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Annex A

Public consultation on the draft guidance on the scientific requirements for a notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU)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

European Food Safety Authority (EFSA)

Annex to: Guidance on the scientific requirements for a notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283. doi:10.2903/j.efsa.2024.8966

Annex A – Technical report: Outcome of the public consultation on the draft guidance on the scientific requirements for a notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283

Overview

A total of 56 comments were submitted by 7 interested parties from 5 countries. All the comments are published on the OpenEFSA portal as received (https://open.efsa.europa.eu/consultations/a0cTk00000099bxIAA?status=Closed&search=guidance). Comments therein are addressed under the respective entry.

Table 1 depicts the 7 interested parties that have participated in the public consultation and their country of origin. These include 4 food industry associations and/or organisations, 2 national authoritative bodies and 1 person on his/her personal capacity.

The comments that have been submitted in relation to this public consultation are addressed below. In particular, among the 56 comments received, 8 were duplicate comments. Therefore, 48 comments are addressed in the present report. The guidance on scientific requirements for traditional foods and the guidance on scientific requirements for novel foods share several principles in common. Consequently, comments submitted for the guidance on traditional foods also apply to the guidance on novel foods. As a result, the reader is directed to the responses provided in Annex A 'Outcome of the public consultation' of the guidance on the scientific requirements for novel foods (EFSA NDA Panel, 2024) for the comments that are common between the two guidance documents.

European Food Safety Authority (EFSA) wishes to thank all stakeholders for their comments.

Table 1: Stakeholders contributing to the public consultation

Organisation name	Country
Atova Regulatory Consulting SL	Spain
Food Supplements Europe	Belgium
German Federal Institute for Risk Assessment	Germany
Ministry of Regional Affairs and Agriculture	Estonia
Nutraveris – a FoodChainID company	France
Pen & Tec Consulting S.L.U. (trading as Argenta®)	Spain
Submission on personal capacity	Belgium

Comments received and replies to comments

Section: Abstract

Comment number	Organisation name	Comment	Reply
1	German Federal Institute for Risk Assessment (BfR) (Germany)	General comment All provided data pertinent to the safety of the traditional food (e.g. study reports, certificates of analyses, etc.) should preferably be provided in English.	EFSA is going to release a new administrative guidance on traditional foods, which will be completed at the same time as this scientific guidance. The new administrative guidance will include a requirement for data submission in English, consistent with other EFSA administrative guidelines. Under 'General principles', the scientific guidance on traditional foods references the administrative guidance on traditional foods. Applicants are advised to follow the administrative guidance when submitting a traditional food notification/application (EFSA, 2024). No changes were introduced in the guidance.

Section: Scope

Comment number	Organisation name	Comment	Reply
2	Food Supplements Europe (Belgium)	Food Supplements Europe welcomes that EFSA continuously updates its scientific guidance to keep track of new developments in the area of risk assessment. Certain comments we made in the context of the guidance on novel foods are also pertinent for this guidance and we would ask EFSA to retain consistency between both documents.	EFSA confirms that consistency will be maintained between the guidance on novel foods and traditional foods. Changes in the guidance on traditional foods following the public consultation will be introduced in the guidance on Novel Foods, if pertinent, and vice versa.

