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## Guidance 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

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### Abstract

Following the adoption of Regulation (EU) 2015/2283 of the European Parliament and of the Council on Novel Foods, the European Commission requested EFSA to develop a scientific and technical guidance for the preparation and presentation 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 the applicant in 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. Besides, its normal consumption should not be nutritionally disadvantageous. To that end, information is requested on the description, production process, composition, stability data, specifications, data from experience of continued use in a third country and on the proposed conditions of use of the traditional food for the EU market. The structure of the notification dossier should follow the sections presented in this guidance. 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 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 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.

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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 presentation 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.

The guidance document was subject to public consultation (from 18 February to 21 April 2016) and a stakeholder meeting (11 April 2016) before finalisation.

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## Background as provided by the European Commission

On 25 November 2015, the European Parliament and the Council adopted the Regulation of the European Parliament and of the Council on novel foods.<sup>1</sup>

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 novel food concerned is as safe as food from a comparable food category already existing on the market within the Union;
- 2) whether the composition of the novel food and the conditions of its use do not pose a safety risk to human health in the Union;
- 3) 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 it 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 applicant may transform the notification into an application, 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 shall adopt implementing rules on administrative and scientific requirements for the preparation and the presentation of the applications for novel foods, as well as for the notifications and applications for traditional foods from third countries for the scientific assessment, respectively, in accordance with Article 13 and Article 20 of the Regulation. These implementing measures need to be complemented with scientific and technical guidance regarding the information that needs to be submitted by the applicants. In this context, the current Commission Recommendation 97/618/EC,<sup>2</sup> which is in place for the additional safety assessment of the novel food applications under the current rules (Regulation (EC) No 258/97<sup>3</sup>), should serve as the basis for updating the guidance on preparation and presentation of applications for novel foods.

## Terms of Reference as provided by the European Commission

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.

## 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)

<sup>1</sup> 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.

<sup>2</sup> Commission Recommendation of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council. OJ L 253, 16.9.1997, p. 1–36.

<sup>3</sup> Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. OJ L 43, 14.2.1997, p. 1–6.

2015/2283 and on the proposed conditions of use. Adherence to this format will also facilitate easy 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.

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.

## Scope

The guidance presented in this document is for preparing and presenting of 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, 2016a).

## 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:
    - 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 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, and with the current and future EU guidelines

and provisions. In addition, several guidance documents from EFSA are of relevance for the preparation 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.

- 2) The term 'notification' means a stand-alone dossier containing the information and the scientific data 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 concerning the data on the history of safe use in a third country. 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 demonstrate the history of safe food use of the traditional food should be comprehensive and complete.
- 4) The identification of data pertinent to the safety of the traditional food should be performed 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 easy access to information and scientific data in dossiers to help the NDA Panel to carry out its evaluation and to deliver its scientific opinion 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, 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 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.
- 8) 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.
- 9) Deviations from the requirements specified in the respective sections described in this guidance should be justified.
- 10) The decision on confidential treatment of information submitted under Article 23 of Regulation 2283/2015 falls under the responsibility of the European Commission. As per Article 23(5) of the Regulation, EFSA shall take necessary measures to ensure appropriate confidentiality of the information received under this Regulation, except for information which is required to be made public in order to protect human health.

## Organisation and content of the dossier

The following information should be provided in the notification and the application, and the structure should follow a common format. Data provided in the dossier should be organised into three parts:

- Part 1 contains the administrative data, such as information related to the applicant.
- Part 2 contains information related to the introduction (Section 2.1), identity (Section 2.2), production process (Section 2.3), compositional data (Section 2.4), specifications (Section 2.5), experience of continued use (Section 2.6) and proposed conditions of use (Section 2.7). It includes a list of all references.
- Part 3 comprises the glossary or abbreviations of terms quoted throughout the dossier, the certificates (on the accreditation of laboratories, certificates of analyses) and contains full copies/reprints 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').

## 1. Part 1: Administrative data

### 1.1. Comprehensive table of contents of the dossier

### 1.2. Applicant

#### 1.2.1. Company/organisation

Provide the name and address of the company or organisation.<sup>4</sup>

#### 1.2.2. Contact person

Indicate the contact person authorised to communicate with EFSA on behalf of the applicant.<sup>5</sup>

### 1.3. Specifications

Please select one of the options below:

- a notification for authorisation of traditional foods from a third country which fall under Article 14 of Regulation (EU) 2015/2283;
- an application for the authorisation of traditional foods from a third country under Article 16 of Regulation (EU) 2015/2283 concerning the data on the history of safe use in a third country.

