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 (revision 1)

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GUIDANCE

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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 (Revision 1)[1]

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Abstract

Following the adoption of Regulation (EU) 2015/2283 on Novel Foods, the European Commission requested EFSA to develop a scientific and technical guidance for the preparation and submission of notifications for traditional foods from third countries. This guidance presents a common format for the organisation of the information to be presented by applicant for the preparation of a well-structured dossier. The safety of a traditional food should be substantiated by reliable data on its composition, its experience of continued use and its proposed conditions of use. Its normal consumption should not be nutritionally disadvantageous. This guidance is also intended to support applicants in providing the type and quality of information EU Member States and EFSA need for the assessments of traditional foods from third countries. 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.

This guidance was originally adopted by the NDA Panel in 2016. It has been revised in 2020 to inform applicants of the new provisions introduced by Regulation (EC) No 178/2002, as amended by Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain. It is applicable to all notifications and applications submitted as of 27 March 2021. The 2016 version remains applicable to notifications and applications submitted before 27 March 2021.

[1] The revision aims to inform applicants of the new requirements set out in the General Food Law (Regulation (EC) No 178/2002, as amended by Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain, and to guide to EFSA's practical arrangements implementing these new requirements. For this purpose, the revision concerns only the administrative part. The scientific content remains unchanged. The present guidance (revision 1) was endorsed on 21 January 2021 by the Panel on Nutrition, Novel Foods and Food Allergens (NDA): Dominique Turck, Jacqueline Castenmiller, Stefaan de Henauw, Karen-Ildico Hirsch-Ernst, John Kearney, Helle Katrine Knutsen, Alexandre Maciuk, Inge Mangelsdorf, Harry J McArdle, Androniki Naska, Carmen Pelaez, Kristina Pentieva, Alfonso Siani, Frank Thies, Sophia Tsabouri and Marco Vinceti.

[2] As of 1 July 2018, it has been renamed 'Panel on Nutrition, Novel Foods and Food Allergens (NDA)'

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Amendment: An editorial change was carried out on the third bullet point on page 3 that does not materially affect the contents of this scientific Guidance. To avoid confusion, the original version of the Guidance has been removed from the EFSA Journal, but is available on request.

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Summary

Following the adoption of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, the European Commission requested the European Food Safety Authority (EFSA) to develop a scientific and technical guidance for the preparation and submission of notifications for traditional foods from third countries.

This guidance presents a common format for the organisation of the information to be presented in order to assist applicants in preparing well-structured notification dossiers pursuant to Article 14 and applications concerning the data on the history of safe use in a third country pursuant to Article 16 of Regulation (EU) 2015/2283.

As outlined in Regulation 2283/2015, the safety of a traditional food should be substantiated by reliable data on its composition, its experience of continued use and its proposed conditions of use. Besides, its normal consumption should not be nutritionally disadvantageous. To that end, information is requested on the description, production process, composition, stability data and specifications of the traditional food, experience of continued use in a third country and on the proposed conditions of use of the traditional food for the European Union (EU) market. The structure of the dossier should follow the sections presented in this guidance.

This guidance for traditional foods from third countries is also intended to support applicants in providing the type and quality of information EU Member States and EFSA need to conclude whether there are reasoned safety objections to the placing on the market within the Union of the traditional food at the proposed conditions of use.

A notification or application should be comprehensive and complete. The applicant should integrate the information on the composition and the experience of continued use and provide a concise overall consideration on how the data substantiate the history of safe use of the traditional food and how they relate to the proposed conditions of use intended for the EU market. 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.

This guidance, after being subjected to public consultation, was adopted by the NDA Panel on 22 September 2016.

This guidance has been revised to inform applicants of the new provisions introduced by Regulation (EC) No 178/2002[3](i.e. the General Food Law, hereinafter GFL Regulation), as amended by Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain (hereinafter 'Transparency Regulation'). They concern the pre-submission phase and the application procedure and are applicable to all traditional food notifications and applications submitted as of 27 March 2021:

- possibility to request general pre-submission advice (Article 32a(1) of GFL Regulation);
- mandatory notification of studies commissioned/carried out by business operators to support a traditional food notification or application (Article 32b of GFL Regulation);
- Where the Commission requests the opinion of EFSA in accordance with Article 16 of Regulation (EU) 2015/2283, publication of all information submitted in support of a traditional food application unless granted confidential status by EFSA pursuant to Article 23 of this Regulation (Articles 38 and 39-39e of the GFL Regulation); the publication of non-confidential information in support of Traditional Food Notifications, is only applicable when EFSA issues duly reasoned safety objections. The responsibility of confidentiality assessment in case of Traditional Food Notifications, remain with the Commission.
- public consultation on the non-confidential version of submitted applications (Article 32c(2) of GFL Regulation) (not applicable to traditional food notifications).

