Draft guidance on the scientific requirements for a notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283

EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA)

Endorsement for public consultation (subject to editorial changes by the Panel)	31 January 2024
Adoption date	Dd mm yyyy
Implementation date	Dd mm yyyy

Abstract

The European Commission requested EFSA to update the scientific guidance for the preparation of notifications for authorisation of traditional foods, previously developed following the adoption of Regulation (EU) 2015/2283 on novel foods. This guidance document provides advice on the scientific information needed to be provided by applicants when submitting traditional food notifications pursuant to Article 14 and traditional food applications pursuant to Article 16 of Regulation (EU) 2015/2283. The safety of a traditional food should be substantiated by data on its composition, its experience of continued use and its proposed conditions of use. Its normal consumption should not be nutritionally disadvantageous. The applicant should integrate the information on the composition and the experience of continued use and provide a concise overall consideration on how this substantiates the history of safe use of the traditional food and how this relates to the proposed conditions of use for the EU. Where potential health hazards have been identified on the basis of the composition and/or data from the experience of continued use, they should be discussed. On the basis of the information provided, EFSA will assess the safety related to the consumption of the traditional food under the proposed conditions of use.

Keywords

EFSA guidance, novel foods, traditional foods, third country, primary production, safety

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Acknowledgements:

Suggested citation:

ISSN:

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Background as provided by the European Commission in 2015 (not for comments)

On 25 November 2015, the European Parliament and the Council adopted the Regulation on novel foods.[1]

The Regulation requires that all applications for the authorisation of novel foods shall be submitted to the Commission who may then request a risk assessment from the European Food Safety Authority (EFSA). In assessing the safety of novel foods, EFSA shall, where appropriate, consider the following:

1) whether the food does not, on the basis of the scientific evidence available, pose a safety risk to human health;
2) a novel food, which is intended to replace another food, does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

The Regulation also introduces a special procedure for safety assessment for traditional foods from third countries, based on a history of safe food use. In this case, a notification for the placing on the market of a traditional food from a third country is sent to the Commission who forwards the valid notification to all the Member States and EFSA. A Member State or EFSA may submit duly reasoned safety objections on the placing on the market of the notified food. In this latter case, the Commission will not authorise the placing on the market of the traditional food concerned. However, the applicant may submit an application following the requirements of Article 16 of the Regulation on novel foods, for which a safety evaluation will be requested from EFSA. In assessing the safety of novel foods, EFSA shall, where appropriate, consider the following:

1) whether the history of safe food use in a third country is substantiated by reliable data submitted by the applicant;
2) whether the composition of the food and the conditions of its use do not pose a safety risk to human health in the Union;
3) where the traditional food from the third country is intended to replace another food, whether it does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

The Commission also adopted implementing rules on administrative and scientific requirements for the preparation and the presentation of the applications for novel foods[2] , as well as for the notifications and applications for traditional foods from third countries for the scientific assessment[3], respectively, in

[1] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001. OJ L 327, 11.12.2015, p. 1–22.

[2] Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 64.

[3] Commission Implementing Regulation (EU) 2017/2468 of 20 December 2017 laying down administrative and scientific requirements concerning traditional foods from third countries in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 301.12.2017, p. 55).

accordance with Article 13 and Article 20 of the Regulation. These implementing measures are supported by scientific and technical guidance regarding the information that needs to be submitted by the applicants by the present guidance and the guidance on novel foods.

Terms of Reference as provided by the European Commission in 2015 (not for comments)

In accordance with Article 29 of Regulation (EC) No 178/2002, the European Commission asks EFSA to update and develop scientific and technical guidance for the preparation and presentation of applications for authorisation of novel foods, and to develop scientific and technical guidance for notifications and applications for authorisation of traditional foods from third countries.

Background and Terms of Reference as provided by the European Commission in 2020 (not for comments)

The European Commission asked EFSA to update the "Guidance on the preparation and submission of the notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283"4 in order to align it to Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain5 (hereinafter "Transparency Regulation"), which applies as of 27 March 2021.

The revision concerned only the administrative part concerning certain obligation on the part of the applicant and did not involve a request for an update on the scientific content.

Background as provided by the European Commission in 2023 (not for comments)

Following the adoption of Regulation (EU) 2015/2283 on novel foods, the Commission asked EFSA to develop scientific and technical guidance for notifications and applications for authorisation of traditional foods from third countries. EFSA adopted its guidance document on the preparation and presentation of the notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283 on 22 September 2016.

The EFSA guidance document identified the essential safety elements that need to be part of traditional food notifications and applications pursuant to Articles 14 and 16, respectively, of Regulation (EU) 2015/2283 to support their safety, and served as the basis for the implementation of Commission Implementing Regulation (EU) 2017/2468. As this Regulation came into effect after the EFSA guidance was developed and implemented, there is a need to ensure full consistency between Regulation (EU)

[4] http://www.efsa.europa.eu/en/efsajournal/pub/4594

[5] 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 (OJ L 231, 6.9.2019, p. 1).

2015/2283 and Implementing Regulation (EU) 2017/2468 to better assist and support applicants in the preparation of notifications/applications of traditional foods from third countries. In addition, since the start of its implementation on 1 January 2018 when Regulation (EU) 2015/2283 came into effect considerable experience has been gained by EFSA in assessing traditional foods from third countries. Given the above, there is a need to update the EFSA guidance document on traditional foods from third countries to the state of the regulatory and scientific part so it can better serve its intended purpose to assist applicants in the preparation of notifications/applications of traditional foods from third countries, and the Member States and EFSA to evaluate and conclude on their safety.

Terms of Reference as provided by the European Commission in 2023 (not for comments)

In accordance with Article 31 of Regulation (EC) No 178/2002, the European Commission asks the European Food Safety Authority to update the guidance document for notifications and applications for authorisation of traditional foods from third countries.

Objectives

This guidance is intended to explain the type and quality of scientific information EFSA needs to conclude whether or not the traditional food is safe under the proposed conditions of use. The scientific requirements for an application for a novel food are dealt with by a separate guidance document by the EFSA NDA Panel (EFSA NDA Panel, 2021).

The guidance will be kept under review and it will be further updated as appropriate in the light of experience gained from the evaluation of traditional foods from third countries or under any legal revision.

Scope

The guidance presented in this document is provided to assist applicants with the scientific requirements in preparing and submitting notifications for authorisation of traditional foods from third countries which fall under Article 14 of Regulation (EU) 2015/2283. This guidance is also applicable to applications for the authorisation of traditional foods from third countries under Article 16 of Regulation (EU) 2015/2283 concerning the data on the history of safe use in a third country. Where Article 16 applications under Regulation (EU) 2015/2283 concern data other than the history of safe use in a third country, applicants are referred to the guidance on the preparation and presentation of an application for authorisation of a novel food (EFSA NDA Panel, 2021).

Procedural aspects linked to the submission of a notification and application for authorisation of a traditional food in the context of Regulation (EU) 2015/2283 are not in the scope of this guidance document. Instead, applicants are advised to consult the EFSA Administrative guidance for the preparation of notifications/applications on traditional foods from third country pursuant to Article 14 of Regulation (EU) 2015/2283 (add reference), the EFSA Administrative guidance for the processing of

applications for regulated products (EFSA, 2021b), and the EFSA Catalogue of support initiatives during the life-cycle of applications for regulated products (EFSA, 2021d).