### 1.4. Regulatory status outside the European Union

If the traditional food has been submitted by the applicant to a regulatory body for authorisation outside the EU, please indicate the status of the evaluation by each regulatory body (if more than one), as appropriate:

- Under consideration

Specify the proposed conditions of use (if they are different), the date of submission, and the recipient regulatory body.

- Withdrawn

Specify the conditions of use (if they are different) of the traditional food which was withdrawn, the date of withdrawal, the reasons for withdrawal. Indicate the regulatory body at the time of withdrawal.

- Authorised

Specify the conditions of use (if they are different) of the traditional food which has been approved, the date of approval. Indicate the authorising regulatory body, and if available, provide a copy of the scientific opinion of the regulatory body which authorised the traditional food (in Part 3).

- Rejected

Specify the date and the reasons of rejection. Indicate the regulatory body which rejected the traditional food, and if available, provide a copy of the scientific opinion of the regulatory body which rejected the traditional food (in Part 3).

<sup>4</sup> In case more than one company or organisation submits a dossier, provide their names and addresses. Only one contact person should be authorised to communicate with EFSA.

<sup>5</sup> To facilitate communication, only one contact person should be indicated per dossier.

## 2. Part 2: Characterisation of the traditional food, technical and scientific data

### 2.1. Introduction

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.

### 2.2. Identity of the traditional food

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.

#### 2.2.1. 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).

#### 2.2.2. 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<sup>6</sup> and fungi,<sup>7</sup> 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, 2016b). 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

#### 2.2.3. Food consisting of, isolated from or produced from plants or their parts<sup>8</sup>

- 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,<sup>9</sup> 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)

<sup>6</sup> For algae species: The Algae database ([www.algaebase.org](http://www.algaebase.org))

<sup>7</sup> For the identification of fungi: The *Index fungorum*: <http://www.indexfungorum.org/names/names.asp> for identification of fungi.

<sup>8</sup> 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).

<sup>9</sup> The Plant List ([www.theplantlist.org](http://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.

- Part(s) used (e.g. root, leaf, seed, etc.)
- Geographical origin (continent, country, region)

#### 2.2.4. 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).

#### 2.2.5. 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 2.2.2.

- Biological source (taxonomic information on family, genus, species, subspecies, variety)
- For plants,<sup>9</sup> algae<sup>6</sup> and fungi,<sup>7</sup> 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.

### 2.3. Production process

#### 2.3.1. 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.

### 2.3.2. Non-confidential description of the production process

If the detailed description on the production process (Section 2.3.1) contains confidential elements, the applicant is asked to provide a non-confidential summary of the production process of between half to a maximum of a page in length.

## 2.4. 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 2.4.1 outlines general data requirements applicable to all traditional foods. Sections 2.4.2 and 2.4.3 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.<sup>10</sup>

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 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 2.5). 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.

### 2.4.1. 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.

### 2.4.2. 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)

<sup>10</sup> As defined by the Scientific Committee (EFSA Scientific Committee, 2011), <https://www.efsa.europa.eu/en/efsajournal/pub/2438>

- 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).

### 2.4.3. 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; section 3.2) 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),<sup>11</sup>
- The EFSA Chemical Hazard Database (S-IN, 2015).

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).

### 2.4.4. 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.

<sup>11</sup> <https://www.efsa.europa.eu/en/data/compendium-botanicals>

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.

## 2.5. 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 2.2–2.4, 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, 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.

## 2.6. 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.

### 2.6.1. 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.

#### **2.6.1.1. 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.

#### **2.6.1.2. 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.

#### **2.6.1.3. 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.

#### **2.6.1.4. 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.

#### **2.6.1.5. 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.

#### **2.6.1.6. 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).

## 2.6.2. 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).

## 2.7. 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'.

### 2.7.1. Target population

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

### 2.7.2. 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<sup>12</sup> 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.

### 2.7.3. 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.

### 2.7.4. 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.

## 2.8. 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.

## 3. Part 3: Annexes to the dossier

- The glossary or abbreviations of terms quoted throughout the dossier
- The certificates (on the accreditation of laboratories, certificates of analyses)
- Full copies/reprints of all pertinent scientific data (published and unpublished)
- Full study reports

<sup>12</sup> Preferably the EFSA Food classification system should be used (EFSA, 2011).

- Scientific opinions of national/international regulatory bodies
- Full texts of all cited non-scientific references ('grey literature').

## References

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## Abbreviations

CAS	Chemical Abstracts Service
GC-MS	gas chromatography-mass spectrometry
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
NMR	nuclear magnetic resonance
UV-VIS	UV-visible spectroscopy