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Outcome of a public consultation on the draft guidance on the preparation and presentation of the notification and application for authorisation of traditional foods from third countries in the context of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

European Food Safety Authority

Abstract

The European Food Safety Authority (EFSA) carried out a public consultation to receive input from the scientific community and all interested parties on the draft guidance on the preparation and presentation of the notification and application for authorisation of traditional foods from third countries, prepared by the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) and endorsed by the Panel for public consultation at its Plenary meeting on 1 February 2016. The written public consultation for this document was open from 18 February 2016 to 21 April 2016. EFSA received 60 comments from 18 interested parties. As part of EFSA's public consultation, a stakeholders' meeting was held in Brussels on 11 April 2016. EFSA and its NDA Panel wish to thank all stakeholders for their contributions. The current report summarises the outcome of the public consultation, and includes a brief summary of the comments received and how the comments were addressed. The NDA Panel prepared an updated version of the guidance taking into account the comments received. The guidance was discussed and adopted at the NDA Plenary meeting on 22 September 2016, and is published in the EFSA Journal.

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Key words: guidance, novel foods, traditional foods, third country, safety, public consultation

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1. Introduction

1.1. 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 foods¹.

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 these types 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/EC², which is in place for the additional safety assessment of the novel food applications under the current rules (Regulation (EC) No 258/97³), should serve as the basis for updating the guidance on preparation and presentation of applications for novel foods.

1.2. 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.

¹ Regulation (EU) 2015/2283 of the European Parliament and of the Council 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 (2013/0435 (COD)) [OJ L 327, 11.12.2015, p. 1–22].

² OJ L 253, 16.9.1997, p. 1.

³ OJ L 43, 14.2.1997, p. 1.

1.3. Consideration

Upon a request from the European Commission, the EFSA NDA Panel developed a draft guidance on the preparation and presentation of a notification for authorisation of traditional foods from third countries. In line with EFSA's policy on openness and transparency, and in order for EFSA to receive comments on its work from the scientific community and stakeholders, EFSA engages in public consultations on key issues. Accordingly, the draft guidance was published on EFSA's website for comments (18 February 2016 to 21 April 2016) (see Appendix A) and a stakeholders' meeting was held in Brussels on 11 April 2016⁴. The NDA Panel prepared an updated version of the guidance, taking into account the comments received. The updated guidance was discussed and adopted at the NDA Plenary meeting on 22 September 2016, and is published in the EFSA Journal (EFSA NDA Panel, 2016a). EFSA is committed to publishing the comments received during the public consultation, as well as a report on the outcome of the consultation.

2. Screening and evaluation of comments received

2.1. Comments received

EFSA received 60 written comments from 18 interested parties, including risk assessment bodies from European Member States and from third countries, consultants, the food industry and food industry associations.

Comments related to policy or risk management aspects were considered to be outside the scope of the consultation, and are not addressed in this report.

Table 1: List of organisations submitting comments

Organisation	Country
AESGP - the Association of the European Self-Medication Industry	BE
Individual commenter	UK
Australian Embassy Brussels - Agriculture Section	AU
Casa de Mesquite	US
Committee "Novel Foods and New Technologies" of the Codex Alimentarius Austriacus Commission	AT
ELC - Federation of European Specialty Food Ingredients Industries	BE
Food Law Consult	BE
Food Safety Authority of Ireland	IE
Food Supplements Europe	BE
Independent Expert and Consultant,	PK
Intertek Scientific & Regulatory Consultancy	UK
National Food Agency	SE
Nutraveris	FR
OPPASS - Office of Pesticide Programs Administrative Support Systems	BE
Pen & Tec Consulting	CH
Secretaría de Economía (Secretariat of Economy of a non-EU country)	MX
Tea & Herbal Infusions Europe (THIE)	DE
UK Advisory Committee on Novel Foods and Processes	UK

AU: Australia; AT: Austria; BE: Belgium; CH: Switzerland; DE: Germany; FR: France; IE: Ireland; MX: Mexico; PK: Pakistan; SE: Sweden; UK: United Kingdom; US: United States.

All written comments received are listed in Appendix B.

A summary of the comments received is given below.

⁴ <https://www.efsa.europa.eu/en/events/event/160411>

2.2. General comments

2.2.1. Comments related to risk management

EFSA would like to highlight that the following comments (1 to 9) are considered to be related to risk management. These comments are not further discussed in the present report as they are not part of EFSA's remit, and thus they were not taken into account when updating the draft guidance.

Comments received:

1. Information was asked how changes to an approved traditional food's specification, production process or composition would be managed.
2. Why the regulatory framework does not provide the possibility for proprietary data protection.
3. Clarification was asked for the term "significant" number of people in at least one third country used in Regulation (EU) 2015/2283 for the definition of '*History of safe food use in a third country*'.
4. Whether a food derived from solvent extraction can still be considered from primary production.
5. Questions were raised related to foods already on the EU market before 1997 and to foods entering the market after 1997 which did not require marketing authorisation.
6. Questions whether specific food items (e.g. corn smut) are considered "traditional foods".
7. Questions related to the interpretation of legal terms (e.g. "*primary food production*").
8. It was stated that an update of the definition of an engineered nanomaterial would require some changes to this guidance.
9. Whether it is necessary to provide translations of foreign texts.

2.2.2. Generic comments

Comments received:

10. It was requested to stress in the title of the guidance that traditional foods from third countries are novel foods.
11. It was suggested to give greater emphasis to a flexible approach, particularly regarding whole foods, to ensure that appropriate information for the food is supplied.
12. It was noted that traditional foods of a region/country are the embodiment of traditional wisdom derived over centuries and that their controls, parameters, processes are sometimes not explainable fully as scientific descriptions. It is therefore almost impossible to derive a scientific description in the application.
13. It was proposed to involve experts of the EFSA Working Group on Botanicals and to make reference to the EFSA guidance on the safety assessment of botanicals and botanical preparations.
14. The majority of the really useful literature is in the form of grey literature, unpublished theses, obscure anthropological monographs, local government documents, etc. that will be missed by a systematic review following the EFSA guidance on systematic reviews (as requested by the general principles). It was requested that more emphasis be placed on a typical scientific review than a "systematic computer data base search".

Panel consideration of comments received:

Ad10. The title of the guidance was extended and refers now to Regulation (EU) 2015/2283.

Ad11. The Panel considers that the guidance provides sufficient flexibility to cover both whole and processed foods. General principle No. 9 indicates that deviations are possible but should be justified.

- Ad12. The Panel agrees with this comment and refers to section 2.6 of the guidance which explicitly indicates that non-scientific data such as information from cookbooks, recipes and other anecdotal data, may also contribute to data on the experience of continued use.
- Ad13. The Panel notes that experts of the EFSA Working Group on Botanicals were consulted during the public consultation phase, and that their comments are reflected in changes in several sections of the guidance (including the sections on the description of the traditional food, production process, compositional data, specifications and data from the experience of continued use). The guidance also makes reference to the EFSA guidance on the safety assessment of botanicals and botanical preparations (EFSA SC, 2009).
- Ad14. General principle No 4 of the guidance referring to EFSA's systematic review principles was extended with the emphasis to provide also information on how non-scientific literature was identified.