Section: General principle

Comment number	Organisation name	Comment	Reply
3	German Federal Institute for Risk Assessment (BfR) (Germany)	Page 10, line 271 After "traditional food" the word "food" is duplicated.	The suggested editorial change has been implemented in this guidance.
4	Food Supplements Europe (Belgium)	Line 231 When new or updated guidance is published, it would be good to specify from what moment the guidance will apply to ensure a smooth transition. In the area traditional foods from third countries, the applications can cover a wide range of products, each with their specificities. Given that these foods are part of the diet in the third countries, not all information may be available in all details to the applicant but may also not be essential for identifying safety concerns. It would be good if this guidance could therefore indicate in this section (as the novel food guidance did), what data are essential and what data could potentially be waived with appropriate justification. Published literature could in this respect play an important role. Moreover, we consider that, since traditional foods from third countries can only originate from primary production, the guidance can be simplified and all requirements that cannot apply to such products should be removed.	The applicability of this guidance will be communicated. As reported in Recital 4) data on composition, experience of continued use, proposed conditions of use and specifications are crucial for the assessment of traditional foods. Traditional foods are derived from primary production and may originate from various sources, such as microorganisms, fungi, algae, plants, and animals. Traditional foods can also be processed or unprocessed. Therefore, depending on the specific traditional food being notified, the applicant should provide the relevant information pertaining to it. As reported in Recital 7) deviations from the requirements specified in the respective sections of this guidance document must be justified. No changes were introduced in the guidance.
5	Submission on Personal Capacity (Belgium)	The general principle on NAM (line 284) is not enough elaborated in the draft guidance. A reference is made only to published research "see line 839" which is simply a result of a literature search. The use of NAM as a general	The Panel acknowledges that the principle on NAM (New Approach Methodologies) is not relevant for traditional foods, which rely on compositional data and history of safe food use in a third countries and not on toxicological studies. Thus, the Panel decides to remove the reference to NAMs. Furthermore, a modification has been made to section 5.7 'Other

		principle needs to be well integrated in this draft with proper recommendations of its applicability.	information' to clarify that the safety of traditional foods is endorsed by 'history of safe food use,' and that toxicological studies available in the literature can also contribute to ensuring the safety of traditional foods. Thus, Recital n° 9 has been deleted. A clarification sentence has been added in section 5.7 'Other information'.
6	Pen & Tec Consulting S.L.U. (trading as Argenta®) (Spain)	Lines 234, 252, 254, 256. "Regulation 2015/2283": Inconsistent reference. Elsewhere it is referred to as "Regulation (EU) 2015/2283". Line 236. "Article 32b of the General Food Law": "Regulation (EC) No 178/2002 (hereinafter "General Food Law")" or similar introduction to what General Food Law stands for is missing from the guidance. Line 238. "…provisions of transparency and confidentiality (Article 39 of the General Food Law)": Add "(Article 38 of the General Food Law)" after the word "transparency". Article 39 relates to confidentiality only. Lines 277-278. "Information on the accreditation of involved facilities and certificates of analyses should be provided": Which kind of accreditation does EFSA consider adequate?	The suggested editorial changes have been implemented in the guidance. Regarding accreditation, please refer to the reply to comment 638 in Annex A 'outcome of the public consultation on the guidance on novel foods (EFSA NDA Panel, 2024).
7	Atova Regulatory Consulting SL (Spain)	(Line 271, page 10) The applicant should provide their considerations at the end of individual sections on how the information supports the safety of the traditional food food (TYPO – repeated word) under the proposed conditions of use.	The suggested editorial change has been implemented in this guidance.

Section: Characterisation of the traditional food, technical and scientific data

Comment number	Organisation name	Comment	Reply
8	Food Supplements Europe (Belgium)	Line 286 Given that only products of primary production can qualify as traditional food from third countries, many of the data requirements in this section may be redundant. It is recommended to revise this section to focus only on data that can apply to foods within the scope of the traditional food procedure.	See reply to comment 4 above.

Section: 1. Identity of the traditional food

Comment number	Organisation name	Comment	Reply
9	Pen & Tec Consulting S.L.U. (trading as Argenta®) (Spain)	Line 296. "Regulation (EU) 2283/2015": It should say "Regulation (EU) 2015/2283".	The suggested editorial change has been implemented in this guidance.