[3] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, as amended by Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, PE/41/2019/REV/1. OJ L 231, 6.9.2019, p. 1–28.

For detailed information, please refer to the corresponding practical arrangements available on the EFSA website.[4]

Applicants should also note that notifications and applications must continue to be submitted using the e-submission system available through the European Commission website or the EFSA website.[5]

Before submitting a traditional food notification or application, applicants are also advised to consult the EFSA Administrative guidance for the processing of applications for regulated products (EFSA, 2021a) and the EFSA Catalogue of support initiatives during the life-cycle of applications for regulated products (EFSA, 2021b) for an overview of the support initiatives provided by EFSA to applicants.

This revised guidance supersedes the previous version of the guidance for all traditional food notifications and applications submitted as of 27 March 2021. For applications submitted before that date, the previous version of the guidance published in 2016[6] remains applicable.

[4] https://www.efsa.europa.eu/en/corporate/pub/tr-practical-arrangements
[5] https://www.efsa.europa.eu/en/applications/toolkit
[6] https://www.efsa.europa.eu/en/efsajournal/pub/4590

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Background

On 25 November 2015, the European Parliament and the Council adopted the Regulation on novel foods.[7]

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. 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[8], as well as for the notifications and applications for traditional foods from third countries for the scientific assessment[9], respectively, in 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 2014

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.

[7] 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.

[8] 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.

[9] 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).

Background and Terms of Reference as provided by the European Commission in 2020

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"[10] in order to align it to Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain [11] (hereinafter "Transparency Regulation"), which applies as of 27 March 2021.

The revision concerns only the administrative part. The scientific content remains unchanged.

Objectives

This guidance presents a common format for the organisation of the information to be presented in order to assist the applicant in the preparation of a well-structured notification dossier on the 'history of safe food use in a third country' of a traditional food as defined by Article 3 of Regulation (EU) 2015/2283 and on the proposed conditions of use. Adherence to this format will also facilitate access to information and scientific data in notifications to help the European Union (EU) Member States and EFSA in carrying out their evaluation in an effective and consistent way.

This guidance is also intended to support applicants in providing the type and quality of information EU Member States and EFSA need to conclude on the safety of the traditional food under the proposed conditions of use. The requirements for preparing and submitting a dossier for a novel food are dealt with by a separate guidance document by the EFSA NDA Panel (EFSA NDA Panel, 2021b).

It is intended that 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 for 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, 2021a).

Definition

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:

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

[11] 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).

– 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[12] 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.

General principles

1) This document should be read in conjunction with Regulation (EU) 2015/2283 of the European Parliament and of the Council on Novel Foods, with the General Food Law[13] Regulation which has set out new provisions in the pre-submission phase and in the application procedure that are applicable to all notifications and applications submitted as of 27 March 2021, with EFSA's Practical Arrangements on pre-submission phase and public consultations[14] (EFSA, 2021c), as well as with EFSA's Practical Arrangements concerning transparency and confidentiality[15] (EFSA, 2021d), available on EFSA's website. In case of discrepancy between the content of this document and a provision of an applicable legal act, or of EFSA's Practical Arrangements, the legal act and the latter prevail.

Several scientific guidance documents from EFSA may also be of relevance for the preparation and submission of a notification of a traditional food from third countries. They are listed throughout the present document. Since revisions may occur, the applicant should refer to the most up-to-date version of the guidance documents. Other EFSA guidance documents might be applicable in specific cases. Applicants are therefore advised to consult the EFSA webpage and consider the most up-to-date versions of the available and applicable guidance documents.[16]

Before submitting an application, applicants are also recommended to consult the EFSA Administrative guidance for the processing of applications for regulated products (EFSA, 2021a) and the EFSA's Catalogue of support initiatives during the life-cycle of applications for

[12] 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.
[13] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, as amended by Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, PE/41/2019/REV/1. OJ L 231, 6.9.2019, p. 1–28.
[14] See Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission phase and public consultations
[15] See Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements concerning transparency and confidentiality
[16] https://www.efsa.europa.eu/en/applications/nutrition/regulationsandguidance

regulated products (EFSA, 2021b) for an overview of the support initiatives provided by EFSA to applicants.

