of the relevant file in the application dossier *(e.g. in-vitro_ames_test.pdf)*	
Section of the dossier the study relates to *(e.g. 2.10.3 "subchronic toxicity")*	

Results of the study

Parameters[9]	**Exposure** *(days)*	**Sex**	**Dose group** *(g/kg bw)* *(Number of columns can be changed, according to the conducted study)*					
			Control *(mean)* ± SD	**Dose A** *(mean)* ± SD	**Dose B** *(mean)* ± SD	**Dose C** *(mean)* ± SD	**…**	**…**
Parameter a *(unit)*		M						
		F						
Parameter b *(unit)*		M						
		F						
Parameter c *(unit)*		M						
		F						
…		M						
		F						

[8] Example: Statistically significantly different from control at $p<0.05$ (indicate the statistical test used). The footnote should be inserted in the table for those values which are statistically significantly different from the control.

[9] The number of parameters presented in the rows below is only indicative, it may be changed according to the study. Unit of measurement for each parameter has to be indicated.

Appendix B.4. Summary table of human studies on the novel food (or its constituents of potential safety concern)

Overview table of the human studies provided on the novel food. This table should be provided as a separate appendix of the technical dossier. The data of the intervention and observational studies in humans should be organised according to a hierarchy of study designs and research questions, reflecting the relative strength of evidence which may be obtained from different types of studies. Studies with the highest level of scientific evidence should be presented first.

Appendix B.4. - Summaries of human data relevant on the novel food (or its constituents of potential safety concern)									
Reference *(author, year, title of the study)*	**Study report provided in the application dossier** *(indicate the name of the file)*	**Study design** *(e.g. randomised, double-blind, placebo controlled study)*	**Study population**	**Duration of the study**	**Tested material**	**Dosage** *(specific amount, number, and frequency of doses over the specified time-period)*	**Power calculations performed** *(if yes, for which endpoints)*	**Safety-related parameters investigated** *(e.g. physical examination, blood chemistry, haematology, urine analysis, blood pressure and organ function tests and/or monitoring of adverse reactions)*	**Summarised results**