Section:1.1 Chemical substances

Comment number	Organisation name	Comment	Reply
10	Pen & Tec Consulting S.L.U. (trading as Argenta®) (Spain)	Lines 304-308. "This section concerns traditional foods which fall under one of the categories covered by sections 1.2–1.5, and are derived from primary production and not from chemical synthesis. In such instances, the traditional food has been processed to consist of or to contain (a) substance(s) of higher purity or (a) substance(s) of particular interest. The requirements to be addressed in these	The suggested changes have been implemented in this guidance.

		sections relate to those specific pure substance(s) in the traditional food.": This paragraph could be made clearer. Suggested edit: "This section concerns traditional foods which fall under one of the categories covered by sections 1.2–1.5, and are derived from primary production and not from chemical synthesis. The requirements in this section apply to the traditional food which has been processed to consist of or to contain (a) substance(s) of higher purity or (a) substance(s) of particular interest. The requirements to be addressed in this section relate to those specific pure substance(s) in the traditional food." Line 319. "SMILES Canonical and SMILES Isometric": It should rather say Canonical SMILES and isomeric SMILES. Note the typo in 'isomeric'.	

Section: 1.2 Foods consisting of, isolated from or produced from microorganisms

Comment number	Organisation name	Comment	Reply
11	Food Supplements Europe (Belgium)	Line 353-354 We fail to see why whole genome sequence data should systematically be provided for any micro-organism used in addition to the other data requirements that enable already to establish the identity of the micro-organism. In particular for QPS microorganism, this is a requirement that should be waived. This is particularly relevant because of traditional food from third countries no protection of proprietary data can be obtained.	Data on whole genome sequence (WGS) are crucial in evaluating microorganisms. Consequently, WGS data are to be provided even though they are not subject to proprietary claim (as in the context of traditional foods). Please also refer to the reply to comment 435 in Annex A 'outcome of the public consultation on the guidance on novel foods (EFSA NDA Panel, 2024).

12	Pen & Tec Consulting S.L.U. (trading as Argenta®) (Spain)	Line 335. "EFSA QPS": Reference to the relevant EFSA guidance on QPS is missing, unlike in the draft novel food guidance (EFSA BIOHAZ Panel, 2023).	The suggested editorial change has been implemented in this guidance.
13	Atova Regulatory Consulting SL (Spain)	(Line 343-354, page 12) Suggest further clarification and make a distinction between the type of microorganism and the data requirements as per the referenced guidelines. For example, as per EFSA FEEDAP Panel, 2018, AMR is only required for bacteria.	This section has been aligned to the guidance on novel foods.

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Section: 1.3 Food consisting of, isolated from or produced from plants, macroscopic fungi and algae or their part

Comment number	Organisation name	Comment	Reply
14	Nutraveris - a FoodChainID company (France)	Can EFSA clarifies authentification methods for botanicals, notably all methods not based on DNA analysis. Is HPTLC a valid method? What are the requirements for macroscopic/microscopic verification?	Please refer to the reply to comment 68 in Annex A 'outcome of the public consultation on the guidance on novel foods (EFSA NDA Panel, 2024).
15	Food Supplements Europe (Belgium)	Lines 382-385 The provision of growing region(s) of the source organism (continent, country, region) and, when relevant, season of harvesting and growing conditions to produce the source organism (i.e., cultivated or from the wild, conditions of cultivation) are parameters that are applied during quality control when sourcing raw materials. They will not be part of the specifications. In particular if the source materials are general food commodities the provisions of these details would not be of relevance for the safety assessment. It is suggested to add "where relevant". Line 386 The submission of a Non-GMO statement is	Please refer to the reply to comment 436 in Annex A 'outcome of the public consultation on the guidance on novel foods (EFSA NDA Panel, 2024).

		irrelevant as this falls outside the scope of the traditional food from third countries.	
16	Pen & Tec Consulting S.L.U. (trading as Argenta®) (Spain)	Line 386. "Non-GMO statement.": Is it sufficient to provide a statement by the applicant, or do EFSA expect a more official document?	Please refer to the reply to comment 643 in Annex A 'outcome of the public consultation on the guidance on novel foods (EFSA NDA Panel, 2024).