2) 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 for the safety assessment of the traditional food from third countries, including the applicant's response to duly reasoned safety objections raised by EFSA and/or Member State(s) on the safety of a traditional food evaluated in the context of a notification submitted under Article 14 of Regulation 2015/2283. Hereafter, the term 'dossier' is used to denote notifications and applications.
3) It is the duty of the applicant to provide all of the available and reliable data (including both data in favour and not in favour) that are pertinent to the safety of the traditional food. As such, the dossier to support the safety of the traditional food and to demonstrate its history of safe food use in a third country should be comprehensive and complete.
4) Data and information pertinent to the safety of the traditional food should be identified and documented in order to demonstrate that the dossier covers the complete information available on the 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 reported. Where applicable, the published literature should be reviewed by taking into account systematic review principles (EFSA, 2010). Information on the search strategy for data in the non-peer reviewed literature (grey literature) should also be provided. Full study reports should be provided if available.
5) This guidance presents a common format for the organisation of the information in order to assist applicants in the preparation of well-structured dossiers. Adherence to this format will facilitate access to the information and scientific data in dossiers to help EFSA and the Member State Competent Authorities to carry out their evaluation and to deliver their scientific opinions in an effective and consistent way.
6) As outlined in Regulation 2283/2015, the safety of a traditional food should be substantiated by reliable data on its composition, its experience of continued use/history of safe food use as a traditional food in a third country for a period of at least 25 years, 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.
7) The structure of the notification and application should follow the sections presented in this guidance which also reflect the relevant sections of the application e-submission system. The information required on the identity of the traditional food (Section 2), production process (Section 3), compositional data (Section 4), specifications (Section 5), data from experience of continued use (Section 6), and proposed conditions of uses of the traditional food (Section 7) constitute the minimum information and data requirements which must be fulfilled in notifications and applications for new traditional food.
8) The applicant should provide its considerations at the end of individual sections on how the information supports the safety of the traditional food under the proposed conditions of use. Uncertainties should be addressed, and a critical appraisal on data potentially not in favour of the safety of the traditional food should be provided.
9) Analyses/tests should be performed in a competent facility that can certify the data. Quality systems in place for control/documentation should be indicated. Information on the accreditation of involved facilities and certificates of analyses should be provided. Whenever official national and/or international guidelines and quality systems were followed, the applicant should indicate compliance.
10) Deviations from the requirements specified in the respective sections described in this guidance should be justified.
11) The applicant may submit a request to treat certain part of the information submitted under Regulation (EU) 2015/2283 as confidential. The assessment of the confidentiality requests is performed in accordance with the relevant provisions of GFL Regulation (Articles 38 and 39-

39e of the GFL Regulation) and Article 23 of Regulation (EU) 2015/2283. They are to be read in conjunction with case law, as well as, where EFSA is asked to provide an opinion, with EFSA's Practical Arrangements concerning transparency and confidentiality[17] (EFSA, 2021d), which provide a comprehensive description of applicable procedures and provisions.

12) In accordance with Directive 2010/63/E[18] on the protection of animals used for experimental and other scientific purposes, and as reiterated in Regulation (EU) 2015/2283, tests on animals should be replaced, reduced or refined. Duplication of animal testing should be avoided, where possible.

Structure of the dossier

The structure of the notification and application should follow the common format required by the e-submission system, which is available through European Commission's and EFSA's website.[19]

Information provided in the application should be organised as follows:

- Administrative data
- Public summary
- Technical dossier

Administrative data

The following information should be provided via the e-submission system:

- Identity of the traditional food to be authorised (name, description and novel food category);
- Applicant's contact details (name of entity, email, address, post-code, phone, website, country);
- Person responsible for the dossier contact details (name of person responsible, applicant/company name, email, address, post-code, phone, website, country);
- If appropriate, confidentiality requests on one or more of the items listed in Article 23(4) of Regulation 2015/2283;
- Proposed entry in the Union list (conditions of use, specific labelling requirements, other requirements);
- Regulatory status outside the EU;
- Cover Letter, specifying the content of the submission.

