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Draft guidance on the preparation and presentation of a notification for authorisation of Traditional Foods from third countries

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)

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 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 notification dossier. The history of safe use of a Traditional Food should be substantiated by data on its composition and its experience of use. The proposed conditions of use in the EU market should not raise safety concern. The normal consumption of the traditional food should not be nutritionally disadvantageous. To that end, information is requested on the description, production process, compositional data, specifications, experience of use, and proposed conditions of use of the Traditional Food for the EU market. The application should be comprehensive and complete. Where potential health hazards have been identified on the basis of the composition and/or data from the experience of use, they should be presented, discussed and adequately addressed in the proposed conditions of use to ensure that the consumption of the Traditional Food is safe for the target population. 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 in the EU. On the basis of the information provided, EFSA will assess whether there are reasoned safety objections related to the consumption of the Traditional Food under the proposed conditions of use.

Keywords: guidance, Novel foods, Traditional Foods, third countries, notifications, authorisation

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Summary

Following the adoption of the new Regulation (EU) 2015/2283 of the European Parliament and of the Council on Novel Foods, the European Commission requested the European Food Safety Authority 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 notification dossier.

As outlined in Regulation 2015/2283, the history of safe use of a Traditional Food should be substantiated by data on its composition and its experience of use. The proposed conditions of use in the EU market should not raise safety concern. The normal consumption of the traditional food should not be nutritionally disadvantageous. To that end, information is requested on the description, production process, compositional data, specifications, experience of use, and 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 for notifications of 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.

The application should be comprehensive and complete. Where potential health hazards have been identified on the basis of the composition and/or data from the experience of use, they should be presented, discussed and adequately addressed in the proposed conditions of use to ensure that the consumption of the Traditional Food is safe for the target population. 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 in the EU.

On the basis of the information provided, EFSA will assess whether there are reasoned safety objections related to the consumption of the Traditional Food under the proposed conditions of use.

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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[1].

The Regulation foresees 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:

(a) whether the novel food concerned is as safe as food from a comparable food category already existing on the market within the Union;

(b) 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;

(c) 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 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 these types of novel foods, EFSA shall, where appropriate, consider the following:

(a) whether the history of safe food use in a third country is substantiated by reliable data submitted by the applicant;

(b) whether the composition of the food and the conditions of its use do not pose a safety risk to human health in the Union;

(c) 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[2], which is in place for the additional safety assessment of the novel food applications under the current rules (Regulation (EC) No 258/97[3]), 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 the European Food Safety Authority 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

[1] Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, amending Regulation (EU)
[2] OJ L 253, 16.9.1997, p. 1.
[3] OJ L 43, 14.2.1997, p. 1.

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 easy access to information and scientific data in notifications to help EU Member States and EFSA in carrying out their evaluation in an effective and consistent way.

This Guidance for notifications of 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.

Scope

The Guidance presented in this document is for preparing and presenting the data on the history of safe food use in a third country and on the proposed conditions of use for notifications of Traditional Foods under Article 14 and for applications for the authorisation of Traditional Foods from third countries under Article 16 of Regulation (EU) 2015/2283.

For the preparation and presenting of information other than on the history of safe food use in a third country and on the proposed conditions of use, in response to the reasoned safety objections under Article 16 of the Regulation (EU) 2015/2283, the applicant should consider the Guidance on the preparation and presentation of applications for authorisation of a novel food (EFSA, 2016).

The Guidance will be kept under review and it will be amended and updated as appropriate in the light of experience gained from evaluations of notifications for traditional foods.