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

Comment number	Organisation name	Comment	Reply
17	Nutraveris - a FoodChainID company (France)	EFSA mentions only DNA-based methods for verification of identity of food from animal sources. However, most of animals can be identified without DNA based methods. Can EFSA clarify acceptable the non-DNA-based methods acceptable (description of the animals, statements from the applicant, etc).	DNA-based authentication is mentioned as an example. Any other methods to demonstrate the identity can be used. The term 'certification' has been added as an example to demonstrate the identity.
18	Pen & Tec Consulting S.L.U. (trading as Argenta®) (Spain)	Lines 395-396. "Regulation (EU) No 2015/1162": It should say "Regulation (EU) 2015/1162" or "Commission Regulation (EU) 2015/1162". Line 402. "Non-GMO statement.": Is it sufficient to provide a statement by the applicant, or do EFSA expect a more official document?	The suggested editorial change has been implemented in this guidance. Regarding the 'Non-GMO statement, please refer to the reply to comment 644 in Annex A 'outcome of the public consultation on the guidance on novel foods (EFSA NDA Panel, 2024).

Section: 2. Production process

Section: 2.1 General provisions

Comment number	Organisation name	Comment	Reply
19	Food Supplements Europe (Belgium)	Lines 450-453 Compliance with applicable legislation is a condition that must be met in all cases. It is therefore not of particular relevance for the safety assessment. Can the guidance explain why a declaration of compliance with this regulation or any other relevant legal document with regards to food contact material is required and specify under what form this need to be provided. i.e. what is meant by 'legal document'? Line 459-467 Food manufacturing in the EU must be compliant with the provisions of Regulation (EC) 852/2004. It is a legal requirement to have such procedures in place. The requirement of information on the quality assurance system should be restricted to those parameters that are essential for risk assessment. In this case, a statement confirming conformity with legislation should suffice (e.g. HACCP).	Text has been changed to improve clarity. Please also refer to the reply to comment 437 in Annex A 'outcome of the public consultation on the guidance on novel foods (EFSA NDA Panel, 2024).

Section: 2.2 Considerations for specific production process steps

Comment number	Organisation name	Comment	Reply
20	Pen & Tec Consulting S.L.U. (trading as Argenta®) (Spain)	Line 474. "Description of feed": Please clarify what information is required here, e.g. is it the nutritional profile or composition, or something else.	Please refer to the reply to comment 646 in Annex A 'outcome of the public consultation on the guidance on novel foods (EFSA NDA Panel, 2024).

Section: 2.4 Additional considerations

Comment number	Organisation name	Comment	Reply
21	Food Supplements Europe (Belgium)	Lines 539-542 It is unreasonable to request food safety management systems (e.g., HACCP plan) to be provided in case the traditional food is manufactured by different producers/processes in the third country. Justifying consistency is indeed required, but the number of producers may be significant, and applicant are not likely to have access of such information. The applicant can only provide information for the processing that is described in the application. In addition, HACCP plans are quality systems intended to meet regulatory requirements and are controlled by enforcement. Not all such information is required for the safety assessment, which should be guided by the compositional data and the description of the manufacturing process.	The HACCP plan should cover the manufacturing sites mentioned in the traditional food notification. In line with the guidance on novel foods, this section has been amended to improve clarity.
22	Pen & Tec Consulting S.L.U. (trading as Argenta®) (Spain)	Line 545. "Regulation (EU) 2283/2015": It should say "Regulation (EU) 2015/2283".	The suggested editorial change has been implemented in this guidance.

Section: 3. Compositional data

Comment number	Organisation name	Comment	Reply
23	German Federal Institute for Risk Assessment (BfR) (Germany)	Page 18, lines 558 - 562 If there are major deviations between the compositional data in the batches of the traditional food and the data from literature, it would be desirable that	The Panel acknowledges the comment. The need to provide this information has been added in the guidance.

