**Part B: «Novel traditional foods»**

**Document checklist for material evaluation of «novel traditional foods»**

Novel traditional foods are defined in Article 15, paragraph 1, letter k of the Ordinance on Foodstuffs and Utility Articles (FUAO, SR 817.02). They include foods from the primary production of novel foods in the categories microorganisms, fungi, algae (Art. 15 para. 1 let. b FUAO), plants or parts of plants (Art. 15 para. 1 let. d FUAO), animals or parts of animals (Art. 15 para. 1 let. e FUAO) and foods from cell and tissue cultures derived from these raw materials (Art. 15 para. 1 let. f FUAO) that have a history of safe food use in a country other than Switzerland and the European Union (EU). Primary production covers both animals and plants (Art. 8 Foodstuffs Act; FSA; SR 817.0).

This checklist supplements the application form, which must always be completed in full, signed and returned. In a structured form, it contains all necessary information to be documented and submitted for the material evaluation of a «novel traditional food». This checklist is based on the EFSA guidance document «[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](https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2016.4590)», the requirements of which have been adapted to those of Switzerland.

This checklist is intended to assist the applicant in preparing a complete and well-structured dossier. The dossier should include the type and quality of information that Switzerland requires for the evaluation of traditional foods from a country outside Switzerland and the EU. The structure should follow the sections presented in this checklist. In addition, the documentation must be complete and enclosed with the approval dossier.

The normal consumption of a traditional novel food must be safe and must not have any nutritional disadvantages. Evidence of this must be provided by analogy with the proven «history of safe food use» for at least 25 years in a country outside Switzerland and the EU. Information must therefore be documented and submitted on the food, production process, composition, stability data, specifications, data from experience of continued use for at least 25 years in a country outside the EU and Switzerland, and the proposed conditions of use of the traditional food.

Furthermore, the applicant must show, in a concise overall consideration in the concluding remarks, how this documented information substantiates the history of safe use of the traditional food and how this safety assessment with the corresponding conditions of use for Switzerland can be related to the safety for the Swiss population. Where this overall consideration of the safety assessment is substantiated based on the composition and/or data from the experience of continuous use over at least 25 years, this should be discussed.

The safety of a traditional food should be traceable using the data documented in the dossier on its composition, the experience of its use in the country outside Switzerland and the EU, and the corresponding conditions of use.

The application should therefore contain sufficient information and scientific documentation to enable the FSVO to assess the safe use of the traditional food from a country outside Switzerland and the EU for the Swiss population. The documents and evidence must refer to the identical foodstuff (e.g. fruit powder in the country of origin and for Switzerland) and must always refer to the same country of origin (all documents from the same country). They must be submitted in an official language of Switzerland or in English.

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| **Product name:** | Please enter name. |
| **Applicant:** | Please enter name. |
| **Date:** | Click or start typing to enter a date. |

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| **Type of application:**  (Please tick as appropriate)  ☐ Application for approval of a traditional food from a country outside Switzerland and the EU in accordance with Art. 3 of the FDHA Ordinance on Novel Foods (SR 817.022.1)   |  |  | | --- | --- | | ☐ | Application to add, delete or modify the following aspects of an already approved traditional food (please tick as appropriate and explain if necessary): | |  | the conditions of use  the specifications  the labelling requirements  the country of origin  other: Click or start typing here to enter text.  Click or start typing here to enter text. | |

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| **Documents to be submitted** |
| Fully completed application form with handwritten signature (only if not already submitted to clarify the classification).   * **A separate application form must be submitted for each product.** * **The application form must be submitted by post.** |
| Dossier with concluding remarks, structured as per this form (see below).   * **A separate complete dossier must be submitted for each product.** * **The dossier can be submitted by post or electronically.** |
| Enclosures to support information in the dossier (originals)   * **These documents can be submitted by post or electronically.** |

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| **Dossier**  The following information should be included and structured as per this checklist. The information in the dossier should be divided into the following three parts:   |  |  |  | | --- | --- | --- | |  | * **Part 1:** | General information | |  | * **Part 2:** | Information on the novel food (description, identity, specifications, production process, compositional data, experience of use and proposed conditions of use). Any differences between current and earlier/traditional circumstances (e.g. due to changes in the production process, breeding, etc.) must be clearly indicated. This part must additionally contain a list of all references. | |  | * **Part 3:** | * Glossary or abbreviations of terms quoted throughout the dossier * Certificates such as certificates of analyses * Full copies/print-outs of all pertinent scientific data (published and unpublished), study reports and scientific opinions of national/international regulatory bodies. * Full texts of all cited non-scientific references («grey literature»). | |