Definitions

As per Article 3, paragraph 2 of Regulation (EU) 2015/2283

(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 Member States to the Union and that falls under at least one of the following categories:

(i) food with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997;

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

(iii) food consisting of, isolated from or produced from material of mineral origin;

(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, micro-organisms, fungi or algae;

(vii) food resulting from a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances;

(viii) food consisting of engineered nanomaterials as defined in point (f) of this paragraph;

(ix) vitamins, minerals and other substances used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013, where:

– a production process not used for food production within the Union before 15 May 1997 has been applied as referred to in point (a) (vii) of this paragraph; or

– they contain or consist of engineered nanomaterials;

(x) food used exclusively in food supplements within the Union before 15 May 1997, where it is intended to be used in foods other than food supplements as defined in point (a) of Article 2 of Directive 2002/46/EC;"

(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

- 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 current and future EU guidelines and Regulations. In addition, several Guidances 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 Guidances. In addition, this list is not exhaustive; other EFSA Guidances might be applicable in specific cases and should be considered by the applicant where relevant.
- The term "notification dossier" hereafter means a stand-alone dossier containing the information and the scientific data submitted for the assessment of the Traditional Food from third countries.
- As outlined in Regulation 2283/2015, the history of safe use of a Traditional Food should be substantiated by data on its composition and its experience of use. The proposed conditions of use in the EU market should not raise safety concern. The normal consumption of the traditional food should not be nutritionally disadvantageous. In order to perform the assessment, information is requested on the description (section 2), production process (section 3), compositional data (section 4), specifications (section 5), data from experience of use (section 6) and proposed conditions of use in the EU market (section 7). The structure of the notification dossier should follow the sections presented in this Guidance.
- It is the duty of the applicant to provide all of the available data (including both data in favour and not in favour) that are pertinent to the safety of the Traditional Food.
- As such, the notification dossier should be comprehensive and complete. The identification of data pertinent to the safety of the Traditional Food must be performed and documented in order to demonstrate that the notification covers the complete information available on the Traditional Food. The published literature should be reviewed following systematic review principles (EFSA, 2010). The methods used to identify relevant data, including databases used and criteria of literature searches, should be reported. Full study reports should be provided if available.
- 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.
- Deviations from the requirements specified in the respective sections described in this Guidance should be justified.
- 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.
- The decision on confidential treatment of information submitted under Article 23 of Regulation 2283/2015 falls under the responsibility of the European Commission. The applicant is referred to the relevant implementing acts from 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 notification

The following information should be provided in the notification dossier and the structure should follow a common format, i.e. **order and numbering system for the two Parts, their main headings and first and second sub-headings**. Data provided in the notification dossier should be organised into **two parts:**

- **Part 1** contains information related to the introduction (section 1), description (section 2), production process (section 3), compositional data (section 4), specifications (section 5), data from experience of use (section 6), proposed conditions of use in the EU market (section 7) and concluding remarks (section 8).
- **Part 2** comprises the glossary or abbreviations of terms quoted throughout the notification dossier, the certificates (certificates of analyses, certificates of accreditation of laboratories) and all pertinent scientific data (published and unpublished) including copies/reprints of pertinent publications, full study reports, and scientific opinions of national/international regulatory bodies.

Structure of Part 1

Introduction

The nature of the Traditional Food should be summarised in an introductory paragraph, including the source, the principle of the production process and typical compositional features. Its traditional use in a third country and intended use on the EU market should be briefly described.

1. Description of the Traditional Food

The following information should be provided, depending on the category under which the Traditional Food falls:

1.1. Foods consisting of, isolated from or produced from microorganisms, fungi or algae

- Taxonomic classification of the microorganism, fungi or algae and identification procedure
- Synonyms that may be used interchangeably with the preferred scientific name
- Genetic characterisation (molecular typing) for unicellular organisms
- Origin and history of the organism
- Deposition in an officially-recognized culture collection with access number

1.2. Foods consisting of, isolated from or produced from plants or their parts

- Scientific (Latin) name (botanical family, genus, species, subspecies, variety with author's name, chemotype, if applicable)
- Synonyms (botanical name) that may be used interchangeably with the preferred scientific name
- Common names (if a trivial or common name is used extensively, it should be linked to the scientific name and part used)
- Part used (e.g. root, leaf, seed)
- Geographical origin (continent, country, region)

1.3. 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 common name is used extensively, it should be linked to the scientific name and part used)

- Part used
- Geographical origin (continent, country, region)

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

This section concerns cultures of multicellular origin (animals, plants including multicellular algae, and mushrooms). Foods originating from cultures of unicellular organisms should be addressed under 2.1.