		the applicant describes those and discusses them if possible.	
24	Submission on Personal Capacity (Belgium)	There is a misconception about the "comparator" mentioned in lines 655, 656, 724. I would suggest to include a definition of "comparator" under line 201 Definitions. Further, to stay consistent with the use of this term under the lines 903 and 907, unless in the Definition it is clearly stated that "an alternative or another food" is already qualified as a comparator. Further: replace: 651 Whenever relevant (e.g. having an impact on safety or being potentially nutritionally 652 disadvantageous), the applicant should compare the content of constituents such as micronutrients, 653 antinutrients or substances of toxicological concern in the traditional food with the contents in foods 654 currently consumed in the EU. In such cases exposure estimates may be needed for the concerned 655 substance(s) coming from the traditional food and the comparator(s). Ideally but not necessarily, the 656 comparator should be a food that can reasonably reflect the anticipated consumption pattern of the 657 traditional food. by 651 If a comparator is not available, this should be justified. Otherwise, 652 the applicant should compare the content of constituents such as micronutrients, 653 antinutrients or substances of toxicological concern in the traditional food with the contents in foods 654 currently consumed in the EU. In such cases exposure estimates may be needed for the concerned 655	The Panel acknowledges the comment. The paragraph has been reformulated to better clarify the concept of comparator. The Panel acknowledges that the term ‘comparator’ used in section 3.4.1 has a different meaning and thus the term ‘comparator’ has been replaced with ‘control’.

		substance(s) coming from the traditional food and the comparator(s). Ideally but not necessarily, the 656 comparator should be a food that can reasonably reflect the anticipated consumption pattern of the 657 traditional food.	
25	Atova Regulatory Consulting SL (Spain)	(Line 562, page 18) Annex C incorrectly titled Annex B at the end of the document.	The suggested editorial change has been implemented in this guidance.

Section: 3.1.1 Analytical methods

Comment number	Organisation name	Comment	Reply
26	Food Supplements Europe (Belgium)	Line 581 When analyses are not performed in accredited labs, could the guidance elaborate as to what would be acceptable justification?	Please refer to the reply to comment 432 in Annex A 'outcome of the public consultation on the guidance on novel foods (EFSA NDA Panel, 2024).
27	Pen & Tec Consulting S.L.U. (trading as Argenta®) (Spain)	Lines 574-575. "The respective methods of analysis should be described alongside their references." Methods & their validations are proprietary information for the labs & therefore there is strong resistance from labs to share this information with the applicant. What would be EFSA advice in these cases? Line 576. "information on the matrix accreditation": Are there any specific accreditation standards/certificates EFSA is referring to?	Please refer to the reply to comment 648 in Annex A 'outcome of the public consultation on the guidance on novel foods (EFSA NDA Panel, 2024).

Section: 3.1.2 Addressing compositional variability

Comment number	Organisation name	Comment	Reply
28	Pen & Tec Consulting S.L.U. (trading as Argenta®) (Spain)	Lines 588-589. "independently produced (i.e., with independent batches of raw materials)": For traditional foods that are still at pilot scale e.g. startups, purchasing 5 batches of each raw material may not be feasible. Will EFSA accept exceptions to this request? Lines 593-595. "Moreover, compositional data should also cover the whole variability spectrum of the production process parameters (e.g., highest and lowest amount of solvents used, range of temperatures applied)": Do EFSA expect 5 batches for each extreme of the spectrum to be covered?	The guidance recommends to provide at least 5 batches of the traditional foods. However, as indicated in Recital 7, applicants can deviate from the requirements set in the guidance as long as the deviations are justified. Please also refer to the reply to comment 649 in Annex A 'outcome of the public consultation on the guidance on novel foods (EFSA NDA Panel, 2024).

Section: 3.1.3 Sampling practices

Comment number	Organisation name	Comment	Reply
29	Ministry of Regional Affairs and Agriculture (Estonia)	Line 602- would it be possible to refer to a document(s) that explain the principles of representative sampling? Line 604- would it be possible to give examples of sampling protocols?	Please refer to the reply to comment 276 in Annex A 'outcome of the public consultation on the guidance on novel foods (EFSA NDA Panel, 2024).