2.2.3. Comments related to the structure of the guidance document

Comments received:

15. It was requested that all sections of the draft guidance on the preparation and presentation of an application for authorisation of a novel food should also be covered for the guidance for traditional foods.
16. The term "Summary of the application" was proposed instead of "introduction" for section 2.1.

Panel consideration of comments received:

- Ad15. The Panel notes that the differences in the structure and requirements between the guidance documents for traditional foods and for other novel foods derive from the legislation and the mandate received from the Commission.
- Ad16. The Panel notes that this section should provide a brief introduction of the nature of the traditional food rather than a summary of the notification. The Panel therefore prefers to keep the term "Introduction" for section 2.1.

2.3. Specific comments

2.3.1. General principles

Comments received:

17. It was asked whether no timeframes are given for confidentiality of data and whether EFSA could confirm the timeframe for approved confidentiality agreements.

Panel consideration of comments received:

- Ad17. The Panel refers to general principle No 10 of the guidance addressing confidentiality.

2.3.2. Description of the Traditional Food

Comments received:

18. Guidance was asked on the requested level of detail for the genetic characterisation of unicellular organisms.
19. It was asked why genetic characterisation (molecular typing) was only required for unicellular organisms and not for plants and animals.
20. It was asked whether the deposition in an officially-recognised culture collection implies that the notification would only apply to foods exclusively produced from that accession.

21. It was asked on what basis it will be determined whether the end product can still be considered the plant or one or more of its traditional processed forms.
22. It was asked which chromatography will be valid to assure that the full spectrum of the plant/plant part (preparation) is confirmed and which ranges will be allowed to deviate from this standard.
23. It was stated that the requested information might be highly detailed and this might unnecessarily hinder the process.
24. It was asked whether a separate notification would be requested for each variety of the same plant species aimed for export.
25. It was stated that Section 2.2.4 (Food consisting of, isolated from or produced from animals or their parts) should be clear that it also covers insects.
26. It was stated that it might be confusing to include "cell cultures". It was asked how cell cultures can be derived from primary production within the meaning of traditional food in Article 3 (c) of Regulation (EU) 2015/2283.

Panel consideration of comments received:

- Ad18. It was clarified in section 2.2.2 of the guidance document that unicellular organisms should be genetically identified and characterised at species and strain level 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, 2016b).
- Ad19. For unicellular organisms, molecular biological methods are state of the art methods (in addition to phenotypic characterisation). Molecular methods may also be used for multicellular plants and animals and in some instances may be useful for the identification. However, the Panel considers that many of the varieties or strains of plants and animals, respectively, can be identified and appropriately characterised by their phenotype (e.g. morphology, biochemistry).
- Ad20. The deposition in an officially-recognised culture collection does not imply that the notification would only apply to foods exclusively produced from that accession, but should be equivalent to the microorganism deposited in this collection;
- Ad21. This will be determined on a case-by-case basis. As indicated in section 2.6.1 of the guidance, the documentation on the experience of continued food use in the third country should relate to the traditional food as it is intended to be placed on the EU market.
- Ad22. The analytical methods to be used depend on the characteristics of the traditional food.
- Ad23. The Panel considers that a detailed description of the traditional food is essential in order to evaluate whether and to which extent the data on the experience of continued food use concerns the notified traditional food. It is also necessary for setting the specifications.
- Ad24. The Panel considers that if a notification covers more than one variety of the same species, then information should be provided demonstrating that the different varieties do not have relevant different characteristics (particularly regarding composition) which could affect the food's nutritional value or the level of undesirable substances.
- Ad25. The Panel acknowledges that insects are widely consumed in many third countries and confirms that section 2.2.4 is the appropriate section for providing a detailed description on the food if it consists of, is isolated from, or is produced from insects. However, the Panel considers that it is not necessary to single out one specific class of animal in this section of the guidance.
- Ad26. Point (a) (vi) of Article 3, paragraph 2 of Regulation (EU) 2015/2283 lists "*food consisting of, isolated from or produced from cell culture or tissue culture*" as a category of Novel Foods which is not excluded by point (c) of this Article to qualify as a traditional food.

2.3.3. Production process

Comments received:

27. It was stated that there is no mention of heat-treatment or extraction, for example, yet many traditional foods are in fact prepared in this way.
28. The feasibility and practicability of providing information on the use of pesticides, antimicrobials and antiparasitic agents was questioned.
29. It was stressed that in order to be compliant with GMP, HACCP or other quality standards, the process used to produce the traditional ingredient/food is frequently adapted for the industrial production of the ingredient/food. EFSA should clarify: to what extent modifications of the traditional production process can be accepted for authorisation of traditional foods from third countries and when these changes are too important to justify the similarity between the traditional food and the new product.
30. It was requested to mention insects in this section.
31. It was asked to delete "micro" from the sentence "*The description of the cultivation of plants, fungi, microalgae and microorganisms and the rearing of animals should also include information on the use of pesticides, antimicrobials and antiparasitic agents.*"

Panel consideration of comments received:

- Ad27. The Panel notes that section 2.3 (production process) asks to provide a detailed description of the production process by which the raw material is converted into the traditional food. "Heat treatment" was added.
- Ad28. The Panel considers that information on the use of pesticides, antimicrobials and antiparasitic agents is of relevance for setting specifications and for control purposes, particularly when substances are used which are not specifically regulated in the EU.
- Ad29. EFSA will evaluate whether the industrial (large scale) production process could have effects on the composition, particularly regarding the level of nutrients and of undesirable substances. A sentence was added in section 2.3.1.
- Ad30. The Panel considers that it is not necessary to single out one specific class of animal.
- Ad31. The proposal was applied.

2.3.4. Compositional data

Comments received:

32. It was stated that it is impossible to keep the number of unknown components as low as possible, since the majority of plants contain thousands of phytochemicals/secondary metabolites of which many are unknown.
33. It was stated that a helpful basis for considering the potential for new foods to be food allergens would be information on the level of protein present and whether whole foods are related to foods or food ingredients that are known food allergens.
34. Line 380 mentions "Potential allergens". Every food and food ingredient is a "potential allergen" for someone in the world. It would be useful to clarify what information is required here and for what purpose.
35. Two comments proposed that three (instead of five) batches should be sufficient. It was stated that [five] seems a bit excessive when generally three is considered sufficient in most cases.
36. In the case that a food is produced with a micro-organism, fungi or algae, the source could also be genetically modified. In this case, we assume additional testing is required following

- EFSA guidance for genetically modified microorganisms (GMM). In addition, it should be clear that the food falls within the scope of the NF Regulation & not the GMM regulation (e.g. absence of GMM & rDNA). No reference is made to the EFSA GMM guidance.
37. It was proposed to change the sentence "*The information should include qualitative and quantitative data on the composition, as well as physico-chemical, biochemical and microbiological properties of the Traditional Food.*" to "*.....physico-chemical and biochemical properties and microbiological characterization of the Traditional Food.*"
 38. It was argued that there should be no need to repeat analytical studies in competent laboratories if already available from peer-reviewed scientific journals, and should not be needed to be repeated by a commercial lab.
 39. EFSA indicates that at least five representative batches of the product have to be analysed. However, batches are analysed at the end of the production process, and are therefore analysed in different times. Do the analyses on the five batches need to be performed simultaneously, or are analyses performed separately acceptable?