Public summary

A short summary of the dossier should be provided. This document will be made available to the public and should not contain any confidential information. The public summary will be published together with the non-confidential version of the dossier on the OpenEFSA portal.[20]

Technical dossier

It should contain information related to the pre-application information (Section 1), identity (Section 2), production process (Section 3), compositional data (Section 4), specifications (Section 5), data from experience of continued use (Section 6), proposed conditions of use (Section 7), concluding remarks (Section 8), and all annexes and references (Section 9) in support of the application: the

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

[18] 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.

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

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

certificates (on the accreditation of laboratories, certificates of analyses), full copies of all pertinent scientific data (published and unpublished), full study reports, and scientific opinions of national/international regulatory bodies. It should also contain the full texts of all cited non-scientific references ('grey literature').
The data and scientific information to be included in the technical dossier is detailed below.

1. Pre-application information[21]

All relevant pre-application identification(s) received by EFSA in the pre-submission phase for the regulated product which is the subject matter of the application and information required with regard to notification of studies obligation should be provided.

2. Identity of the traditional food

The traditional food should be briefly described in an introductory paragraph, including the source, the principle of the production process and typical compositional features. Its purpose and intended use should be described.

Information on the identity of the traditional food should be provided, depending on the class(es) under which the traditional food falls. The Panel notes that the proposed classification is based on the chemistry, production process and source of traditional foods, for the purpose of the scientific assessment, and is not meant to reflect the regulatory categories outlined in Article 3(2)a of the Regulation. There may be cases where a traditional food could be allocated to two or more classes (e.g. 'chemical substances' and 'food produced by a microorganism'). In such cases, the relevant information for all applicable classes should be provided.

2.1. Chemical substances

- Chemical name, when appropriate, according to IUPAC nomenclature rules
- CAS number (if this has been attributed) and other identification numbers
- Synonyms, trade names, abbreviations
- Molecular and structural formulae; stereochemistry
- Molecular mass (Da).

2.2. 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[22] and fungi,[23] 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; Information on applicable methods for the characterisation of bacteria and yeasts are provided in the EFSA Health Claim guidance (EFSA NDA Panel, 2021a). Molecular methods allow predictions of genes encoding for toxins, antimicrobial resistance and other pathogenic factors
- Origin of the organism
- If available deposition in an officially recognised culture collection with access number

[21] See Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission phase and public consultations
[22] For algae species: The Algae database (www.algaebase.org).
[23] For the identification of fungi: The *Index fungorum*: http://www.indexfungorum.org/names/names.asp for identification of fungi.

2.3. Food consisting of, isolated from or produced from plants or their parts[24]

- 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,[25] verification of the identity should be 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)

2.4. Food 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).

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

This section concerns cultures derived from multicellular origin (animals, plants, multicellular algae and mushrooms). Foods originated from cultures of unicellular origin should be addressed under Section 2.2.

- Biological source (taxonomic information on family, genus, species, subspecies, variety)
- For plants[26], algae[27] and fungi[28] 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 traditional food
- Type of cultures.

[24] 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).

[25] The Plant List (www.theplantlist.org) resulting from the Collaboration between the Royal Botanic Gardens, Kew and Missouri Botanical Garden; The USDA-ARS Germplasm Resources Information Network (GRIN) database (https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysimple.aspx) in case The Plant List 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.

[26] The Plant List (www.theplantlist.org) resulting from the Collaboration between the Royal Botanic Gardens, Kew and MissouriBotanical Garden; The USDA-ARS Germplasm Resources Information Network (GRIN) database (https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysimple.aspx) in case The Plant List does not provide the required information; The InternationalPlant Names Index (http://www.ipni.org/) in case the two above sources do not provide the required information.

[27] For algae species: The Algae database (www.algaebase.org).

[28] For the identification of fungi: The Index fungorum: http://www.indexfungorum.org/names/names.aspx for identification of fungi.

3. Production process

3.1. Detailed description of the production process

The process(es) employed to produce the traditional food (e.g. chemical synthesis, enzyme-catalysis, fermentation or isolation from a natural source, etc.) should be described. The description of the production process should be detailed enough to provide the information that will form the basis for the evaluation of the bioavailability, nutritional value and safety, which should be addressed in the respective sections. With regard to safety, the description should include information on potential by-products, impurities or contaminants.

Information should 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, cultivation practices, time of harvest in relation to both season and stage of the plant growth); the breeding, rearing, feeding and farming conditions 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 description of the cultivation of plants, fungi, algae and microorganisms, and the rearing of animals should also include information on the use of pesticides, antimicrobials and antiparasitic agents.