Definitions

As per Article 3, paragraph 2 of Regulation (EU) 2015/2283 the following definitions apply:

a) 'Novel food' means any food that was not used for human consumption to a significant degree within the Union before 15 May 1997 irrespective of the dates of accession of the Member States to the Union. In the context of a traditional food from a third country, the following novel foods categories may apply:

ii. food consisting of, isolated from or produced from microorganisms, fungi or algae;

iv. food consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the Union and is consisting of, isolated from or produced from a plant or a variety of the same species obtained by:

- traditional propagating practices which have been used for food production within the Union before 15 May 1997; or
- non-traditional propagating practices which have not been used for food production within the Union before 15 May 1997, where those practices do not give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances;

v. food consisting of, isolated from or produced from animals or their parts, except for animals obtained by traditional breeding practices which have been used for food production within the Union before 15 May 1997 and the food from those animals has a history of safe food use within the Union;

vi. food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, microorganisms, fungi or algae;

b) 'History of safe food use in a third country' means that the safety of the food in question has been confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a significant number of people in at least one third country, prior to a notification referred to in Article 14;

c) 'Traditional food from a third country' means novel food as defined in point (a) of this paragraph, other than novel food as referred to in points (a) (i), (iii), (vii), (viii), (ix) and (x) thereof which is derived from primary production[6] as defined in point 17 of Article 3 of Regulation (EC) No 178/2002 with a history of safe food use in a third country.

[6] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001. OJ 327, 11.12.2015, p. 1-22.

General principles

1) For information on the traditional food notifications procedure, applicants are recommended to consult the EFSA Administrative guidance for the preparation of notifications traditional foods from third countries pursuant to Article 14 of Regulation 2015/2283[7] (EFSA,2021a). The administrative guidance provides also a full description of the requirements introduced by the Transparency Regulation such as the notification of studies obligations (Article 32b of the General Food Law), the possibility to request a General Pre-submission advice (Article 32a of the General Food Law) and provisions of transparency and confidentiality (Article 39 of the General Food Law).

2) Several EFSA scientific guidance documents may also be of relevance for the preparation of traditional food notifications/applications, especially those of the EFSA Scientific Committee[8]. Some of them are listed throughout the present document. Some EFSA guidance documents may be applicable only in specific cases. Over time, new guidance documents may be developed which may be of relevance for traditional food notifications/applications. Applicants are therefore advised to consult the EFSA webpage and consider the most up-to-date versions of the available and applicable guidance documents.

3) The term 'notification' means a stand-alone dossier containing the information and the scientific data submitted under Article 14 of Regulation (EU) 2015/2283. It includes information on the history of safe use in a third country submitted for the safety assessment of the traditional food from third countries. The term 'application' means a stand-alone dossier containing the information and the scientific data submitted under Article 16 of Regulation (EU) 2015/2283. It contains data submitted in the notification for the safety assessment of the traditional food from third countries (article 14 of Regulation 2015/2283), including the applicant's response to duly reasoned safety objections which were raised by EFSA and/or Member States during the evaluation of the notification submitted under Article 14 of Regulation 2015/2283. Hereafter, the term 'dossier' is used to denote notifications and applications.

4) As outlined in Regulation 2015/2283, the safety of a traditional food should be substantiated by reliable data on its composition and its experience of continued use for a period of at least 25 years in the customary diet of a significant number of people in at least one third country (i.e. 'history of safe food use in a third country'), and its proposed conditions of use. Besides, its normal consumption should not be nutritionally disadvantageous. According to the Regulation, also the specifications of the traditional food and conditions of use must be provided. The structure of the dossier should follow the sections presented in this guidance.

5) Data pertinent to the safety of the traditional food must be identified and documented in order to demonstrate that the notification covers the complete information package available on the

[7] https://www.efsa.europa.eu/en/supporting/pub/en-6488
[8] https://efsa.onlinelibrary.wiley.com/doi/toc/10.1002/(ISSN)1831-4732.GUIDANCE

traditional food. Information on the search strategy, including the sources used to retrieve pertinent data (databases, other sources), the terms and limits used (e.g. publication dates, publication types, languages, population, default tags) should be provided. Where applicable, the published literature is to be reviewed taking into account systematic review principles (EFSA, 2010). Full study reports should be provided if available.

6) The applicant should provide their considerations at the end of individual sections on how the information supports the safety of the traditional food food under the proposed conditions of use. Uncertainties must be addressed, and a critical appraisal of data both in favour and not in favour, of the safety of the traditional food is to be provided.

7) Deviations from the requirements specified in the respective sections of this guidance document must be justified.

8) Analyses/tests characterising the traditional food should be performed in a facility qualified for this purpose. Quality systems in place for control/documentation have to be indicated. Information on the accreditation of involved facilities and certificates of analyses should be provided. Whenever official guidelines (e.g. OECD, EMA and ICH) and quality systems (e.g. GLP, GMP, GCP and applicable ISO systems) were followed, the applicant should indicate compliance.

9) Referring to Directive 2010/63/EU[9], Regulation (EU) 2015/2283 emphasizes the 3 R's, i.e. replacing, reducing, refining animal studies. This goal to reduce animal studies to the minimum needed is also in line with the EU's chemicals strategy for sustainability and EFSA's Strategy 2027 to develop and integrate new scientific developments focusing on NAM[10]-based methods and the minimisation of animal testing.

Characterisation of the traditional food, technical and scientific data

The full characterisation of the traditional food under assessment is a key element of the risk assessment. It allows for the identification and characterisation of hazards associated with the traditional food, and it provides the basis for the characterisation of the potential risk posed to consumers from the consumption of the given traditional food under the proposed conditions of use.

1. Identity of the traditional food

Information on the identity of the traditional food must be provided considering the requirements outlined in the subsections listed below. There may be cases where two or more subsections could be of relevance to a traditional food. In those circumstances, the respective information for all relevant subsections should be provided. The subsections below are to be distinguished from the categories

[9] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes, OJ L 276, 20.10.2010, p. 33.
[10] In vitro, in silico and in chemico approaches are often referred to as New Approach Methodologies or NAMs

outlined in Article 3 of Regulation (EU) 2283/2015, to which the applicant must assign their traditional food upon submission of the dossier.

The name of the traditional food in the notification submitted has to reflect its characteristic elements, e.g., its source, the main part(s) of organisms used, specific elements of the production process, and must bear no nutrition or health claims according to Regulation (EU) 2015/2283[11]. Commercial names are to be avoided; scientific names according to the most recent taxonomy or scientific nomenclature are to be included.

1.1 Chemical substances *(blue text unique for traditional foods)*

This section concerns traditional foods which fall under one of the categories covered by sections 1.2–1.5, and are derived from primary production and not from chemical synthesis. In such instances, the traditional food has been processed to consist of or to contain (a) substance(s) of higher purity or (a) substance(s) of particular interest. The requirements to be addressed in these sections relate to those specific pure substance(s) in the traditional food.

The following information must be provided for traditional foods that are single chemical substances, and for each component when the traditional food is a simple mixture

- Chemical name, when appropriate, according to IUPAC nomenclature rules;
- CAS number, European Community (EC) Number - European Chemicals Agency (ECHA) and other relevant identification numbers (e.g. PubChem, E numbers, ChEBI, ChEMBL, Flavis, HMDB/FooDB, Lipidmaps, ChemSpider, IUBMB number);
- Synonyms or common names, trade names, abbreviations;
- Molecular and structural formulae with stereochemistry;
- Molar mass (g/mol) / Molecular mass (Da);
- InChI (International Chemical Identifier) and InChIkey (digital representation of the InChI);
- SMILES Canonical and SMILES Isometric;
- Identity tests of the relevant costituents should be performed with the most relevant analytical techniques (e.g., chromatography, nuclear magnetic resonance, mass spectrometry, FT-IR, UV, optical rotation in the case of chiral compounds).
- Particle size, shape and distribution if particles are present in the final product[12];
- Comparison with chemical standards, certified reference material, authentic biological specimens, naturally occurring compound or other relevant material.