Panel consideration of comments received:

- Ad32. The Panel notes that the respective sentence in the composition section does not refer to the number, but to the amount of unidentified components.
- Ad33. The Panel agrees with this comment and refers to section 2.4 (compositional data) and section 2.6.1.6 (human data).
- Ad34. See Ad33. The evaluation of allergenicity is part of the safety assessment.
- Ad35. The Panel notes that the purpose of batch testing is to show that the compositional data of a traditional food produced with the described production process can meet the proposed specifications. The Panel is aware that the results from neither three nor five batches can provide reassurance that the specifications are constantly met once the traditional food is on the market. However, the Panel considers that five batches will provide more suitable information on the range and variability of compositional parameters of the traditional food. If less than five batches are tested, the applicant should provide a rationale.
- Ad36. For this case (where a food is produced with genetically modified microorganisms (GMMs)), reference to the EFSA GMM guidance was added in the guidance.
- Ad37. The Panel agrees. The sentence was changed accordingly.
- Ad38. Published analytical data on the composition of the traditional food can be used, and in fact may be useful to address the variability of the composition of a traditional food. However, the provided publications should include information on the laboratory where analyses were carried out, on the methods utilised, and that the studies were performed on representative samples of the traditional food.
- Ad39. It is not requested and is not needed to perform the analyses of the batches at the same time.

2.3.5. Stability

Comments received:

40. It was suggested that line 389 could benefit by amending the end to read "...during storage, transport and processing".
41. It was stated that it is not possible to provide such information (*"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)"*) for all possible uses as ingredient of the traditional food when it is present as an ingredient in processed foods. Still, this should be covered by the traditional use itself and thus the information requested under points 1 and 2 of the guidelines (description of the traditional food and production process).
42. It was requested that appropriate scientific narrative/justification can be accepted for the absence of stability tests.

Panel consideration of comments received:

- Ad40. The respective sentence was extended by "transport").
- Ad41. The respective sentence was deleted.
- Ad42. The Panel refers to general principle No 9. This principle is also valid for the stability data.

2.3.6. Specifications

Comments received:

43. It was stated that specifications should also provide batch data from at least five representative batches to demonstrate compliance. In the case of traditional foods, consideration should be given to the time these products have been on the market and how the spread of batches, taking into account seasonal variation, should be presented.

Panel consideration of comments received:

- Ad43. The section on "Specifications" refers to compositional data (section 2.4), where "five independent batches" are mentioned. For the setting of the specifications, also data from the literature to address the variability in the composition of the traditional food should be considered as outlined in this section.

2.3.7. Data from experience of continued use

Comments received:

44. It was asked whether human data from literature are enough to substantiate the safety of the traditional use, and whether no proprietary toxicological tests or clinical studies reporting the lack of side effects are needed?
45. It was stated that also studies reporting beneficial effects should be considered in the systematic review.
46. It was proposed to add a sentence like "In those cases where the traditional food may exert pharmacodynamic effects, specific studies may be required to demonstrate that the proposed consumption and use of the traditional food does not raise safety concerns" (in analogy to "Draft Guidance on the preparation and presentation of an application for authorisation of a Novel Food").

47. Concern was expressed that the guidance asks that the information on the traditional preparation of the food and the traditional exposure in terms of continued use is to be documented rather than based on recorded experience and oral tradition.
48. It was stated that the guidance is not clear on what actual information would be submitted or expected. The EFSA Panel did highlight that each application will be different and will be treated on a case-by-case basis. Given the very broad potential range of information sources, it would be helpful to clarify which sources of information would be deemed as preferred and which could be relied on as secondary sources. Would cookbooks recipe and other non-significant sources really be taken into account by EFSA for the justification of food use or should the applicant consider only scientific publications, monographs as pertinent data, while cookbooks and other sources can only be considered only as supportive data to reinforce pertinent ones?
49. For the section 2.6.1.2 "Characteristics of the population group(s) of consumers", it was proposed that consideration should be given to third country competent authorities providing testimony of traditional safe use in their countries as food, if this is available. For example, a letter of testimony from the ministry of health of a third country.
50. What is the aim of this section (2.6.1.2), considering all the information that is already requested in the previous sections?
51. It was proposed that human data (section 2.6.1.6) should include tolerability and allergenicity as specific issues to demonstrate absence of effects.
52. It was proposed that "Food supplements" should be deleted in section 2.7.2 ("Proposed uses and use levels"), because they are fully covered by "ingredient" (first bullet point) and food category.

Panel consideration of comments received:

- Ad44. Proprietary studies are not required for traditional foods. However, the applicant is requested to provide available toxicological data and/or human data as outlined in general principles No 4 and 5 and in sections 2.6.1.6 (Human data) and 2.6.2 (Other information). Whether the data provided in a notification dossier are sufficient to conclude that there are (or are not) duly reasoned safety objections will be the subject of the evaluation by EFSA and Member States. No change is required in the guidance.
- Ad45. Beneficial effects *per se* are out of the scope of the Regulation. However, studies on beneficial effects may also provide information on relevant safety outcomes. The Panel refers to general principle No 3; "*reporting adverse effects*" in the sentence "*A comprehensive literature review of human studies reporting adverse effects related to the consumption of the traditional food should be performed*" was deleted in section 2.6.1.
- Ad46. The Panel considers that it is out of the scope of this guidance to request studies other than those specified in the Regulation (e.g. data on composition, specifications, data on the experience of use). However, the Panel considers that in cases where there is evidence that a traditional food may exert pharmacodynamic effects, duly reasoned safety objections may be raised within the 4 months deadline outlined in Regulation (EU) 2015/2283, if the notification dossier did not sufficiently address such effects.
- Ad47. The Panel notes that the guidance indicates that both scientific and non-scientific evidence may contribute to establishing the history of food use. However, this evidence needs to be documented and the references should be provided.
- Ad48. The introduction paragraph of section 2.6 ("Data from experience of continued use") lists different types of evidence. The weighing of the evidence may depend on the source, quality and quantity of the data. With respect to the traditional use of a food from a third country, information such as from recipes or anecdotal information may provide relevant information (e.g. on preparation or precautions of use).
- Ad49. The introductory paragraph of the section 2.6 indicates that also "governmental documentation" can contribute to the information to be provided. However, the Panel

considers that governmental testimony without supporting evidence is not sufficient to conclude whether a food has a safe history.