Section: 3.1.4 Compositional analytes

Comment number	Organisation name	Comment	Reply
30	German Federal Institute for Risk Assessment (BfR) (Germany)	Page 20, lines 620 - 623 This sentence implies that if some categories of traditional foods are exempt from an a	The text has been revised to clarify the circumstances under which traditional foods might be exempted for a nano risk assessment.

		priori nano-specific risk assessment that there are other categories of traditional foods that require a priori a nano-specific risk assessment. But then the question arises for which categories of traditional food this might apply and how such a nano-specific risk assessment is performed.	
31	Pen & Tec Consulting S.L.U. (trading as Argenta®) (Spain)	Lines 608-610. "Information on the identity and the quantity of impurities or by-products, residues and chemical and microbiological contaminants should be provided (e.g., heavy metals, mycotoxins, PCBs/dioxins, pesticides, microbial indicators and pathogens).": Could EFSA be more specific about the pathogens and microbial indicators as well as heavy metals and other contaminants such as PCB, dioxins or PAH which are expected to be always provided? Line 627. "(as defined in the Guidance by the EFSA Scientific Committee (2021a)).": For consistency, suggest amending to "(as defined in EFSA Scientific Committee, 2021a)."	The suggested editorial change has been implemented in this guidance. Please refer to the reply to comment 650 in Annex A 'outcome of the public consultation on the guidance on novel foods (EFSA NDA Panel, 2024).

Section: 3.3 Complex mixtures and whole foods

Comment number	Organisation name	Comment	Reply
32	German Federal Institute for Risk Assessment (BfR) (Germany)	Page 21, lines 647-648 Can you specify the kind of qualitative and quantitative data regarding allergenic substances this refers to? I.e., with regard to the EFSA Guidance document of novel foods, this may include protein identification, characterization and allergenicity assessment (based on	There is no requirement for experimental data on the allergenicity of traditional. foods; data from existing literature is considered adequate. Section 5.7 'Other information' already specifies that publications on studies revealing the allergenic potential of the traditional food should be included. Thus, the Panel does not consider necessary to revise the guidance.

		'weight of evidence' approach). Or does this refer to data from the literature only?	
33	Pen & Tec Consulting S.L.U. (trading as Argenta®) (Spain)	Lines 640-641. "The amount of unidentified components should be indicated and should be as low as possible.": Should this be understood to mean that anything that can technically be identified should be identified? To what length should the applicant go to minimise the amount of unidentified components? What is considered a reasonably low amount of unidentified components?	Please refer to the reply to comment 651 in Annex A 'outcome of the public consultation on the guidance on novel foods (EFSA NDA Panel, 2024).

Section: 3.4 Stability

Comment number	Organisation name	Comment	Reply
34	German Federal Institute for Risk Assessment (BfR) (Germany)	Page 22, lines 697 - 702 In chapter 3.1.2 (addressing compositional variability) it is stated that "When several production processes are proposed, such data should be provided for each process." We understand that this means that for each form of the traditional food (e.g. raw powder of a plant versus ready-to-drink product made thereof) that is produced by a different production process a whole set of compositional data have to be provided. Regarding the data on stability, we are of the opinion that also here for each form of the traditional food a complete set of data on stability testing should be provided by the applicant. We therefore propose to add a sentence similar to the one above: "When	The sentence has been added in the guidance.

		several production processes leading to different forms of the traditional food are proposed, such data should be provided for each process.”	
35	Food Supplements Europe (Belgium)	Lines 699-700 Can the guidance specify what is acceptable as scientific arguments in this context?	Please refer to the reply to comment 438 in Annex A ‘outcome of the public consultation on the guidance on novel foods (EFSA NDA Panel, 2024).

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

Comment number	Organisation name	Comment	Reply
36	Pen & Tec Consulting S.L.U. (trading as Argenta®) (Spain)	Lines 716-717. "the impact on the traditional food of this processing is to be investigated": How many batches of the traditional food shall be tested when investigating impact of processing? Lines 724-726. "The use of proper comparators (e.g., the product manufactured with the same process/recipe without containing the traditional food as ingredient) is necessary.": Should this be understood that investigating by conducting a literature search for possible impact of processing is not an option?	Please refer to the reply to comment 652 in Annex A ‘outcome of the public consultation on the guidance on novel foods (EFSA NDA Panel, 2024).