[11] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001

[12] Applicable when (EFSA Scientific Committee, 2021a) applies.

1.2 Foods consisting of, isolated from or produced from microorganisms

The scientific requirements for the taxonomic and hazard identification of microorganisms intentionally used in the food chain (including bacteria, yeasts, filamentous fungi and microalgae/protists) depend on the particular role of the microorganism and the qualified presumption of safety (QPS) status.

In the context of traditional foods, microorganisms can have different roles:

- as traditional food itself, i.e., traditional foods consisting of viable cells (active agents) or non-viable cells (biomasses);
- used in the production of traditional foods, e.g., traditional foods isolated from or produced from microorganisms (production strains).

The EFSA QPS provides a safety pre-assessment of microbial strains belonging to QPS taxonomic units (TUs). The lowest TU for which the QPS status is granted is the species level for bacteria, yeasts and microalgae/protists. Only unambiguously identified microbial strains belonging to QPS TUs can benefit from the risk assessment approach based on QPS. Safety concerns related to a QPS TU are reflected, when possible, as 'qualifications', which should be tested at strain and/or product level.

Overall scientific requirements for the taxonomic and hazard identification of microorganisms as traditional foods or used in the production of traditional foods are listed below (detailed description in Annex A), including references to relevant EFSA guidance documents for additional information:

- Unambiguous taxonomic identification at species level and certificate of deposition (including accession number) in an internationally recognised culture collection having acquired the status of International Depositary Authority under the Budapest Treaty (EFSA FEEDAP Panel, 2018; EFSA, 2021e);
- Characterisation of genes of potential concern, i.e., acquired antimicrobial resistance (AMR) genes, toxigenicity and pathogenicity traits (EFSA FEEDAP Panel, 2018; EFSA, 2021e; EFSA BIOHAZ Panel, 2023a);
- Assessment of the capacity of the microbial strain to produce antimicrobial compounds unless a QPS TU or a TU known not to produce antimicrobials of clinical relevance for use in humans and animals (EFSA FEEDAP Panel, 2018);
- Whole genome sequence (WGS) data according to the 'EFSA statement on the requirements for WGS analysis of microorganisms intentionally used in the food chain' (EFSA, 2021e).

Additionally, the presence of viable cells in the traditional food has to be tested in the case of i) biomasses as traditional foods, ii) QPS TUs with the qualification 'for production purposes only', and iii) non-QPS production strains (EFSA FEEDAP Panel, 2018).

The presence of DNA from the production strain in the traditional food has to be tested for production strains harbouring acquired AMR genes (additional requirements in section 2.1.3 of EFSA FEEDAP Panel, 2018).

Moreover, any relevant EFSA guidance document regarding the risk assessment of microorganisms available at the time of submitting the traditional food notification should be considered. Adherence to the most recent applicable requirements throughout the process is requested.

1.3 Food consisting of, isolated from or produced from plants, macroscopic fungi and algae or their parts[13]

The following information must be provided in the case of traditional foods consisting of, isolated from or produced from plants[14], macroscopic fungi and algae or their parts. In case of a mixture of source material, the information is to be reported for each source organism and the percentages of each source in the mixture must be specified.

- Scientific (Latin) name and taxonomy (family, genus, species, and if applicable subspecies, variety with author's name, chemotype, strain) according to the international codes of nomenclature for plants[15] and for macroscopic fungi and algae[16];
- Accepted synonyms;
- Trivial or common names used to identify the traditional food intended to be marketed;
- For plants, experimental verification of the identity of the plant (e.g., authentic plant specimen deposit in a recognised herbarium, macroscopic/microscopic verification with comparison to an authentic standard, chemical fingerprint compared to standard, DNA-based authentication);
- For macroscopic fungi and algae, verification of the identity according to internationally recognised databases and methodology and, if available, deposition in an internationally recognised culture collection with access number;
- Part(s) used;
- Growing region(s) of the source organism (continent, country, region) and, when relevant, season of harvesting;
- Growing conditions to produce the source organism (i.e., cultivated or from the wild, conditions of cultivation);
- Non-GMO statement.

1.4 Food consisting of, isolated from or produced from animals or their parts

The following information is to be provided for traditional foods isolated from or produced from animals or their parts:

- Scientific (Latin) name (family, genus, species, subspecies, breed, if applicable);
- Accepted synonyms;
- Trivial or common names used to identify the traditional food intended to be marketed;
- Verification of the identity (e.g., DNA-based authentication);

[13] These requirements are in line with the EFSA Scientific Committee guidance on the safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements (EFSA Scientific Committee, 2009).

[14] These requirements are in line with the EFSA Scientific Committee guidance on the safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements (EFSA Scientific Committee, 2009).

[15] Plants of the World Online (https://powo.science.kew.org/) facilitated by the Royal Botanic Gardens, Kew; The USDA-ARS Germplasm Resources Information Network (GRIN) database (https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysimple.aspx) in case Plants of the World Online does not provide the required information; The International Plant Names Index (http://www.ipni.org/) in case the two above sources do not provide the required information.

[16] Mycobank (www.mycobank.org), Index fungorum (https://www.indexfungorum.org), Catalogue of Life (CoL), Integrated Taxonomic Information System (ITIS), Global Biodiversity Information Facility (GBIF), Encyclopedia of Life (EOL)

- Suitability of the animal sources for human consumption according to Regulation (EU) No 2015/1162[17];
- Health status of the source animal, age, access to herd/lot health certification;
- Part(s) used (e.g., organ(s) or tissue(s));
- Geographical origin (continent, country, region), farming and husbandry conditions;
- Origin of the initial livestock (e.g., national repository). In case the source of the traditional food is provided by external vendors, supporting documents should be provided;
- Non-GMO statement.

1.5 Food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, fungi or algae

This section concerns cell/tissue cultures derived from multicellular origin (animals, plants including macroscopic fungi, and algae). For foods consisting of, isolated from, or produced from cell cultures derived from microorganisms (including bacteria, yeasts, filamentous fungi and microalgae/protists) reference is made to the scientific requirements laid down in section 1.2. The traditional foods defined under this category can be the harvested cells, the biomass or the further processed biomass obtained from cell or tissue culture.

1.5.1 Foods consisting of, isolated from or produced from cell culture or tissue culture derived from animals

- Identity of the source organism as per the relevant requirements in section 1.4;
- When using established cell lines: genetic and phenotypic identity and stability of cells;
- When using primary cells: biopsy location or source material, cell type(s) isolated, genetic, and phenotypic identity of cells;
- Information to attest that the animal cells and tissues used for the preparation of the traditional food comply with inspection requirements;
- Information to attest the absence of any risks of infectivity from viruses or other zoonotic agents e.g., testing for viruses (species-specific viruses), testing for prions in the case of limited health information on source animals.

1.5.2 Foods consisting of, isolated from or produced from cell culture or tissue culture derived from plants, macroscopic fungi or algae

- Identity of the source organism as per the relevant requirements in section 1.3;
- Laboratory or culture collection sourced;
- Identity of the cells or cell lines: part(s) of the organism sourced, cell type isolated, genetic, and phenotypic identity, genetic and phenotypic stability of the cell lines.

[17] Commission Regulation (EU) 2015/1162 of 15 July 2015 amending Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies.

2. Production process *(blue text unique for traditional foods)*

The process(es) employed to produce the traditional food should be thoroughly and completely described. The description of the production process must be detailed enough to provide the information that will form the basis for the evaluation of the composition, bioavailability, nutritional value and safety.

The applicant should describe how the traditional food was or is being traditionally produced in the third country (i.e. steps and conditions applied). The applicant should document with published and/or unpublished information the traditional production process(es).