Ad50. The Panel considers it important to receive information on the characteristics of the population which has consumed the traditional food in the third country. This information is not only of relevance to conclude on the history of food use, but also for the information in section 2.7.1 ("Target population" in the EU market).

Ad51. Section 2.6.1.6 considers allergenicity and was extended by also including "tolerability".

Ad52. "Food supplements" was deleted.

2.3.8. Proposed conditions of use in the EU market

Comments received:

53. It was proposed to add in the second bullet point referring to "food categories" of section 2.7.2 ("Proposed uses and use levels") a footnote in line 492 with a reference to Annex II Part D of Regulation (EG) N°. 1333/2008 – list of food categories.

Panel consideration of comments received:

Ad53. A footnote was added with the indication that applicants should preferably use the EFSA food classification system (FoodEx) (EFSA, 2011).

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Abbreviations

GMM	Genetically modified microorganism
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis Critical Control Point
rDNA	recombinant Deoxyribonucleic Acid

Appendix A – Explanatory text for the public consultation on the draft guidance on the preparation and presentation of the notification for authorisation of traditional foods from third countries

EFSA has launched an open consultation on its draft guidance on the preparation and presentation of a notification for authorisation of Traditional Foods from third countries. This document aims to assist applicants in the preparation of a notification dossier on the “history of safe food use in a third country” of a Traditional Food. It provides a common format for the presentation of the information.

In line with EFSA’s policy on openness and transparency and in order for EFSA to receive comments from the scientific community and stakeholders, EFSA has launched a public consultation on the draft document developed by the NDA Panel of EFSA.

Interested parties are invited to submit written comments **by 21 April 2016**. Please use the [electronic template](#) provided to submit comments and refer to the line and page numbers. Please note that after 2 hours your working session will expire and comments submitted after that time will not be recorded and transmitted. If you would like to submit additional data to support your comments or files send an email to: NDA.PublicConsult.63@efsa.europa.eu. Please note that comments will not be considered if they:

- are submitted after the closing date of the public consultation;
- are not related to the contents of the document;
- contain complaints against institutions, personal accusations, irrelevant or offensive statements or material;
- are related to policy or risk management aspects, which are out of the scope of EFSA's activity.

EFSA will assess all comments from interested parties which are submitted in line with the criteria above. The comments will be further considered by the relevant EFSA Panel and taken into consideration if found to be relevant.

All comments submitted will be published. Comments submitted by individuals in a personal capacity will be presented anonymously. Comments submitted formally on behalf of an organisation will appear with the name of the organisation.

[Submit comments](#) (deadline: 21 April 2016)

Appendix B – Full list of comments submitted by means of the electronic form on the EFSA website

Chapter text	Organisation	Comment text
GENERIC COMMENTS	AESGP	Lines 1-3 EFSA is kindly asked to clarify in the title that such traditional foods from third countries are novel foods so as to avoid any confusion.
GENERIC COMMENTS	Australian Embassy Brussels - Agriculture Section	<ul style="list-style-type: none"> The traditional food notification pathway as outlined in the draft guidance appears to be a positive option for third countries to obtain fast track access to the EU for novel foods that have a history of safe use within the country of origin. The guidelines appear well organised and logical at this stage. However, it should be noted that if EFSA or any EU Member State raise a food safety concern about a food product lodged under the traditional food notification process, the traditional food product may be subject to a more rigorous review (following the more intensive as Novel Food pathway). More clarification is required to determine how handling of "food safety" based complaints in traditional food applications will be managed. This will instil trust in the process to ensure that "food safety" concerns do not potentially become a routine action of EU Member States to deny access to the accelerated pathway that this program has been set up to deliver. Can the Commission provide further clarification and guidance in future consultations about the mechanisms proposed to handling 'food safety' referrals to the novel food pathway, and the methods that they intend to use to distinguish the legitimacy of complaints? Will EFSA be involved in the determination of the validity of food safety complaints for traditional food applications? Comments made by the EFSA panel at the stakeholder workshop indicated that complaints would be handled by the Commission.

Chapter text	Organisation	Comment text
GENERIC COMMENTS	Australian Embassy Brussels - Agriculture Section	<p>* Additional clarification is required about how any changes to an approved traditional or novel food products specification, production process or composition would be managed. More guidance on this is important for the ongoing management and evolution of any novel/traditional food product to avoid situations where minor changes to specifications, production processes or composition could result in the cancellation of an approval or the need to undergo a full re-evaluation process.</p> <p>* The stakeholder workshop saw numerous questions from the audience regarding guidance for food products using new botanical extracts/ extraction methods. More clarity and guidance on this area of novel foods appears to be necessary.</p> <p>* Nanotechnology is rapidly changing area, and obviously places challenges on EFSA to keep abreast. It is expected that the assessment and subsequent guidance relating to novel food applications with a nanotechnology element will become more in depth, as the scientific and regulatory ideologies evolve. The definition of an engineered nanomaterial is due for updating prior to the new rules becoming active on Jan 1 2018. It is likely that some changes to the NF structure/guidance may be required after this update.</p> <p>* No timeframes have been listed for confidentiality of data? Can EFSA please confirm the timeframe for approved confidentiality agreements?</p> <p>* No proprietary data protection is available for traditional foods? What is the rationale for this?</p>
GENERIC COMMENTS	Food Law Consult	Are they toxicologists, immunologists, epidemiologists, nutritionists,... or are there experts involved with a broad knowledge about botanicals, with expertise in pharmacognosy, botany and the traditional use of plants? Why weren't the same experts involved in the EFSA compendium not involved (Robert Anton, Ulla Beckman Sundh, Luc Delmulle, Maria Teresa Nogueira, Kirsten Pilegaard, Mauro Serafini)?
GENERIC COMMENTS	Food Supplements Europe	Food Supplements Europe welcomes the work EFSA undertakes to provide guidance for applications on traditional novel foods from third countries.