Section: 4. Specifications

Comment number	Organisation name	Comment	Reply
37	Submission on personal capacity (Belgium)	Replace: 767 contribution to the intake of certain nutrients. If EU regulatory limits are applicable for the traditional 768 food, then they do not have to be necessarily listed in the specifications. by 767 contribution to the intake of	Please refer to the reply to comment 434 in Annex A ‘outcome of the public consultation on the guidance on novel foods (EFSA NDA Panel, 2024).

		certain nutrients. If EU regulatory limits are applicable for the traditional 768 food, then they do not have to be necessarily listed in the specifications but a reference to the EU regulatory limits should be provided.	
38	Food Supplements Europe (Belgium)	Lines 733- 740 The specifications should not only serve as a tool for risk managers but also for the risk assessor because these are the (sole) criteria that will determine whether the food as placed on the market by any food business operator (and not only the applicant) complies with the authorisation. All data requests should therefore be in function of assessing whether a novel food is safe when placed on the market in accordance with these criteria.	Please refer to the reply to comment 195 in Annex A 'outcome of the public consultation on the guidance on novel foods (EFSA NDA Panel, 2024).
39	Pen & Tec Consulting S.L.U. (trading as Argenta®) (Spain)	Line 745. "proximate analytes (protein, lipids, carbohydrates, ash, and moisture),": Should this include dietary fibre?	Please refer to the reply to comment 640 in Annex A 'outcome of the public consultation on the guidance on novel foods (EFSA NDA Panel, 2024).

Section: 5. Data from experience of continued use of the traditional food in third countries

Comment number	Organisation name	Comment	Reply
40	Nutraveris - a FoodChainID company (France)	EFSA mentions on line 782 that full study reports should be provided for human studies. However, most of the human studies are from literature, and full study reports are not available. In this case, would the publication be acceptable for EFSA?	The guidance has been amended to clarify that study reports should be provided if available.
41	Atova Regulatory Consulting SL (Spain)	(Line 781, page 24) "When searching for 'grey-literature', EFSA's principles	The definition of 'grey literature' is provided in EFSA guidance on systematic review (EFSA, 2010) which is cited in the

		(2010) should also be adhered to". Suggest clarifying what is considered "grey literature" and hence whether a full systematic review is suitable. (Line 783-786, page 24-25) It is assumed that the type of referencing should be provided in English including reports from national/governmental however could EFSA clarify this or whether original copies are acceptable?	guidance on traditional foods: 'Types of publication which are less systematically recorded in bibliographic tools such as catalogues and databases than journals and books'. References should be provided in English and copies are acceptable. These requirements are also specified in the Administrative Guidance for traditional foods (EFSA, 2024) so no need to update this guidance on this regard.

Section: 5.6 Human data

Comment number	Organisation name	Comment	Reply
42	Pen & Tec Consulting S.L.U. (trading as Argenta®) (Spain)	Lines 827-829. "The applicant should provide a comprehensive literature search to retrieve human data related to the safety of the traditional food (e.g. absorption, nutritional, microbiological, allergenic, tolerability, interaction with medicines).": Suggested edit for clarity: "The applicant should provide a comprehensive literature search to retrieve human data related to the safety of the traditional food (e.g. absorption, nutritional, microbiological, and allergenic aspects, tolerability, interaction with medicines).	The suggested editorial change has been implemented in this guidance.