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. The parts of the organism used as a raw material should be specified and information on other starting substances or materials should be provided.

For traditional foods consisting of, isolated from or produced from plant, animal or microbiological sources, the applicant should describe in detail the process by which the raw material is converted into an ingredient or a preparation intended for a food product. Examples may include heat treatment, extraction, distillation, squeezing, fractionation, purification, concentration, fermentation, or other procedure(s). Information on substances used in the manufacturing process, e.g. identity of the extraction solvents, ratio of extraction solvent to the material, reagents, residues remaining in the final product, and any special precautions (light and temperature) should be provided.

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). A production flow chart should be provided, including quality and safety control checks. Standardisation criteria (e.g. chemical markers for the traditional food) should be provided.

For traditional foods consisting of, isolated from or produced from plants specific considerations and complementary information is provided in the EFSA guidance on safety assessment of botanicals and botanical preparations (EFSA Scientific Committee, 2009).

The applicant should consider and address how changes from traditional production processes to industrial (large scale) production will affect the composition, nutritional value and safety of the traditional food.

4. Compositional data

The information should include qualitative and quantitative data on the composition as well as physicochemical and biochemical properties and microbiological characterisation of the traditional food.

Section 4.1 outlines general data requirements applicable to all traditional foods. Sections 4.2 and 4.3 set specific requirements depending on whether the traditional food is a single substance or a simple mixture thereof, a complex mixture or a whole food.[29]

Validated methods should be used for the analyses, preferably applying nationally or internationally recognised methods (e.g. Association of Analytical Communities, American Chemical Society, European Pharmacopoeia). The respective methods of analysis should be described together with relevant references. The information on analyses for substances of toxicological concern should also include their limit of detection and limit of quantification. Certificates of analyses and information on the accreditation of laboratories should be provided. If in-house methods are employed, they should be fully described and the results of the respective validation procedures should be provided. If the

[29] As defined by the Scientific Committee (EFSA Scientific Committee, 2011), https://www.efsa.europa.eu/en/efsajournal/pub/2438

analyses are not performed in accredited laboratories, justification should be provided. 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 on representative samples of the notified traditional food. Available published data can also provide information on the variability of the composition of the traditional food.

Compositional data and their variability should support the setting of specifications of the traditional food how it is intended to be placed on the market (Section 5). The analytical information should be provided on preferably at least five representative batches of the traditional food that have been independently produced (i.e. with independent batches of raw materials). When several production processes are proposed, such data should be provided for each given process.

4.1. General requirements

Information on the identities and the quantities of impurities or by-products, residues and chemical and microbiological contaminants should be provided (e.g. heavy metals, mycotoxins, PCBs/dioxins, pesticides). The type and spectrum of potential target analytes should be considered in the light of the sources and the production process. For example, for substances produced by microbial fermentation, the presence of undesirable metabolites should be investigated; for substances isolated by extraction, data on residues of the solvent used should be provided.

4.2. 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, the following data should be provided:

- Identity tests (e.g. UV-VIS, IR, NMR, GC–MS, LC–MS)
- Physicochemical properties (e.g. appearance, melting point, boiling point)
- Solubility data in water and other common solvents
- Particle size, shape and distribution
- Minimum purity value
- Density and/or viscosity for liquid preparations

For single substances and their mixtures produced with genetically modified microorganisms (GMMs), applicants are referred to the requirements for GMMs Category 1 (i.e. chemically defined purified compounds and their mixtures in which both GMMs and newly introduced genes have been removed, e.g. amino acids, vitamins) as laid down by the EFSA guidance on the risk assessment of GMMs and their products intended for food and feed use (EFSA GMO Panel, 2011).

4.3. Complex mixtures and whole foods

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

A qualitative and quantitative characterisation of the main constituents should 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 nature of the traditional food (e.g. peptides, phospholipids, carotenoids, phenolics, sterols), comprehensive qualitative and quantitative data should be provided.

Qualitative and quantitative data on nutritionally relevant inherent constituents (e.g. micronutrients) should also be given.

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, addictive, psychotropic, allergenic) should be provided.

In addition to analytical data on composition, a literature search should be performed according to the methodology developed by EFSA (EFSA, 2010) to retrieve published compositional data for the

source and the part used in/as traditional food. Information on the used keywords and applied inclusion/exclusion criteria for the literature search should be provided.

Any substances of concern derived from plants should be classified according to their chemical structure. 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.