Chapter text	Organisation	Comment text
GENERIC COMMENTS	Food Supplements Europe	<p>General principles</p> <p>Line 238: Should read: Regulation 2015/2283</p> <p>Line 267: Should read: Regulation 2015/2283</p> <p>Organisation and content of the notification</p> <p>Line 283: In how far is it necessary to provide translations of foreign language texts?</p>
GENERIC COMMENTS	Independent Expert Consultant,	<p>The doc. consultation/160218a.pdf is quite comprehensive in detailing a description for consideration of an application. However, traditional foods have close relationships with region, climate, seasons, local availability of the raw materials. Traditional foods of a region/country are embodiment of traditional wisdoms derived over centuries. It is important to note that their controls, parameters, processes are sometimes not explainable fully as scientific descriptions. Like some traditional prescriptions are foods but meant for treatment of certain ailments, diseases, otherwise considered not treatable by current science. Sometimes a bottle of water / juice , on which certain religious prayers are made by pious religious family traditions, may be used for healing in innumerable causes. So, the raw material has to be of fixed place, touched by a prefixed family holy hands, prayers made on this traditional food has be done at a fixed time of the day in dark room etc. So, it may be almost impossible to derive a scientific description in the application. Foods are generally preserved by acidity, dehydration, freezing and chemicals. These general principles should invariably have role in the traditional foods as well but added factors described above may be totally unscientific but yet a TF may be safe and fit. So, my comment are being sent as general information for your team to be displayed, if desired, as knowledge.</p>
GENERIC COMMENTS	National Food Agency	<p>The National Food Agency welcomes the proposed guidance document. The document covers the most aspects and considerations necessary for a comprehensive assessment.</p> <p>A few comments and suggestions are given for consideration.</p> <p>We recommend that all sections from "Draft guidance on the preparation and presentation of an application for authorisation of a Novel Food" should be covered and addressed in an application, including also sections 7-10. If some are not considered relevant, this should be explained and justified by the applicant.</p> <p>Structure of Part 1</p> <p>Introduction: We recommend that the applicant provide a Summary of the application which includes the pertinent sections indicated here, thus to replace "Introduction" with "Summary of application".</p>

Chapter text	Organisation	Comment text
GENERIC COMMENTS	Nutraveris	L 217-220: History of safe use in a third country is defined as a continued use for at least 25 years in the customary diet of a significant number of people in at least one third country. The term 'significant' is subject to interpretation. Clarifications should be provided on what significant means exactly.
GENERIC COMMENTS	Pen & Tec Consulting	Line 2008: Instead of referring to "point (f) of this paragraph" suggest to refer to "point (f) of Article 3, paragraph 2 of Regulation (EU) 2015/2283" so that it is clear applicants need to check the NF Regulation & not this EFSA guidance document if they want to check point f.
GENERIC COMMENTS	Pen & Tec Consulting	Lines 362, 383, 411: Section numbers mentioned in these lines are incorrect.
GENERIC COMMENTS	Secretaría de Economía	<p>Definitions: line 217-220</p> <p>Se señala el término "historia de uso seguro en un tercer país" que significa que los alimentos deben haber sido consumidos en al menos veinticinco años como parte de la dieta habitual de un número significativo de personas." Al acotar dicha definición a un tercer país la medición será subjetiva, ya que el rango de población entre los países varía considerablemente e incluso los grupos no son homogéneos. Por lo anterior, se solicita aclarar el término con el fin de no causar confusión y evitar ser una barrera comercial para la exportación, principalmente, de alimentos tradicionales de terceros países.</p> <p>Organisation and content of the notification: line 277-280</p> <p>En términos de forma, los números de las secciones indicados en este párrafo, no checan con los numerales de las secciones descritas en líneas más abajo.</p>
GENERIC COMMENTS	Secretaría de Economía	Para poder tener un contexto de la situación de los alimentos tradicionales "europeos" sería interesante saber si ¿Todos los alimentos "tradicionales" europeos y consumidos en Europa han sido estudiados en términos de su composición? Es decir, ¿existe una línea base de los alimentos tradicionales locales?
GENERIC COMMENTS	UK Advisory Committee on Novel Foods and Processes	<p>Given that traditional foods are more likely to be whole foods, the Committee suggested a greater emphasis on a flexible approach is needed to ensure that appropriate information for the food is supplied.</p> <p>From the experience of the Committee in assessing traditional foods such as Baobab and chia they are aware that a proportionate approach is helpful in order to take account of the reassurance of safety provided by a food having been consumed by humans for a long time.</p>

Chapter text	Organisation	Comment text
1. Description of the Traditional Food	Food Law Consult	For the current novel food regulation a substance of one source can be considered novel while the same, identical substance from another source is novel. That doesn't seem a scientific approach. How will EFSA deal with such situations. Can the company with the identical substance refer to an approved substance? Can unnecessary double work be avoided. It's only a matter of dose and conditions of use at that point.
1.1. Foods consisting of, isolated from or produced from microorganisms, fungi or algae	Food Safety Authority of Ireland	I am not sure why "Genetic characterisation (molecular typing) for unicellular organisms" is only required for this category and not for plants or animals? Some further explanation on this requirement for one category only would be useful.
1.1. Foods consisting of, isolated from or produced from microorganisms, fungi or algae	Food Supplements Europe	Line 294: The requested data is on the micro-organism, not on the novel food
1.1. Foods consisting of, isolated from or produced from microorganisms, fungi or algae	Pen & Tec Consulting	Lines 296-300: Points listed are different than in the novel foods guidance document. Suggest to keep it consistent & include same points (e.g. combine).
1.1. Foods consisting of, isolated from or produced from microorganisms, fungi or algae	Secretaría de Economía	líneas 294-300 Algunos puntos requieren mayor claridad. ¿Entraría aquí el caso del huitlacoche (o ya ha entrado antes de 1997 a Europa)? El huitlacoche es un hongo comestible que vive como parásito en las mazorcas del maíz; se presenta como tumores de color gris que cuando maduran liberan esporas negras. El huitlacoche se suele consumir con tortillas. Por ejemplo línea 298. ¿a qué grado de detalle se requiere la caracterización genética de organismos unicelulares? Línea 300. El depósito en una colección reconocida, ¿implicaría que la notificación sólo aplicaría para alimentos derivados únicamente de dicha accesión? es decir ¿solo una cepa, por ejemplo de huitlacoche? eso puede volverse un proceso muy complejo, si se tuviera que realizar una notificación para cada accesión que derive en un alimento.
1.2. Foods consisting of, isolated from or produced from plants or their parts	Food Law Consult	How will be decided that such preparation "give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances"?