Section: 6. Proposed conditions of use for the EU market

Section: 6.1 Target population

Comment number	Organisation name	Comment	Reply
43	Food Supplements Europe (Belgium)	Lines 849-852 The statement "When the novel food is intended to be added as ingredient to foods, or to be consumed as whole food, the proposed target population is the general population including all age groups (i.e. cannot be restricted to subgroups thereof) in accordance with Article 5(6) of Commission Implementing" is not a correct reflection so the legal text which states that "Where it cannot be excluded that a novel food intended for a particular group of the population would be also consumed by other groups of the population the safety data provided shall also cover those groups." It would be best to quote the legal article to avoid confusion. In addition, this legal provision does not prevent a novel food to be intended only for a specific group of the population, e.g. where this is specified by appropriate labelling. In such cases, the EFSA opinion should clearly reflect both what would be the safety conclusion for the general population, as well as for the intended population group requested by the applicant, so the risk manager can consider both and implement appropriate risk management measures where appropriate (such as labelling).	Please refer to the reply to comment 439 in Annex A 'outcome of the public consultation on the guidance on novel foods (EFSA NDA Panel, 2024).

Section: 6.2 Proposed uses and use levels

Comment number	Organisation name	Comment	Reply
44	German Federal Institute for Risk Assessment (BfR) (Germany)	Page 27, lines 869 - 870 The bullet point indicated here as b), should follow the preceding three bullet points and be indicated as (d). General comment In the draft for the guidance on novel foods, there is a fifth bullet point pertaining to the information the applicant should provide in a tabulated format regarding the proposed uses and use levels: "if the novel food is proposed in different forms (e.g., dried, frozen, powder), the food categories and maximum use levels should be proposed for each form of the novel food as requested in points above. It should be specified whether the different forms of the novel food are meant to be utilized singularly and/or in combination in a specific food category." It is also conceivable that a traditional food might be proposed to be used in different forms, e.g. a nut might be intended to be consumed as a dried, whole nut as such but also as a dried powder or similar form. Therefore, the above-mentioned requirements for novel foods on the use of different forms of a novel food, should also apply to traditional foods and be included in the present draft.	The suggested change has been implemented in this guidance.
45	Ministry of Regional Affairs and Agriculture (Estonia)	Line 858-862- Could the food categories of the additive regulation also be considered? Their use would significantly help to carry out the controls in the Member States, as the food categories are also explained in the Commission's guidance document.	The guidance already permits applicants to utilize food additive categories for the intended uses of their traditional food. In particular, the FAIM Tool food categories can be used to indicate the intended uses of the traditional food, as detailed in bullet points a) and b) under section 6.2) No changes were introduced in the guidance.

46	Food Supplements Europe (Belgium)	Lines 867-868 The guidance states that the choice of overly specific food categories may cause difficulties for national authorities in the authorisation process of the novel food. Can the guidance provide more explanation as the nature and reasons underlying these difficulties?	Please refer to the reply to comment 440 in Annex A 'outcome of the public consultation on the guidance on novel foods (EFSA NDA Panel, 2024).

Section: 6.4 Intended role in the diet

Comment number	Organisation name	Comment	Reply
47	Pen & Tec Consulting S.L.U. (trading as Argenta®) (Spain)	Line 906. "6.4 Intended role in the": The caption seems to be incomplete.	The suggested editorial change has been implemented in this guidance.

Section: Annex

Comment number	Organisation name	Comment	Reply
48	German Federal Institute for Risk Assessment (BfR)(Germany)	Page 30, line 937 "Annex B: Compositional data retrieved in peer-reviewed articles (unique for traditional foods)": This should be Annex C!	The suggested editorial change has been implemented in this guidance.

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Abbreviations

AMR	antimicrobial resistance
BfR	German Federal Institute for Risk Assessment
DNA	deoxyribonucleic acid
EC	European Commission
FAIM	Food Additives Intake Model
FEEDAP Panel	Panel on Additives and Products or Substances used in Animal Feed
GMO	genetically modified organism
HACCP	hazard analysis critical control point
NAM	new approach methodology
PAH	polycyclic aromatic hydrocarbon
PCB	polychlorinated biphenyl
QPS	qualified presumption of safety
SMILES	simplified molecular input line entry system
WGS	whole genome sequence