Since the assessment of traditional food as intended to be marketed in the EU gives substantial weight to the 'history of consumption' of the traditional food, the production process(es) used to produce the traditional food should be essentially the same as the traditional production process(es) used in the concerned third country(ies). EFSA acknowledges that the production process(es) of the traditional food as intended to be placed on the EU market might differ from the traditional way of production. Where deviations from the traditional manufacturing occur, the applicant should identify such changes and describe the process(es) actually to be applied to produce the traditional food (e.g. cultivation, harvesting, roasting, extraction, fermentation or isolation from a natural source, etc.) following the requirements outlined below. In such cases, the applicant should assess whether and document how these changes may impact the composition, nutritional value and safety of the traditional food.

2.1 General provisions

Information on all input materials used in the manufacturing process of the traditional food should be presented in a tabulated format, including their functional role, and their regulatory status in the EU (Annex B). Additionally, information on the specification and quality of the input/raw materials and fermentation aids has to be provided[18]. Moreover, every material in contact with food during the production process (e.g., plastic containers) should comply with Regulation (EC) No 1935/2004[19] and a declaration of compliance with this regulation or any other relevant legal document with regards to food contact material, should be provided. Considering all steps during the production process, the production yield, i.e., the resulting amount of a traditional food from its raw materials, should be calculated, providing also the 'processing factors'[20], when applicable. Regarding safety, the description has to include information on potential by-products, impurities, or contaminants. Formation of processing contaminants should be also considered based on the processes applied and a description of the parameters that may lead to the formation of a given processing contaminant should be included.
Operational limits and key parameters of the production process should be given. Measures implemented for production control and quality and safety assurance should be described (e.g., HACCP, GMP, ISO). The implementation of food safety management systems in place to produce the traditional

[18] Quality of the input material can be proven for commercial products by the certificates of analysis of the purchased products or by specifications for non-commercial products and certificates of analysis that prove the product complies with specifications

[19] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, OJ L 338 13.11.2004, p. 4

[20] The ratio of the concentration of a chemical substance in a product to the concentration of the same substance in the starting material (the source)

foods should cover procedures based on the HACCP principles in line with Regulation (EC) No 852/2004 on the hygiene of foodstuffs[21]. These procedures should be detailed, including critical control points, operational prerequisite programmes, monitored parameters, corrective actions, verification procedures, frequency of analysis, analytical methods, etc. A production flow chart should be provided, including quality and safety control checks. If applicable, standardisation criteria (e.g., chemical markers for the traditional food) should be provided.

2.2 Considerations for specific production process steps

Information must also be provided on the handling of the sources, for example, the propagation, growth and harvesting conditions for plants and fungi (e.g., wild or cultivated, type of cultivation and cultivation practices, composition of fertilisers used, time of harvest in relation to both season and stage of the plant growth); the cultivation conditions for aquacultures (e.g., measures in place to ensure water quality, temperature, length of growth in the water, composition of fertilisers used); the breeding, rearing, feeding and farming conditions along with the description of feed and certificates of feed compliance with EU Regulations for farmed animals or the hunting, catching or collecting and killing of wild living animals; the culture conditions for microorganisms and algae, and cell culture or tissue culture from plants and animals. The parts of the organism used as a raw material must be specified and information on other starting substances or materials should be provided. The description of the cultivation of plants, fungi, algae and microorganisms and the rearing of animals should also include information on the use of pesticides, hormones, veterinary drugs, antimicrobials and antiparasitic agents or feed additives. Biological agents (e.g., parasites, bacteria, endophytes, viruses, prions) that can infect organisms or tissue cultures used to produce the traditional food or be hosted by these organisms (animals, plants, fungi, algae and microorganisms) should be considered in the assessment. Information and measures in place to mitigate the respective risks should be provided and the impact of these agents to human health should be discussed.

Post-harvest handling, e.g., transport, drying techniques and storage conditions (duration, light, moisture, and temperature) of unprocessed foods and the raw materials for further processing should be described.

In cases when food enzymes of microbial origin are used as processing aids for the production of a traditional food, the processes and operational conditions in place for the inactivation/removal of these enzymes are to be provided and the presence or absence of these enzymes in the traditional food has to be demonstrated experimentally along with their enzymatic activity, if present (EFSA CEP Panel, 2021). The safety of the food enzyme(s) used in the manufacture of the traditional food is subject to the provisions of Regulation (EC) No 1332/2008[22] and therefore, it is outside the scope of this guidance, which concerns the assessment of the safety of the traditional food according to the provisions of Regulation (EU) 2015/2283. Therefore, the applicant is requested to provide information about the status of the enzyme(s) according to Regulation (EC) No 1332/2008. Food enzymes used in the production of traditional food should preferably have been already assessed with a positive outcome by the EFSA Panel on Food

[21] Regulation (EC) No 852/2004 of the European parliament and of the council of 29 April 2004 on the hygiene of foodstuffs, OJ L 139 30.4.2004, p. 1

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

Contact Materials, Enzymes and Processing Aids (EFSA CEP Panel). In case the food enzymes have not been assessed or the risk assessment is still in progress, additional data on the microorganisms used to produce the food enzymes could be requested to establish the safety of the traditional food, in line with the scientific criteria outlined in relevant EFSA guidance documents (EFSA FEEDAP Panel, 2018; EFSA, 2021e). The assessment of the traditional food will be without prejudice to the safety assessment of the food enzyme per se.

2.3 Considerations for specific traditional food categories

For traditional foods consisting of, isolated from or produced from plants, fungi, algae or animals, a detailed description of the process(es) by which the raw material is converted into an ingredient or a food product, must be provided. Examples may include e.g., heat treatment, extraction, distillation, fractionation, purification, concentration, fermentation, or other procedure(s). Information on substances used in the manufacturing process, e.g., identity and purity of the extraction solvents, ratio of extraction solvent to the material, reagents, additives, residues remaining in the final product and any special precautions (e.g., protection from light and controlled temperature) should be provided.

Regarding production processes employing microorganisms, the techniques used to remove/inactivate microbial cells during downstream processing should be described in detail, with full provision of operational conditions (e.g., time, temperature, kinetics, etc.). In case of a traditional food consisting of viable cells, information on the techniques/methods and operational conditions used to ensure microbial viability must also be reported. The applicant should investigate, and report whether the specific production conditions of the traditional food (e.g., due to processing aids or component of the media) may trigger the formation of toxic compounds by microorganisms.

For foods consisting of, isolated from, or produced from cell culture or tissue culture, information is to be provided on the type of cells used as source (e.g., primary cells or established cell lines). In case that primary cells are used, information on the source, purification steps, cell isolation, cell selection, cell subculture, absence of pathogens, and overall sterility of the process is to be provided. If cells from established cell lines are used, information must be provided on the source, the cell line preparation, the cell banking process, as well as the passage number of aliquot of cells used. Description of any modifications made to the cells used (e.g., selection, differentiation, immortalisation, adaptations, reprogramming), and the link of such modifications with the production of substances of possible concern must be included. All processes applied for the treatment, extraction, screening, and selection of cell lines or tissues must be provided in detail including all chemicals and biological materials used, and including the impurities that may result from their use. The genetic stability of the cells throughout the production (e.g., karyotypes, whole genome sequencing) is to be demonstrated, by comparison of the starting material and the cells at the end of the production process. Also changes of the morphology, markers of differentiation and other phenotypic features of the cells at the start and at the end of the production process should be investigated and described. Information on the compliance with Good Cell Culture Practices[23] should be provided, as well as on the compliance with applicable relevant standards, such as those outlined in the EMA Guidance document on the derivation and characterisation of cell

[23] https://publications.jrc.ec.europa.eu/repository/handle/JRC59782
https://www.oecd-ilibrary.org/environment/guidance-document-on-good-in-vitro-method-practices-givimp/good-cell-culture-practice-gccp_9789264304796-16-en

substrates used for production of biotechnological/biological products[24].