Chapter text	Organisation	Comment text
1.2. Foods consisting of, isolated from or produced from plants or their parts	Food Supplements Europe	Line 301: The requested data is on the plant, not on the novel food.
1.2. Foods consisting of, isolated from or produced from plants or their parts	OPPASS	<p>3rd country botanical foods: Which priority methodologies will be applied in order to determine whether the end product can still be considered :1. the plant, 2. the plant in one or more of its traditional processed forms ? Which chromatography will be valid to assure that the full spectrum of the plant/plant part (preparation) is confirmed and which ranges will be allowed to deviate from this standard? Such identity profiles are paramount priority, not only to assure quality-safety requirements, but also to clarify the present situation on the EU market, where the arbitrary implementation of the NF regulation is the source of serious concern: At least 700 traditionally used plant preparations that were on the market to a significant degree before 1997 and for which ample history of consumption was provided, remains unevaluated for more than 7 years in Belgium and other member states. Part of those reached a positive list (see Belfrit). Some turned into NF overnight and inadvertently and inconsiderate of the already submitted data. The rest is quarantined in a legal void for more than 7 years already, mainly due to the (absence of) decision made by CAFAB in 2009, as reported in EC/42/2009/4. A report in which the indecisions, misconceptions, contradictions and open ends are firmly captured in institutional tortuosity. However, as a result, the remaining botanicals were systematically declared 'plant remedies' and the 'intended use' medicinal. A remarkable point of view since The Council of Europe' has accepted the concept of 'Homeostasis' which clearly refers to the body's own physiological reactivity , as different from the therapeutical and pharmacological use which goes outside this homeostatic range. Traditional herbals share this physiological activity with all common vegetables, spices, etc.. Another argument used by the MS administrations was that these plants were predominantly on the market as concentrated dry extracts, and as such to be considered NF. A derisory argumentation since these dry extracts are the concentrates of the original watery (polar) decoction/soup/infusion and, as such, the only phyto- and bio-equivalent form of the original traditional preparation. The dry extract, by the way, was invented in 1835 by Alexander von Liebig, in order to facilitate the distribution of soup for the destituted. Under the circumstances it beggars belief that the EU markets are now flooded with hydro-alcoholic, alcoholic and supercritical extracts, that do not correspond in any way to the traditional identity profile, nor to the traditional safety profile. Moreover the majority of these products were not on the market before 1997. But such isolates obtain a NNF marketing authorisation referring to the name and all the characteristics of the plant to which it hardly bears any resemblance. On the other hand, traditionally processed botanical foods, with a known safety-profile and meeting the full-spectrum identity profile whither away in the waiting rooms of the NF administration although they were on the market since the mid-eighties in EU. It is our firm opinion the Efsa should draw a clear line between those based on identity standards in order to positively validate the traditionally used foodstuff and distinguish these from the really 'novel' supercritical extracts.</p>

Chapter text	Organisation	Comment text
1.2. Foods consisting of, isolated from or produced from plants or their parts	OPPASS	<p>Regarding the alinea on phytochemical profile composition:</p> <p>In our opinion the point stating that the number of unknown components should be kept as low as possible is impossible to comply with, since the majority of plants contain thousands of phytochemicals /secondary metabolites of which many are unknown. Those are proven safe empirically. Moreover, it is impossible to, even remotely, quantify the parts that you don't know. Ash residue tests may be as near as it gets...</p>
1.2. Foods consisting of, isolated from or produced from plants or their parts	Secretaría de Economía	<p>Líneas 301 -310</p> <p>Mismos comentarios que para la sección 1.1 en términos de que se podría estar solicitando información con un muy alto grado de detalle que podría complicar innecesariamente el trámite para lo cual sería muy útil saber hasta dónde aplica el término "if applicable": ¿se necesitaría una notificación para cada variedad de una misma especie de planta que se quisiera exportar (p.ej. nopales variedad 1 y variedad 2)? ¿qué pasa en el caso por ejemplo de aquellos alimentos tradicionales que no han sido catalogados en listas de variedades comerciales, y que no fueran tan uniformes como estas?</p>
1.3. Food consisting of, isolated from or produced from animals or their parts	Anonymous	<p>Introduction</p> <p>1. Description of the Traditional Food</p> <p>1.1 Food consisting of, isolated from or produced from animals or their parts The mopane worm (MW), the edible larvae of the Saturniid moth <i>Imbrasis beilina</i> is one of the best – known and most economically important forestry resource products of the mopane woodland in southern Zimbabwe, Botswana and the northern Transvaal (Timberlake, 1996; Bradley and Dewes 1993).</p> <p>2. Production process Following harvesting, the caterpillars are eviscerated, boiled and dried in the sun, after which they can be stored for almost a year. Thus, the consumption of mopane worms can occur over a considerably longer period than the harvest, provided processing and storage procedures are adequate to avoid spoiling (Hobane, 1994, 1995 Gondo, 2001).</p> <p>Different glove types can be used for harvesting and degutting (squeezing) suitability, PVC gloves, commercial leather gloves and household kitchen gloves.</p> <p>Drying is the major part in processing. Some harvesters use a tower system or use black plastic bags with a clear plastic cover on which the MW spread under the heat of the sun, usually about 30 – 40 degree Celsius. The Mopane worms take about 1.5-2 days to dry, this method is cheap and effective, also locally cut wooden pegs could replace the metal pegs.</p>

Chapter text	Organisation	Comment text
		<p>Where affordable dehydration in a ventilated drying oven, at low temperature: the temperatures mentioned (Rumpold and Schluter 2013a) range from 60°C to 110°C. Dehydration at 90°C in dry air is often practised, for durations of more than five hours. At this temperature, a pasteurisation heat treatment is applied, with very high pasteurisation values. This obtains a satisfactory level of pasteurisation, even from thawed raw insects. In the latter case, the dehydration treatment also ensures cooking for insects that were not previously cooked</p> <p>3. Compositional Data</p> <p>One of the key advantages of dried MW is that they have three times the protein content of beef by unit weight, and can be stored for many months. Mopane's nutritional value exceeds that of other sources of protein such as chicken, milk and beef. Its energy content is 444 calories/100 gramme (protein content is 56.8 grammes. It is maintained that 100 g of dried worms provides up to 76% of a humans daily protein need, and many of the required vitamins and minerals as they contain significant amounts of phosphorus, iron and calcium. MW are also rich in unsaturated fatty acids, as the fatty acid composition for total fatty acids and unsaturated fatty acids is reported to be 40.5% and 57.0%, respectively. In addition, the consumption of mopane worms also provides in the intake of a certain amount of roughage. In the light of these statistics mopane worms can clearly play a vital role in human survival in times of economic and climate stress (Martin Potgieter, Makhado, Annelize Potgieter (2012) Department of Biodiversity, University of Limpopo, South Africa)</p> <p>Several cases of food allergy due to ingestion of insects have been reported in the literature. The insects incriminated were the mealworm (<i>Tenebrio molitor</i>), superworm (<i>Zophobas morio</i>), silkworm (<i>Bombyx mori</i>), red palm weevil (<i>Rhynchophorus ferrugineus</i>) and the mopane worm (<i>Gonimbrasia belina</i>).</p> <p>Also documented is a case of a 36-year-old woman from the Tswana ethnic group in Botswana, who was diagnosed with food allergy. She presented with itchy skin rash, facial swelling, and mild hypotension after eating mopane worm. She was treated and her symptoms resolved after 4 days (Mopane worm allergy in a 36-year-old woman: a case report: Okezie, Kgomotso, Letswiti 2010)</p> <p>3.1 Stability</p> <p>According to Ashipala et al. 1996), following harvesting, the caterpillars are eviscerated, boiled and dried in the sun, after which they can be store</p>
1.3. Food consisting of, isolated from or produced from animals or their parts	Food Supplements Europe	Line 311: The requested data is on the animal, not on the novel food. It should be indicated that this includes insects.
1.3. Food consisting of, isolated from or produced from animals or their parts	Intertek Scientifi &Regulatory Consultancy	311 It should be clearly stated here that insects are considered animals for the purpose of this guidance. The word "insect" is not mentioned anywhere in this document.