Particular attention should be given to the possible presence of genotoxic and/or carcinogenic substances.

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

- The EFSA Compendium of Botanicals which provides information on naturally occurring substances that may be of concern for human health (EFSA, 2012),[30]
- The EFSA Chemical Hazard Database (S-IN, 2015)[31] and subsequent updates,

For complex mixtures produced with GMMs, applicants are referred to the requirements for GMMs Category 2 (i.e. complex products in which both GMMs and newly introduced genes are no longer present, e.g. cell extracts, most enzyme preparations) as laid down by the EFSA guidance on the risk assessment of GMMs and their products intended for food and feed use (EFSA GMO Panel, 2011).

4.4. Stability

The stability of the traditional food should be evaluated in order to identify hazards which might arise during storage and transport. The nature of degradation products should be characterised.

Stability tests should therefore focus on those compounds and parameters of the traditional food which may be susceptible to changes during storage and which may directly affect its safety or serve as indicators for alterations which could have an impact on the safety of the food.

Depending on the nature and type of the traditional food, the stability testing should address the physicochemical, biochemical and microbiological stability of the traditional food under normal conditions of storage, including the effects of packaging, the storage temperature and the environment (light, oxygen, moisture, relative humidity). Information on the normal storage conditions of traditional food should be provided as well as on the storage conditions under which the stability testing was performed. The stability testing should be provided on preferably at least five representative batches of the traditional food that have been independently produced (i.e. with independent batches of raw materials).

The duration of the stability testing may depend on the type of the traditional food and its proposed uses and should cover at least the end of the shelf-life. Accelerated conditions (usually at higher temperature) may be used as an alternative to stability testing under normal conditions.

Information on ingredients added to the traditional food to improve its stability should be provided.

5. Specifications

The specifications define the key parameters which characterise and substantiate the identity of the traditional food, as well as limits for these parameters and for other relevant physicochemical, biochemical and microbiological properties. The specifications will be used as key parameters, among other compositional data, to evaluate whether the data provided to substantiate the 'history of safe food use' are relevant to the traditional food intended to be placed on the EU market. In addition, the limits set in the specifications for toxicologically and/or nutritionally relevant components will be considered in the risk assessment.

On the basis of the analytical data on the traditional food provided in Sections 2 and 4, the applicant should propose specifications, in the form of a table, which should include the limits and information on the exact method for each of the selected parameter.

The specifications should include nutritional or biologically active components or, when these are not known, on selected chemical markers. The specifications should also include concentrations of the major groups of constituents present in the food including, for example, amino acids and proteins,

[30] https://www.efsa.europa.eu/en/data/compendium-botanicals
[31] https://www.efsa.europa.eu/en/press/news/180719

lipids, carbohydrates, inorganic ions, polyphenols, alkaloids, terpenes, alkenylbenzenes, lignin, saponins, chitin, as well as the main substances within these classes.

A rationale for the selected parameters should be provided. As a minimum, the specification should include 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, maximum levels of contaminants (e.g. microorganisms, mycotoxins, heavy metals, pesticide residues, polycyclic aromatic hydrocarbons) should be included.

6. Data from experience of continued use

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

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. Further information might be obtained from cookbooks, recipes and anecdotal data. The reliability and weight of the data will be assessed in the light of their source, qualitative and quantitative nature.

It is important to characterise as much as possible the traditional modalities of use in terms of preparation type, extent of use and duration of the exposure. A food traditionally consumed only at special occasions, or exclusively in combination with another food/substance, may cause health concerns/adverse effects when consumed in larger quantities, for longer duration or in a different combination or context. It is possible that the food could be used, cooked and consumed differently by consumers in the EU, as compared to that in the third country.

6.1. Experience of continued food use in the third country

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, information on precautions. A comprehensive literature review of human studies 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. Where applicable, the published literature should be reviewed by taking into account systematic review principles (EFSA, 2010). Information on the search strategy for data in the non-peer reviewed literature ('grey literature') should also be provided. Full study reports should be provided if available.

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

6.1.1. 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 consumed;
- 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;
- clear distinction should be made between the intakes of a part of a botanical as such, preparations made of it (e.g. tea), or e.g. an intake of essential oil;
- the length and continuity of its use over time.

6.1.2. Characteristics of the population group(s) of consumers

Documentation should be provided on whether a 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, ethnic background, physiological and/or disease conditions. Information on the size of the population or population groups which have consumed the traditional food should be provided.