- Biological source (taxonomic information on family, genus, species, subspecies, variety)
- 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 culture

2. Production process

The process employed to produce the Traditional Food should be described. The description should be detailed enough to allow conclusions to be drawn regarding the impact of the complete production process on the safety and nutritional value of the Traditional Food. It should specifically focus on potential by-products, impurities or chemical and microbiological contaminants that could raise safety concerns.

This section should include information on the 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, microalgae, and cell cultures from multicellular organisms. The description of the cultivation of plants, fungi, microalgae and microorganisms, and of the rearing of animals, should also include information on the use of pesticides, antimicrobials and antiparasitic agents.

The transport and storage conditions of the raw materials used for further processing, and of unprocessed Traditional Foods, should be described.

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

The applicant should describe in detail the process by which the raw material is converted into the Traditional Food. Operational limits and key parameters of the production process should be given. Measures implemented for production control and quality assurance should be described (e.g. HACCP, GMP, and ISO). A production flow chart should be provided, including information on quality control checks.

3. Compositional data

The information should include qualitative and quantitative data on the composition, as well as physico-chemical, biochemical and microbiological properties of the Traditional Food.

Validated methods should be used for the analyses, preferably nationally or internationally recognised methods (e.g. AOAC International, American Chemical Society (ACS), European Pharmacopea). The respective methods of analysis [with their limit of detection (LOD) and limit of quantification (LOQ)] should be described together with relevant references. 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.

Compositional data and their variability should support the setting of specifications which is representative of the product to be marketed (Section 5). The analytical information should preferably

be provided on at least five representative batches of the Traditional Food that have been independently produced (i.e. with independent batches of raw materials).

A qualitative and quantitative characterisation of the main constituents should be performed, at least via sum parameters. For whole foods this should include proximates analyses (i.e. ash, moisture, protein, fat, carbohydrate). On the basis of these data, a mass balance should be set up. The amount of unidentified constituents (calculated as 100 % minus the percentage characterised) 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, and sterols), comprehensive qualitative and quantitative data should be provided. Data from taxonomically related species should be taken into consideration for the identification of relevant components.

Qualitative and quantitative data on nutritionally relevant inherent constituents (e.g. micronutrients) should also be given. The content and effect of anti-nutritional factors in the Traditional Food (e.g. inhibiting absorption or modifying bioavailability of nutrients) and other interactions with nutrients should be assessed.

In addition, qualitative and quantitative data on toxic, addictive, psychotropic or other substances of possible concern to human health contained in the Traditional Food should be provided. Furthermore special attention should be given to the presence of potential allergens.

Information should also be provided on the identities and quantities of impurities or by-products, residues and contaminants. The type and spectrum of potential target analytes should be considered in the light of the sources and the production process (Section 3). For example, for substances produced via microbial fermentation, the presence of undesirable metabolites, such as mycotoxins, has to be investigated. For substances isolated via extraction, residues of the employed solvent should be provided.

3.1. Stability

The stability of the Traditional Food should be evaluated in order to identify hazards which might arise during storage.

Stability tests should therefore focus on those constituents 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. The nature of degradation products should be identified.

Depending on the nature and type of the Traditional Food, the assessment should cover the physico-chemical, biochemical and/or microbiological stability of the Traditional Food under normal conditions of storage, including the effects of packaging, storage temperature and the environment (light, oxygen, moisture, relative humidity). Information on the normal storage conditions of the Traditional Food should be provided, as well as on the storage conditions under which the stability testing was performed.

If the Traditional Food is intended to be used as an ingredient added to other foods, its stability in the processed foods should be investigated (e.g. effect of processing temperature, pH, and other constituents in the processed foods).

4. 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 physico-chemical, biochemical and microbiological properties. The specifications will be used, among other compositional data, to evaluate whether the data provided to substantiate the history of safe food use regards the Traditional Food intended to be placed on the EU market. In addition, the assessment will consider whether the limits set in the specifications for toxicologically and/or nutritionally relevant components raise any safety concern.