Chapter text	Organisation	Comment text
1.4. Food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, fungi or algae	ELC - Federation of European Specialty Food Ingredients Industries	Line 319: Is it not confusing to include "cell cultures"? How can cell cultures be derived from primary production within the meaning of traditional food in Article 3 (c) of Regulation 2015/2283?
2. Production process	AESGP	Lines 330-334 EFSA is kindly asked to clarify why – unlike the other guidance on the preparation and presentation of an application for authorisation of a Novel Food – no reference is made to the specific considerations and complementary information provided in the EFSA Guidance on safety assessment of botanicals and botanical preparations (EFSA, 2009).
2. Production process	Committee "Novel Foods and New Technologies" of the Codex Alimentarius Austriacus Commission	replace "microalgae" by "algae" in analogy to category "Foods consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, fungi or algae"
2. Production process	Food Law Consult	For plants 'primary production' means the production growing of primary products including harvesting, It also includes the harvesting of wild products; Can you tell me if certain plant preparations would fall under this definition. E.g. do dried plants or powders or other preparations will be considered under this? Besides that under category iv there's an exception for foods from "traditional propagating practices". Is there a legal definition? What is understood under this term?

Chapter text	Organisation	Comment text
2. Production process	Intertek Scientific & Regulatory Consultancy	<p>329 "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), (ii), (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"</p> <p>These points in Article 3, point 17 are very very non-specific:</p> <p>"primary production" means the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products;</p> <p>There is no mention of heat-treatment or extraction for example, yet many traditional foods are in fact prepared in this way. The EFSA guidance is an opportunity for working rules to be laid down on what can and can not be typically accepted as "Primary production" for the case of notification. An example might be that laid down under Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods ANNEX II</p> <p>List of traditional food preparation processes</p> <p>Chopping Coating Heating, cooking, baking, frying (up to 240 °C at atmospheric pressure) and pressure cooking (up to 120 °C) Cooling Cutting Distillation/rectification Drying Emulsification Evaporation Extraction, incl. solvent extraction in accordance with Directive 88/344/EEC Fermentation Filtration Grinding Infusion Maceration Microbiological processes Mixing Peeling Percolation Pressing Refrigeration/Freezing Roasting/Grilling Squeezing Steeping</p>
2. Production process	Intertek Scientific & Regulatory Consultancy	341 Insects should also be mentioned here for clarity

Chapter text	Organisation	Comment text
2. Production process	Nutraveris	L 330 In order to be compliant with GMP, HACCP or other quality standards, the process used to produce traditional ingredient/food is frequently adapted for the industrial production of the ingredient/food. EFSA should clarify: to what extent modifications of the traditional production process can be accepted for authorization of traditional foods from third countries and when these changes are too important to justify the similarity between the traditional food and the new product.
2. Production process	Tea & Herbal Infusions Europe (THIE)	Line 341: This paragraph specifies that in case of an application "information on the use of pesticides, antimicrobials and antiparasitic agents" should be given. THIE feels that this requirement is not practicable as the necessities to apply these agents may vary depending on climate, infestation and other conditions; furthermore, changes of substances are necessary in order to avoid resistances. Accordingly THIE proposes to delete this sentence.
3. Compositional data	Committee "Novel Foods and New Technologies" of the Codex Alimentarius Austriacus Commission	add in line 353 "physico-chemical and biochemical properties and microbiological characterization of the Traditional Food."
3. Compositional data	Food Safety Authority of Ireland	On line 363 it specifies "five representative batches". This seems a bit excessive when currently generally three is considered sufficient in most cases? Line 380 mentions "Potential allergens". Every food and food ingredient is a "potential allergen" for someone in the world so this should be narrowed down in case a certain level of paranoia sets in and everything is seen as a "potential allergen. For example in the EU only 14 products require labelling under Regulation (EU) No 1169/2011. At that two of those (sulphites and gluten) are not considered allergens per se and so 12 foods and food ingredients require labelling. So it would be useful to clarify what information is required here and for what purpose.
3. Compositional data	Food Supplements Europe	Line 363: Information on 3 batches should be sufficient.
3. Compositional data	Intertek Scientific & Regulatory Consultancy	385 Is solvent extraction "primary production". Care is needed here.
3. Compositional data	Nutraveris	L 363 EFSA indicates that at least five representative batches of the product have to be analyzed. However, batches are analyzed at the end of the production process, and are therefore analyzed in different times. Do the analyses on the five batches need to be performed simultaneously, or are analyses performed separately acceptable?
3. Compositional data	Pen & Tec Consulting	In the case that a food is produced from a micro-organism, fungi or algae the source could also be genetically modified. In this case, we assume additional testing is required following EFSA guidance for GMM. In addition, it should be clear that the food falls within the scope of the NF Regulation & not the GMM regulation (e.g. absence of GMM & rDNA). No reference is made to the EFSA GMM guidance - recommend to include this in the relevant parts.

Chapter text	Organisation	Comment text
3. Compositional data	Tea & Herbal Infusions Europe (THIE)	Line 351 ff: Regarding chapter "3 Compositional data" THIE would like to strengthen that a practicable interpretation of the requirements specified is necessary as parts of plants are natural products which vary considerably in terms of their main and minor constituents. It would be appreciated to have an example of what is expected in case of plant parts.
3. Compositional data	UK Advisory Committee on Novel Foods and Processes	p11 from line 380 – The Committee noted that while special mention has been made of considering the potential for new foods to be food allergens, the information or issues to consider in relation to this have not been identified. A helpful basis for considering this issue would be to require information on the level of protein present and whether whole foods are related to foods or food ingredients that are known food allergens.
3.1. Stability	Food Safety Authority of Ireland	Line 389 could benefit by amending the end to read ..."during storage, transport and processing". Handling would normally be included here also but that is addressed later.
3.1. Stability	Food Supplements Europe	Line 400: It is likely not possible to be able to provide such information for all possible uses as ingredient of the traditional food when it is present as an ingredient in processed foods. Still, this should be covered by the traditional use itself and thus the information requested under points 1 and 2 of the guidelines (description of the traditional food and production process).
4. Specifications	Casa de Mesquite	<p>On page 8 line 251 is stated 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.</p> <p>In our case at least, human food use from pods of the leguminous tree Prosopis in the western hemisphere, the majority of the really useful literature is in the form of grey literature, unpublished theses, obscure anthropological monographs, local government documents, etc that will be missed by a systematic review. I have been working in the area for more than 35 years and plan to submit many citations that would be missed by a typical systematic review. If the EU prefers I would be pleased to submit PDFs of those documents. "I request that more emphasis be placed on a typical scientific review than a "systematic computer data base search"</p> <p>On page 8 line 61 it is stated "Analyses/tests should be performed in a competent facility that can certify the data" It is respectively requested that data that exists in peer reviewed scientific journals do not need to be repeated by a commercial lab. Repeating all of these analyses that already exists in the literature will be an enormous financial burden that will probably prohibit entry of exciting new products.</p> <p>On page 10 line 355 it is stated " "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"</p>