2.4 Additional considerations

In case the traditional food is manufactured by different producers/processes, consistency in production methods among different producers/processes must be demonstrated and food safety management systems (e.g., HACCP plan) should be provided from all producers/processes covering the entire production process. The variability of the supplying starting materials is to be investigated and be covered by the analytical data provided. Any changes to the production process that might occur during the risk assessment must be duly notified to EFSA by the applicant. Moreover, as stipulated in Article 25 (a) of Regulation (EU) 2283/2015, changes occurring after the risk assessment and or after the eventual authorisation of the traditional food that might impact its safety must be immediately notified to the EC.

3. Compositional data *(blue text unique for traditional foods)*

Compositional data serve as a tool to characterise the traditional food and its constituents, encompassing both qualitative and quantitative information on the chemical, physicochemical, microbiological, and nutritional attributes of the traditional food. They should facilitate an in-depth exploration of the compositional characteristics of the traditional food, linked to its source and employed production process. Variability of compositional data between different batches should be analysed and discussed, towards investigating the ability of the food business operator to produce the traditional food in a consistent and reproducible manner, while being the basis for hazard identification and establishment of the specification parameters. Section 3.1 outlines the general data requirements applicable to all traditional foods, while section 3.2 and section 3.3 set specific requirements, depending on whether the traditional food is a single substance or a simple mixture, a complex mixture or a whole food.[25]

The applicant should also provide compositional data from publications on the variability of the traditional food, when available. The applicant should provide, in a tabulated format, the range of the values of the parameters analysed in the batches of the traditional food, and those reported in the retrieved publications. For the ranges presented in the table the publications from which they are taken should be clearly indicated (Annex C).

In case changes have been introduced in the process employed to produce the traditional food intended to be placed on the EU market as compared to the traditional production process, the applicant should compare the compositional profile (including new substances potentially resulting from the modification of the production process) of the traditional food produced with the applied production process *versus* the traditional process. The applicant should discuss how the changes in the compositional profile may impact the nutritional value and/or the safety of the traditional food.

[24] https://www.ema.europa.eu/en/documents/scientific-guideline/ich-q-5-d-derivation-characterisation-cell-substrates-used-production-biotechnological/biological-products-step-5_en.pdf

[25] as defined by the EFSA Scientific Committee (2011a)

3.1 General requirements

3.1.1 Analytical methods

Validated methods, preferably nationally or internationally recognised (e.g., Association of Official Analytical Chemists, European Pharmacopoeia, International Organization for Standardization) should be used for the analyses. The respective methods of analysis should be described alongside their references. The limits of detection (LOD) and quantification (LOQ) should be mentioned. Certificates of analyses, and information on the matrix accreditation[26] and the scope of accreditation of the laboratories should be provided. If in-house methods are employed, the analytical protocols implemented should be fully described, and the results of the respective method validation procedures should be provided. If an analytical method is used for a food matrix beyond the scope[27] of accreditation / standardisation, it should be treated as in-house method (the same applies in cases that standard methods are modified). If the analyses are not performed in accredited laboratories, a justification should be provided. A table with all the analytical methods employed and the corresponding analytes should be provided. The table should include the name of the method, the reference, the main analytical technique(s) employed, as well as the respective LOD and LOQ.

3.1.2 Addressing compositional variability

Compositional data and their variability should support the setting of specifications of the traditional food[28] (section 4). The analytical information should be provided on at least five representative batches of the traditional food that have been independently produced (i.e., with independent batches of raw materials)[29]. The examined batches should be sampled in a manner adequate to address potential compositional variations (e.g., seasonal) of the raw materials. Additional batches of the traditional food may also be needed to explore the variability of potentially harmful substances present in the traditional food or its source. When several production processes are proposed, such data should be provided for each process. Moreover, compositional data should also cover the whole variability spectrum of the production process parameters (e.g., highest and lowest amount of solvents used, range of temperatures applied). The compositional variability should be discussed, highlighting the reasons for the variation in results.

Analytical data from publications can also be used if the publications provide sufficient information on the laboratory where analyses have been carried out, the methods utilised, and if the studies were performed with representative samples of the traditional food. Available published data can also contribute to provide information on the variability of the composition of the traditional food.

[26] Matrix accreditation evaluates a laboratory's competence in accurately analyzing specific food samples, ensuring quality and reliability in testing diverse and complex matrices. Such accreditation is crucial as validated analytical methods for one product may not be applicable to other types of products.

[27] employed to analyse another type of food matrix

[28] As defined in section 1

[29] Batch as defined in Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances, OJ L 050, 20.2.2004, p.44

3.1.3 Sampling practices

Principles of representative sampling should be considered (e.g., sample size, containers, conditions), and the rationale on why the employed sampling plan is considered representative should be provided. Information on any relevant existing legally defined or standard sampling protocols should be considered and provided. On each certificate of analysis, the name of the traditional food batch analysed, the date of production and the date of analysis should be stated.

3.1.4 Compositional analytes *(blue text unique for traditional foods)*

Information on the identity and the quantity of impurities or by-products, residues and chemical and microbiological contaminants should be provided (e.g., heavy metals, mycotoxins, PCBs/dioxins, pesticides, microbial indicators and pathogens). The potential target analytes should be selected considering the sources and the production process, regulatory levels as well as the information available in the scientific literature. For example, for substances obtained by chemical synthesis, residual starting materials and by-products anticipated from side-reactions should be analysed; for substances produced by microbial fermentation, the presence of undesirable metabolites should be investigated; for substances isolated by extraction, data on residual solvents should be provided.

If the publications retrieved by the applicant indicate the potential presence of substances of toxicological concern (e.g. toxins, pathogens, antinutrients, contaminants) in the traditional food or its source, the applicant should provide quantitative data on those substances in the batches of the traditional food, obtained using internationally recognized/validated analytical methods.

Considering their nature and in order to avoid unnecessary testing, some categories of traditional foods do not require a priori a nano-specific risk assessment, e.g., (i) microorganisms (e.g., bacteria, yeasts, fungi), (ii) unmodified proteins (including enzymes) and amino acids, (iii) whole foods (e.g., seeds, fruits, insects). Therefore, if the manufacturing process does not include any step that may lead to the presence of small particles (e.g., spray-drying, micronisation, encapsulation, filtration), and if it can be demonstrated that a traditional food falls under one of the above or similar categories, the traditional food may qualify for exemption from the characterisation and/or demonstration of the absence of small particles (as defined in the Guidance by the EFSA Scientific Committee (2021a)).

3.2 Single substances and simple mixtures thereof

Simple mixtures are mixtures whose components can be fully chemically characterised. For simple mixtures of defined substances, information on the identities and the relative ratios of all components should be provided. This should allow the elaboration of a mass balance. For single substances and substances in simple mixtures, the identity-relevant analytical data outlined in section 1.1 should be provided.

3.3 Complex mixtures and whole foods *(blue text unique for traditional foods)*

Complex mixtures (e.g., extracts, protein hydrolysates) and whole foods (e.g., milk, meat, fruits, seeds, insects) are defined as those traditional foods where all constituents cannot be fully chemically characterised and/or identified.

A qualitative and quantitative characterisation of the main constituents is to be performed, at least via

sum parameters. For whole foods, this should include proximate analyses (i.e., ash, moisture, protein, fat, carbohydrates). On the basis of these data, a mass balance should be calculated. The amount of unidentified components should be indicated and should be as low as possible.