6.1.3. Role in the diet

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

6.1.4. Information on the handling and preparation of the food

This section should provide documentation concerning the handling, including storage, and the preparation of the 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.

6.1.5. Precautions for the preparation and restrictions of use

Information on any prohibition or restrictions imposed in respect of the food in the third countries, precautions to be taken during its preparation, any kind of treatment or methods to reduce levels of toxic, allergenic or antinutritional substances or to improve digestibility, should be provided, as well as information on reported limitations and restrictions for sensitive/specific population groups.

6.1.6. Human data

The applicant should document their comprehensive literature search for available human data related to the safety of the traditional food (e.g. kinetic data, toxicological, nutritional, microbiological, allergenic, tolerability, interaction with medicines). These 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 family).

6.2. Other information

All other available information relevant for the safety assessment of the traditional food should be provided. This could include non-food uses (e.g. cosmetic, medical, feed) and animal studies (e.g. toxicity studies).

7. Proposed conditions of use for the EU market

A rationale for the target population, proposed uses and use levels, precautions and restrictions of use should be provided with cross-referencing to relevant data on the 'history of safe food use'.

7.1. Target population

The applicant should unambiguously specify the intended target population, e.g. the general population or certain defined population subgroups.

7.2. Proposed uses and use levels

It is of utmost importance that the information provided in this section is precise, complete and free of ambiguity. When proposing uses and use levels, all available information on safety should be taken into consideration.

The applicant should specify:

- the form of uses (e.g. as whole food, ingredient);
- the food categories[32] in which the traditional food (if an ingredient) is proposed to be used;
- whether the traditional food is intended to replace another food;
- the proposed maximum use level(s) and concentration(s) in final product(s);
- the proposed daily intakes for different age/gender groups as appropriate.

7.3. Intended role in the diet

Where a traditional food is intended to replace 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.

7.4. 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 specify the population (sub)groups (including population groups with certain physiological conditions) which should avoid consumption of the traditional food and include the rationale. The applicant should also indicate any other restrictions of use and precautions related to the handling, preparation and consumption of the traditional food.

Any effect(s) of potential overconsumption on population or subgroups of population should be described.

8. 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.

9. References and Annexes to the dossier

Electronic copies of all pertinent studies (published and unpublished, proprietary and not proprietary) submitted in support of the dossier, including electronic copies of protocols and full study reports of clinical studies unpublished and/or proprietary to applicant should be uploaded in the e-submission system as part of the technical dossier.

EFSA strongly recommends that each document, including annexes (i.e. study reports, raw data, published studies, the certificates on the accreditation of laboratories, certificates of analyses and any other document in the technical dossier) be electronically **searchable** and accessible to allow downloading and printing of the file. This applies to **all documents or information** uploaded as part of the initial submission, or later during the risk assessment process.

The applicant must ensure that terms and conditions asserted by any rightsholder of studies, information or data submitted to EFSA are fully satisfied. The applicant may consult with copyright licensing authorities (i.e. at national level) for guidance on purchasing the appropriate licenses to provide studies, information or data to EFSA, taking into account the proactive disclosure requirements as detailed above. For publications already available to the public upon payment of fees (e.g. studies published in scientific journals) for which the applicant does not have or cannot obtain intellectual

[32] Preferably the EFSA Food classification system should be used (EFSA, 2011).

property rights for the purposes of the proactive public disclosure requirements, the applicant must provide (a) a copy of the relevant publications along with the relevant bibliographic references/citations for scientific assessment purposes only, in the confidential version of its application and (b) these relevant bibliographic references/citations where these publications are available to the public in the non-confidential version of its application for public dissemination on the OpenEFSA portal.[33]

A list of annexes and a list of references, glossary or abbreviations of terms quoted throughout the dossier should be also included.

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

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Abbreviations

CAS	Chemical Abstracts Service
EC	European Commission
GC–MS	gas chromatography–mass spectrometry
GFL	General Food Law
GMM	genetically modified microorganisms
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis Critical Control Point
IR	infrared spectroscopy
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LC–MS	liquid chromatography–mass spectrometry
NDA	EFSA Panel on Dietetic Products, Nutrition and Allergies. As of 1 July 2018, it has been renamed 'Panel on nutrition, novel foods and food allergens'
NMR	nuclear magnetic resonance
TR	Transparency Regulation
UV-VIS	UV-visible spectroscopy