On the basis of the analytical characterisation of the Traditional Food (sections 2 and 4), the applicant should propose specifications, in the form of a table.

A rationale for the selected parameters should be provided. As a minimum, the specifications should include contents and/or limits for the parameters on the identity of the product; the minimal purity; and acceptable limits 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, PAHs) should be included.

The specifications should provide the methods used for the analysis of all parameters.

5. Data from experience of use

This section should provide all data from the experience of 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, 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, and qualitative and quantitative nature.

5.1. Experience of food use in a third country

The documentation on the experience of food use should provide a description of the extent of use of the Traditional Food, the characteristics of consumer groups, the role of the Traditional Food in the diet, as well as information on precautions for the preparation and restrictions of use. A comprehensive literature review of human studies reporting adverse effects related to the consumption of the Traditional Food should be performed.

The documentation provided should unambiguously relate to the Traditional Food that is the subject of the notification.

5.1.1. Extent of use

The applicant should characterise the extent of use of the Traditional Food by documenting:

- The length and continuity of its use over time.
- The quantity of consumption, including information on the serving size(s) and average, high and maximum daily intake levels per person. If available, intake estimates based on food consumption surveys or other intake estimates should be provided.
- Figures on cultivation/harvesting, sales and trade may also provide information.
- The geographical areas (e.g. region, country, continent) where it has been consumed.

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

Documentation should be provided on whether a Traditional Food has been consumed by the general population or whether its consumption was rather or entirely limited to specific sub-populations 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.

5.1.3. Role of the Traditional Food in the diet

Documentation should be provided on the consumption pattern including the frequency, the context of the consumption (e.g. for specific purposes, ceremonies, combined consumption with other foods), and 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.

5.1.4. Precautions for preparation and restrictions of use

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, or any other type of treatment.

Information on precautions to be taken during the preparation of the Traditional Food, any kind of treatment or methods to reduce levels of toxic, allergenic or anti-nutritional substances or to improve digestibility, information on reported limitations and restrictions for sensitive/specific population groups should be provided.

5.1.5. Human data

The applicant should document their comprehensive literature search for human data related to the safety of the Traditional Food (e.g. toxicological, nutritional and microbiological data, or data on allergenicity). These could include intervention and observational studies, case reports and information from surveillance reports.

The applicant should not limit their literature search to the Traditional Food itself, but should also search for data on specific and typical components of the Traditional Food and data on 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).

5.2. Other information

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

6. Proposed conditions of use in 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. For the proposed conditions of use in the EU market, all available information on safety should be taken into consideration.

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 and adequately addressed in the proposed conditions of use to ensure that the consumption of the Traditional Food is safe for the target population.

It is of utmost importance that the information provided in this section is precise, complete and free of any ambiguity.

6.1. Target population

The applicant should unambiguously specify the intended target population, e.g. adults, the general population or certain defined population sub-groups.

6.2. Proposed uses and use levels

The applicant should specify:

- The form of uses (e.g. as whole food, ingredient, food supplement);
- The food categories in which it is proposed to be used;
- Whether the Traditional Food is intended to replace another food;
- The proposed maximum amounts in final product(s);
- The proposed average and maximum daily intakes for different age/gender groups as appropriate;

6.3. Intended role in the diet

Where a Traditional Food may replace another food, the applicant should demonstrate that it does not differ from that food in a way that consuming it would be nutritionally disadvantageous for the consumer.

6.4. 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.

6.5. Concluding remarks

Where potential health hazards have been identified on the basis of the composition and/or data from the experience of use, they should be presented, discussed and adequately addressed in the proposed conditions of use to ensure that the consumption of the Traditional Food is safe for the target population. 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 food use of the Traditional Food and how this relates to the proposed conditions of use in the EU.

References

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EFSA NDA Panel (EFSA Panel on Dietetic Products Nutrition and Allergies), 2016. Guidance on the preparation and presentation of an application for authorisation of a Novel Food. EFSA Journal 2016; X(X):XXX, XXpp. doi:XX.XXXX/j.efsa.2016.XXXX *(to be completed later)*