For the classes of naturally or chemically derived components which characterise the traditional food (e.g., amino acids, peptides, phospholipids, carotenoids, phenolics, sterols), comprehensive qualitative and quantitative data should be provided.

Qualitative and quantitative data on nutritionally relevant inherent constituents such as micronutrients, antinutrients, and dietary fibre[30] should be provided.

Taking into account the source of the traditional food, qualitative and quantitative data on inherent substances of possible concern to human health (e.g., toxic, allergenic) should be provided. The impact of processing on the compositional profile of the traditional food (e.g., occurrence of heat-induced processing contaminants) should also be considered.

Whenever relevant (e.g. having an impact on safety or being potentially nutritionally disadvantageous), the applicant should compare the content of constituents such as micronutrients, antinutrients or substances of toxicological concern in the traditional food with the contents in foods currently consumed in the EU. In such cases exposure estimates may be needed for the concerned substance(s) coming from the traditional food and the comparator(s). Ideally but not necessarily, the comparator should be a food that can reasonably reflect the anticipated consumption pattern of the traditional food.

In addition to the batch-to-batch analysis, a literature search should be performed according to the methodology developed by (EFSA, 2010) to retrieve published compositional data (chemical, physicochemical, and microbiological) for the source and the part(s) used in/as traditional food, as well as for compositional aspects related to the production process. Information on the used keywords and applied inclusion/exclusion criteria for the literature search should be provided. Considering the retrieved information, the applicant should provide a rationale on the compositional analysis strategy followed.

Any substances of concern derived from starting materials (e.g. plants, algae, fungi) should be classified according to their chemical structure. Particular attention should be given to the possible presence of genotoxic and/or carcinogenic substances.

For plants, levels at which the constituents are present in the respective part of the botanical or botanical preparation should be given where available. It is recommended that chemical fingerprinting of the botanical material is undertaken for this purpose.

The following non-exhaustive list of tools can help identifying the possible substances of concern in a botanical material:

- The EFSA Compendium of Botanicals[31,32], which provides information on naturally occurring substances that may be of concern for human health (EFSA, 2012),

[30] "*dietary fiber" in the context of this Guidance and in EFSA risk assessments of novel foods is understood as defined by EFSA NDA Panel, 2010, i.e. all non-digestible carbohydrates, and not as defined by Regulation (EU) 1169/2011, which sets the additional requirement of having a beneficial physiological effect for edible carbohydrate polymers obtained from food raw material by physical, enzymatic or chemical means, and for edible synthetic carbohydrate polymers.*

[31] https://www.efsa.europa.eu/en/data/compendium-botanicals

[32] https://combodb.ecomole.com/report/

- The EFSA Chemical Hazard Database (OpenFoodTox)[33].

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 notifications for traditional foods which consist of, are isolated from, or are produced from farmed insects, considering the species and substrates to be used, as well as methods for farming and processing.

For viable or non-viable microorganisms as traditional foods, the concentration of, respectively, viable cells (e.g., by viable plate count) or non-viable cells (e.g., by flow cytometry or dry weight, in case of cell wall/membrane integrity or not, respectively) in the traditional food should be reported.

3.4 Stability

The stability of the traditional food has to be evaluated to ensure both the compositional integrity and the safety of the traditional food. Hazards that might arise during storage and transport must be identified and the nature of degradation products should be characterised.

Stability tests should consider compositional qualifiers, as well as constituents and parameters of the traditional food which may be susceptible to changes during storage and which may affect its safety and/or its identity or serve as indicators for alterations that could have an impact on the safety and/or the integrity of the traditional food. The rationale for the parameters selected to be monitored during the stability testing, as well as for those parameters disregarded as not relevant, should be provided.

Depending on the nature, production process and composition of the traditional food, the testing is to address the chemical, physicochemical, and microbiological stability of the traditional food under the intended conditions of storage, taking into account the effect of packaging, and the storage environmental parameters (temperature, light exposure, oxygen, moisture, relative humidity). Information on the intended storage conditions of the traditional food must be provided as well as on the conditions under which the stability testing was performed. The stability testing has to be provided on at least five representative batches of the traditional food that have been independently produced (i.e., with independent batches of raw materials). Testing of a lower number of batches is to be duly supported by scientific arguments. The traditional food batches selected to be monitored at the beginning of the stability testing have to be those monitored for the whole duration of the stability testing. The stability testing results can be taken into consideration when establishing the limits of relevant specification parameters. On the other hand, compliance of the traditional food with the specification parameters throughout the proposed shelf-life should be demonstrated.

The monitoring period of the stability test has to cover at least the end of the proposed shelf-life. Intermediate intervals of testing must be considered, depending on the nature of the traditional food, its composition, as well as the intended shelf-life. Although it is advisable to submit stability testing studies under intended conditions of storage, accelerated conditions may be used as an alternative. Such approaches, usually conducted at higher temperature, are applicable in cases where chemical parameters are monitored. The extrapolation of the results from accelerated conditions to intended conditions of storage must be duly evidenced. Information on ingredients added to the traditional food to improve its stability has to be provided.

[33] https://www.efsa.europa.eu/en/microstrategy/openfoodtox

3.4.1 Impact of processing on the traditional food in the proposed-for-use matrices

If the traditional food is used as an ingredient added to other foods the manufacture of which requires further processing (e.g., heating), the impact on the traditional food of this processing is to be investigated. Also alterations in the processed foods due to the presence of the traditional food should be investigated in foods or in relevant model systems (mimicking the food matrix and the respective processing conditions), taking also into consideration at least the extremes of the possible processing conditions (e.g., highest temperature to which the traditional food will be exposed when used as a food ingredient, lowest and highest pH) as resulting from the proposed uses (section 6.2). More specifically, it should be investigated what happens to relevant components of the traditional food, when it is used as a food ingredient. Interactions with other constituents in the processed foods and the formation of processing contaminants should be investigated. The use of proper comparators (e.g., the product manufactured with the same process/recipe without containing the traditional food as ingredient) is necessary.

Moreover, when the traditional food is subject to further processing that differs from the conventionally applied processing methods, any hazards potentially arising are to be identified and characterised.

4. Specifications

Specifications comprise chemical, physicochemical, nutritional, and microbiological parameters that characterise and substantiate the identity and safety of the traditional food, including the respective numerical ranges or limits.

Specifications serve as a tool for risk managers, i.e., the European Commission and Member States, who decide which of the proposed specification parameters and respective limits will be considered for inclusion and updating of the Union list of novel foods[34] in accordance with Article 9 of Regulation (EU) 2015/2283, when a traditional food is granted marketing authorisation. Given that risk managers may consider not only compositional aspects, applicants should propose also a brief but comprehensive description of the traditional food, incorporating identity parameters such as the name of the source or relevant parts thereof, and the microbial strain used as traditional food or in the production of traditional foods. It is also advisable to provide key descriptors related to the production process.

Applicants have to provide a comprehensive set of compositional specification parameters in a tabulated format. Depending on the identity and composition of the traditional food, the table should include the following:

- the major groups of constituents within the food,
- proximate analytes (protein, lipids, carbohydrates, ash, and moisture),
- more characteristic components (e.g., carotenoids, polyphenols, terpenes, alkenyl benzenes, lignin, saponins, chitin, micronutrients, number of viable/non-viable microorganisms),

[34] Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, OJ L 351, 30.12.2017, p. 72–201

- parameters relevant for the safety of the traditional food at the proposed uses and use levels, (e.g., toxins, alkaloids, phytic acid and other antinutrients, heavy metals, pathogens, impurities, or degradation products from the production process),
- parameters related to the quality and/or stability that may have an impact on the safety of the traditional food (e.g., markers of lipid oxidation, microbial hygiene indicators, or water activity).