Chapter text	Organisation	Comment text
		<p>We respectfully request that for traditional food data that is already reported in the literature i.e protein, sugar, fat, water, minerals, vitamins that LOD and LOQ not be required. If new information is requested or if there is a questionable toxic chemical, then LOD's and LOQ's would be reasonable. Journals such as the British Journal of Nutrition or Food and Agricultural Chemistry almost never report LOD's and LOQ's for traditional food nutrients. It is requested that data published in the refereed literature be accepted without use of LODs or LOQ's.</p> <p>On page 11 line 363 it is stated 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).</p> <p>It is requested that peer reviewed published data and/or unpublished PhD thesis be able to be substituted for these analyses. In our case there is 25 years of peer reviewed publications on the nutritional composition of our flour. Unlike pharmaceutical companies, emerging companies from developing countries do not have the resources to have the published scientific work repeated in very expensive commercial labs. On page 11 line 390 it is stated. 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. Our product is similar to wheat flour, sugar, coco flour with about 5% moisture and an Aw less than 40. For 10 years of commercial activity in the US our product has been stored at ambient temperatures for more than 2 years at a time without noticeable change in flavor or functionality. We request that with a suitable scientific narrative/justification that commercial storage conditions in other countries be accepted without further testing.</p>
4. Specifications	Intertek Scientific & Regulatory Consultancy	418 Specifications should also provide batch data from at least 5 representative batches to demonstrate compliance. In the case of Traditional Foods consideration should be given to the time these products have been on the market and how the spread of batches, taking into account seasonal variation should be presented.
5. Data from experience of use	Food Supplements Europe	Line 422: Should all documentation in foreign languages be translated in English?

Chapter text	Organisation	Comment text
5. Data from experience of use	Nutraveris	L 424-425 EFSA indicates that the type of references substantiating the experience of use of the Traditional food could include scientific publications, scientific expert opinions, monographs, information from international or national organizations, governmental documentation, figures on cultivation/harvesting, sales and trade. Further information might be obtained from cookbooks, recipes and anecdotal data. However, would cookbooks recipe and other non-significant sources really be taken into account by EFSA for the justification of food use or should the applicant consider only scientific publications, monographs as pertinent data, while cookbooks and other sources can only be considered only as supportive data to reinforce pertinent ones?
5. Data from experience of use	UK Advisory Committee on Novel Foods and Processes	p12- The Committee welcomed the emphasis on characterising the safe use of the product in third countries. In particular how the product is prepared and the nature of the traditional exposure in terms of continuous use, the contribution it makes to the diet etc. However, concerns were raised that the emphasis is on the use being 'documented' rather than recording experience and oral tradition.
5.1. Experience of food use in a third country	Australian Embassy Brussels - Agriculture Section	The requirement for traditional notifications to have 25 years of compositional data supporting the "safe use" of a product was another area in which there seems to be some additional work to be completed. In whole, the process to submit the traditional food notification appears relatively clear. What was of concern is that when asked about the 25 year data, the EFSA panel (apart from referring to previous approvals of Chia Seeds and Baobab fruit), did not appear to have clarity on what actual information would be submitted or expected. This suggests that early notification applications could be at risk of not being approved due to uncertainty in this part of the process. The guidance document indicates that 'data' can include scientific publications, scientific expert opinions, monographs, information from international or national organisations, governmental documentation, figures on cultivation, harvesting, sales, trade, cookbooks, recipes, anecdotal data. The EFSA panel did highlight that each application will be different and will be treated on a case by case basis. Given the very broad potential range of information sources, it would be helpful to clarify which sources of information would be deemed as preferred and which could be relied on as secondary sources. It will be interesting to see the approach of EFSA in practical terms when traditional food notifications are submitted for assessment and comment.
5.1. Experience of food use in a third country	Secretaría de Economía	Líneas 430-432. Sería más objetivo considerar tanto la revisión de literatura sobre estudios de "efectos adversos" como la revisión de literatura que reporte "efectos benéficos" a partir del consumo del alimento tradicional.
5.1.2. Characteristics of the population group(s) of consumers	Intertek Scientifi &Regulatory Consultancy	443 Consideration should be given to third country competent authorities providing testimony of traditional safe use In their countries as food if this is available. For example a letter of testimony from the ministry of health of a third country.

Chapter text	Organisation	Comment text
5.1.2. Characteristics of the population group(s) of consumers	Secretaría de Economía	Líneas 443-448 Se solicitan las siguientes aclaraciones: ¿cuál es la finalidad que se persigue al solicitar este tipo de información y qué sería lo que ésta aporta?. Lo anterior, considerando toda la información previa que ya se solicita, como la relativa a la composición detallada, (incluyendo la posible presencia de compuestos tóxicos, antinutricionales, etc.), así como aspectos de estabilidad, experiencia y extensión de uso, precauciones de uso, etc.
5.1.5. Human data	Committee "Novel Foods and New Technologies" of the Codex Alimentarius Austriacus Commission	add a sentence like „In those cases where the Traditional Food may exert pharmacodynamic effects, specific studies may be required to demonstrate that the proposed consumption and use of the Traditional Food does not raise safety concerns.” (in analogy to „Draft Guidance on the preparation and presentation of an application for authorization of a Novel Food”, chapter 9.7 line 787 – 790)
5.1.5. Human data	Intertek Scientific & Regulatory Consultancy	471 Human data should include tolerability and allergenicity as specific issues to demonstrate absence of effects
5.1.5. Human data	Nutraveris	L 463-471 In paragraph 5.1.5 'Human data', EFSA indicates that the safety of the Traditional food should be document through a comprehensive literature search for human data. This search should be extended to data on specific and typical component of the food and data on similar foods from the same or other closely related sources. Does this mean that only Human data from literature is enough to substantiate the safety of the Traditional use, and that no proprietary toxicological tests or clinical studies reporting the lack of side effects are needed ?
6.2. Proposed uses and use levels	AESGP	Line 494 EFSA is kindly requested to clarify the proposed maximum amounts to be specified in case of final product(s) marketed as powder or as concentrates and intended to be consumed as reconstituted following manufacturers' instructions.
6.2. Proposed uses and use levels	Committee "Novel Foods and New Technologies" of the Codex Alimentarius Austriacus Commission	Add a footnote in line 492 with a reference to Annex II Part D of Regulation (EG) N°. 1333/2008 – list of food categories
6.2. Proposed uses and use levels	Food Supplements Europe	Line 491: A novel food is not used as food supplement, but as an ingredient in any food, including food supplements ((i.e. food supplements are a food category). As such this is covered by the second bullet in line 492. We suggest deleting "food supplement" here, as it is not correct