The rationale for each proposed specification parameter and respective limits has to be provided.

The table must include minimum and/or maximum specification limits for each selected parameter. The specifications, including their limits, should be supported by the available information on the chemical, physicochemical and microbiological composition of the traditional food including the results from the available batch-to-batch analysis and the stability testing. They should be verifiable by means of the analytical techniques as indicated in section 3. Information on the employed analytical techniques and their sensitivity (LOD/LOQ) should be provided.

In general, the proposed maximum specification limits for undesirable substances should be as low as possible. Existing health-based guidance values (HBGV) for substances of potential toxicological concern, but also dietary reference values (DRV) including tolerable upper intake levels (UL) for micronutrients and exposure estimates to such compounds, should be considered when proposing the maximum specification limits. Minimum specification limits for nutrients may be necessary to ensure that a minimum level is present in the traditional food, especially when a traditional food represents a potential alternative or is intended to replace an existing food on the market, which provides a relevant contribution to the intake of certain nutrients. If EU regulatory limits are applicable for the traditional food, then they do not have to be necessarily listed in the specifications.

5. Data from experience of continued use of the traditional food in third countries *(this section is unique for traditional foods)*

This section should provide all available data from the experience of continued use which are pertinent to the safety assessment of the traditional food.

The supporting documentation on the experience of the continued food use should provide a description of the extent of use of the traditional food, the population group for which the traditional food has been a part of their diet, information on its preparation and handling, its role in the diet, and the precautions consumers apply. A comprehensive literature review of human studies and reports related to the consumption of the traditional food should be performed. Information on the search strategy, including the sources used to retrieve pertinent data (databases, other sources), the terms and limits used (e.g. publication dates, publication types, languages, population, default tags) should be reported. The published literature should be reviewed by considering systematic review principles indicated by EFSA (2010). When searching for 'grey-literature', EFSA's principles (2010) should also be adhered to. Full study reports of human studies should be provided.

The type of references could include scientific publications, scientific expert opinions, monographs, information from international or national organisations, governmental documentation, figures on

cultivation/harvesting, and sales and trade. Additional information may be provided from cookbooks, recipes and anecdotal data.

The documentation provided should relate to the traditional food as it is intended to be placed on the EU market.

The applicant should present the data supporting the experience of continued use of the traditional food in third countries in a tabulated format (Annex D).

5.1 Extent of use

The applicant should characterise the extent of use of the traditional food by documenting:

- the place of production and volume of the traditional food produced per year in the third country or countries;
- the geographical areas (e.g. region, country, continent) where it has been or is being consumed;
- If available, the quantity of consumption, information on the serving size(s), average, high and if available maximum intake levels per person should be provided. If available, intake estimates based on food consumption surveys or other estimates should be provided;
- for botanicals, clear distinction should be made between the intakes of a part of a botanical as such and preparations made of it (e.g. a herbal tea prepared from the traditional food, an essential oil prepared from the traditional food);
- the duration and continuity of its use over time.

5.2 Characteristics of the population group(s) of consumers

Documentation should be provided on whether the traditional food has been consumed by the general population or whether its consumption was rather or entirely limited to specific subpopulations defined by, for example, their age, sex, ethnicity, physiological and/or disease conditions. Information on the size of the population or population groups which have consumed the traditional food should be provided.

5.3 Role in the diet

Documentation should be provided on the consumption pattern, including the frequency, the context of the consumption (e.g. for specific purposes, ceremonies, combined consumption with other foods), the type of dish or meal for which the traditional food is used (e.g. as a snack, main dish, ingredient or spice for specified foods or meals). Information on the contribution of the traditional food to the overall macro- and micronutrient intake of the population should be provided.

5.4 Information on the handling and preparation of the traditional food

This section should provide documentation concerning the handling, including storage, and the preparation of the traditional food prior to its consumption, e.g. breakup or milling, peeling, removing or making use of only specific parts of the food, any kind of heat treatment (cooking method), or any other type of treatment.

5.5 Precautions for the preparation and restrictions of use of the traditional food

The applicant should provide information on any precautions that have been traditionally applied during the preparation of the traditional food, any kind of treatment or methods that may be deemed to reduce levels of toxic, allergenic or antinutritional substances or to improve digestibility, as well as information on reported limitations and restrictions for sensitive/specific population groups. Information on prohibitions or restrictions of use imposed to the traditional food in the third countries should be provided, if applicable.

5.6 Human data

The applicant should provide a comprehensive literature search to retrieve human data related to the safety of the traditional food (e.g. absorption, nutritional, microbiological, allergenic, tolerability, interaction with medicines). Human data could include human intervention and observational studies, case reports and information from surveillance reports.

The applicant should not only consider and limit their literature search to the traditional food itself, but should also consider searching for studies with specific and typical components of the traditional food and for studies with similar foods from the same or other closely related sources (e.g. other varieties or subspecies or related species of the same genus or the same family).

5.7 Other information

The applicant should provide toxicological studies (e.g. *in vitro* studies, genotoxicity studies, 90-day repeated dose studies) relevant for the safety assessment of the traditional food and/or for the safety assessment of relevant constituents in the traditional food, when available. Publications on studies which could indicate allergenic potential of the traditional food (e.g. *in silico*, *in vitro*, *in vivo*, human studies including case reports, cross-reactivity studies) should be provided. Publications on non-food uses should also be provided if relevant (e.g. cosmetic, feed studies).

6. Proposed conditions of use for the EU market *(blue text unique for traditional foods)*

A rationale for the target population, proposed uses and use levels, precautions and restrictions of use of the traditional food as intended to be placed on the EU market should be provided with cross-referencing to the relevant data on the 'history of safe food use' of the traditional food in a third country.

6.1 Target population

The applicant should unambiguously specify the intended target population. When the traditional food is intended to be added as ingredient to foods, or to be consumed as whole food, the proposed target population is the general population (i.e. cannot be restricted to subgroups thereof) (as stipulated in Article 5(6) of the Commission Implementing Regulation (EU) 2017/2469).

6.2 Proposed uses and use levels

The applicant should specify the intended uses of the traditional food (e.g. as whole food, ingredient).

If the traditional food is intended to be added as ingredient to foods, the applicant should provide the following information in a tabulated format:

(a) the food categories in which the traditional food is proposed to be added. Food categories can be specified according to the EFSA Food Additive Intake Model (FAIM) tool[35] or the Dietary Exposure (DietEx) tool[36]. All intended uses should be expressed with the use of a unique classification system (i.e. either FAIM tool categories or DietEx tool categories). Codes and names of the proposed food categories should be provided (see examples in tables 1 and 2).

(b) When selecting the FAIM tool categories, please refer to the instructions available on the website[37] particularly in relation to the unspecified food categories displayed in the FAIM tool.

(c) When using DietEx tool, the applicant is advised to use broad FoodEx categories instead of overly specific ones (e.g., yoghurts in general rather than certain types of yoghurts; biscuits in general rather than certain types of biscuits). The choice of overly specific food categories may cause difficulties for national authorities in the authorisation process of the traditional food.

b) the proposed maximum use levels (i.e. maximum concentrations) of the traditional food in each food categories as consumed (e.g. expressed as mg/kg or mg/100g or mg/100 mL).

Tables 1 and 2 display examples how the applicant should present the information on the proposed uses and use levels as described in the points above.

Table 1: Proposed uses and use levels according to the FAIM tool

FAIM tool code	FAIM tool category	Maximum level
01.7.2	Ripened cheese	100 mg/kg

Table 2: Proposed uses and use levels according to DietEx tool

FoodEx code	FoodEx category	Maximum level
A00EY	Cereal bars	10 mg/100 g

When the traditional food is intended to be used as a whole food, the applicant has to indicate the food already consumed in the diet in EU (using either a category in FAIM or in DietEx tool) which can reasonably reflect the anticipated consumption pattern of the traditional food. Applicants should provide their considerations and

[35] The FAIM tool was developed by EFSA for estimating chronic exposure to food additives in the regulatory framework of food additives Regulation (EU) 1333/2008. Considering that the exposure assessment of food additives and intake assessment of NF ingredients share common principles, the FAIM tool can also be used for the intake assessment of NF. See section 7.3 for the use of the FAIM tool to estimate the intake of the NF. FAIM tool is available at: https://www.efsa.europa.eu/en/applications/food-improvement-agents/tools

[36] The DietEx tool was developed by EFSA for estimating chronic exposure to substance present in food, naturally present or intentionally added to foods like Novel Foods. See section 7.3 for the use of DietEx tool to estimate the intake of the NF. DietEx tool is available at: https://www.efsa.europa.eu/en/science/tools-and-resources/dietex

[37] https://www.efsa.europa.eu/sites/default/files/applications/FAIM-instructions.pdf

explanations as to why it is reasonable to expect that the traditional food corresponds to specific food(s) consumed in the EU.

6.3 Anticipated intake of the traditional food

On the basis of the information provided in Sections 6.1 and 6.2, the applicant should estimate the chronic daily intake of the traditional food. This estimate should include both the amount of traditional food consumed per kilogram of body weight and the total absolute amount of traditional food consumed per day. The applicant should provide estimates of the mean and high (95th percentile) anticipated daily intakes of the traditional food for each target population group, including specific population groups such as pregnant and lactating women.

The FAIM tool or the DietEx tool are available to applicants to perform the chronic intake estimate of the traditional food when added to foods. When estimating the intake, the applicant should consider all food categories to which the traditional food is intended to be added for a conservative scenario. Both FAIM and DietEx tools use individual consumption data from the EFSA Comprehensive Food Consumption Database to generate estimates (mean and 95th percentile) for population groups (infants, young and other children, adolescents, adults) throughout several EU countries. It is noted that the DietEx tool provides more refined food categories as compared to the FAIM tool which uses broader food categories. Thus, DietEx allows a more refined selection of food categories and intake estimates of the traditional food.

If the available toxicological data, human data, data on chemical composition or literature review raise concerns regarding an acute effect, the applicant should also consider acute intake estimates of the traditional food.

When a traditional food is reasonably expected to be used as an alternative to another food already consumed in the diet in the EU (e.g. when the traditional food is a whole food – section 6.2), the applicant should use the consumption data of the food already consumed in the EU to estimate the anticipated intake of the traditional food.

6.4 Intended role in the

Where a traditional food is intended or likely to be used as an alternative to another food, the applicant should demonstrate that it does not differ from that food in a way that it would be nutritionally disadvantageous for the consumer.

6.5 Precautions and restrictions of use

When proposing precautions and restrictions of use, all available information on safety should be taken into consideration.

The applicant should indicate any restrictions of use and precautions related to the handling, preparation and consumption of the traditional food.

7. Concluding remarks

The applicant should integrate the information on the composition and the experience of use and provide a concise overall consideration on how this substantiates the history of safe use of the traditional food and how this relates to the proposed conditions of use for the EU market. Where potential health

hazards have been identified on the basis of the composition and/or data from the experience of use, they should be discussed.

References (to be included)

Please refer to the list of references in the draft Guidance on the scientific requirements for an application for authorization of a novel food which is under public consultation.

Abbreviations (to be included)

Please refer to the list of abbreviations in the draft Guidance on the scientific requirements for an application for authorization of a novel food which is under public consultation.

Annexes

Annex A Identity-related requirements for foods consisting of, isolated from or produced from microorganisms

Requirements	Microorganisms as traditional foods	Microorganisms used in the production of traditional foods
Unambiguous taxonomic identification at species level (EFSA FEEDAP Panel, 2018; EFSA, 2021e) Certificate of deposition (including accession number) in an internationally recognised culture collection having acquired the status of International Depositary Authority under the Budapest Treaty (EFSA FEEDAP Panel, 2018)	Mandatory	Mandatory
Acquired antimicrobial resistance genes (EFSA FEEDAP Panel, 2018; EFSA, 2021e; EFSA BIOHAZ Panel, 2023a)	Mandatory for bacteria (regardless of QPS status)	Mandatory for bacteria (regardless of QPS status)
Assessment of the capacity of the microbial strain to produce antimicrobial compounds (EFSA FEEDAP Panel, 2018)	Applicable to TUs: - known to produce antimicrobials relevant to use in humans and animals - not qualifying for the QPS approach - included in the QPS list but for which a qualification regarding antimicrobial production exists	Applicable to TUs: - known to produce antimicrobials relevant to use in humans and animals - not qualifying for the QPS approach - included in the QPS list but for which a qualification regarding antimicrobial production exists
Toxigenicity and pathogenicity trains (EFSA FEEDAP Panel, 2018; EFSA, 2021e)	Applicable to TUs: - not qualifying for the QPS approach - included in the QPS list but for which a qualification regarding toxigenic activity exists	Applicable to TUs: - not qualifying for the QPS approach - included in the QPS list but for which a qualification regarding toxigenic activity exists
Whole genome sequence (WGS) data according to EFSA, 2021e	Mandatory	Mandatory
Presence of viable cells in the traditional food to be tested (EFSA FEEDAP Panel, 2018)	Applicable to: - Biomasses - QPS TUs with the qualification 'for production purposes only'	Applicable to: - QPS TUs with the qualification 'for production purposes only' - Non-QPS TUs
Presence of DNA in the traditional food to be tested (EFSA FEEDAP Panel, 2018)		Applicable to: - strains harbouring acquired AMR genes

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935 ## Annex B: Table of all input materials used in the manufacturing process of the traditional food

Input material	**Chemical identifier (CAS, EC Number etc)**	**CoA**	**Functional Role**	**Regulatory status in EU**
e.g. b-cyclodextrin	7585-39-9 (hydrate)	Name of the CoA document in the dossier	emulsifier	Authorised food additive (E 459)

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937 ## Annex B: Compositional data retrieved in peer-reviewed articles (*unique for traditional foods)*

	Compositional data in the traditional food (TF) notification			**Compositional data retrieved in the literature**			
Compound/ Group	**Concentration as measured in the TF batches (range)**	**Units**	**Analytical technique**	**Concentration (range)**	**Units**	**Analytical technique**	**Reference**
Caffeic acid	5-10	mg/kg	HPLC-UV	2-20	mg/kg	HPLC-UV	XXXX et al.
Saponins	1-2	mg/kg expressed as XXX equivalents	Spectrophotometric method	0.1-1	mg/kg expressed as XXX equivalents	Spectrophotometric method	XXX et al.
Chlorogenic acid	4-6	mg/kg	HPLC-MS/MS	3-5	mg/kg	HPLC-MS/MS	XXXX et al.

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940 Annex D: Information on the 'history of use of the traditional food' in a tabulated format (*unique for traditional foods)*

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Reference	Years of consumption (duration)	Country	Traditional food (TF) consumed, handling and preparation	Extent of use	Role in the diet	Population of consumers
Example: Author, year, journal name	Years when the consumption of the TF occurred	Name of the country where the TF was consumed	Describe how the TF was prepared and consumed. Indicate whether there are deviations from the TF which is intended to be put on the market, and discuss how these deviations may impact the safety profile of the TF intended to be put on the EU market.	Indicate the quantity of TF consumed per person; volume of TF produced per year.	Indicate whether the TF was consumed as a side dish, a snack, consumed only on special occasions.	General population, or specific population groups.

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