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| **Part 1**  **General information** |
| 1. **General information** |
| **1.1. Table of contents of the dossier** |
| Click or start typing here to enter text. |
| * 1. **Legal status outside Switzerland (e.g. in the EU, country of origin, etc.)** |
| If the applicant has submitted the traditional food to one or more approval authorities outside Switzerland for authorisation/approval, please indicate the assessment status at each approval authority:  **Under consideration**:  Date of submission: Click or start typing to enter a date.  Proposed conditions of use  Click or start typing here to enter text.  Competent authority  Click or start typing here to enter text. |
| **Withdrawn**:  Date of withdrawal: Click or start typing to enter a date.  Reasons for withdrawal  Click or start typing here to enter text.  Conditions of use (if different) of the withdrawn traditional food  Click or start typing here to enter text.  Competent authority at the time of withdrawal  Click or start typing here to enter text. |
| **Approved**:  Date of approval: Click or start typing to enter a date.  Conditions of use for the approved traditional food  Click or start typing here to enter text.  Approval authority: Click or start typing here to enter text.  Enclosure: If available, a copy of the scientific opinion of the authority that approved the traditional food (in Part 3). |
| **Rejected**:  Date of rejection: Click or start typing to enter a date.  Reasons for rejection:  Click or start typing here to enter text.  Explanation given by the authority that rejected the traditional food: Click or start typing here to enter text.  Enclosure: If available, a copy of the scientific opinion of the authority that rejected the traditional food (in Part 3). |

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| **Part 2:**  **Characterisation of the traditional food, technical and scientific data** |

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| **2. Characterisation of the novel traditional food (technical and scientific data)** |
| **2.1. Brief description of the novel traditional food (stating sources) Any differences between current and traditional circumstances must be clearly indicated.** |
| **Brief description of the novel traditional food**  Click or start typing here to enter text.  **Origin of the novel traditional food**  (particularly country of origin, for which the information and evidence, especially evidence of traditional consumption, is submitted)  Click or start typing here to enter text.  **Brief description of the production process of the novel traditional food**  Click or start typing here to enter text.  **Typical composition of the novel traditional food**  Click or start typing here to enter text.  **Purpose of the novel traditional food**  Click or start typing here to enter text.  **Intended use of the novel traditional food**  Click or start typing here to enter text. |

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| **2.2. Identity of the novel traditional food**  Information on the identity of the traditional food should be provided, depending on the class(es) under which the traditional food falls.  There may be cases where a traditional food could be allocated to two or more classes. In such cases, the relevant information for all applicable classes should be provided. |
| **2.2.1 Foods consisting of, isolated from or produced from microorganisms, fungi or algae** |
| 1. Scientific (Latin) name (family, genus, species, strain) according to the international codes of nomenclature (official/accepted scientific name) |
| Click or start typing here to enter text. |
| 1. Synonyms that may be used interchangeably with the official/accepted scientific name, and other names |
| Click or start typing here to enter text. |
| 1. For algae[[1]](#footnote-1) and fungi[[2]](#footnote-2), verification of the identity according to internationally recognised databases and methodology |
| Click or start typing here to enter text. |
| 1. For bacteria and yeasts (unicellular organisms): verification of the species and strain identity according to internationally accepted methods   (Resources: information on applicable methods for the characterisation of bacteria and yeasts is provided in the EFSA Health Claim guidance (EFSA NDA Panel, 2016b[[3]](#footnote-3)). Molecular methods allow predictions of genes encoding for toxins, antimicrobial resistance and other pathogenic factors.) |
| Click or start typing here to enter text. |
| 1. Origin of the organism |
| Click or start typing here to enter text. |
| 1. If available, deposition in an officially recognised culture collection with access number |
| Click or start typing here to enter text. |
| **2.2.2 Food consisting of, isolated from or produced from plants or their parts**[[4]](#footnote-4) |
| 1. Scientific (Latin) name (botanical family, genus, species, subspecies, variety, with author’s name, chemotype, if applicable) according to the international codes of nomenclature (official/accepted scientific name) |
| Click or start typing here to enter text. |
| 1. Synonyms (botanical name) that may be used interchangeably with the preferred scientific name |
| Click or start typing here to enter text. |
| 1. For plants[[5]](#footnote-5), verification of the identity should be according to internationally recognised databases and methodology. |
| Click or start typing here to enter text. |
| 1. Common names (if a trivial or a common name is used, it should be linked to the scientific name and part used) |
| Click or start typing here to enter text. |
| 1. Part(s) used (e.g. root, leaf, seed, etc.): Please tick or complete as appropriate (if applicable, more than one part of the plant may be indicated) |
| |  |  |  | | --- | --- | --- | | All plant parts | Vegetation | Leaf | | Seed | Root | Rhizome | | Bulb | Fruit | Flowers | | Bark | Wood | Above-ground parts | | Shoots | Stem | Exudate | | Other (please indicate which): Click or start typing here to enter text. | | |   Please explain if necessary: Click or start typing here to enter text. |
| 1. Geographical origin (continent, country, region) |
| Click or start typing here to enter text. |
| **2.2.3 Food consisting of, isolated from or produced from animals or their parts** |
| 1. Scientific (Latin) name (zoological family, genus, species, subspecies, breed, if applicable) |
| Click or start typing here to enter text. |
| 1. Synonyms that may be used interchangeably with the preferred scientific name |
| Click or start typing here to enter text. |
| 1. Common names (if a trivial or a common name is used, it should be linked to the scientific name and part used) |
| Click or start typing here to enter text. |
| 1. Part(s) used |
| Click or start typing here to enter text. |
| 1. Geographical origin (continent, country, region) |
| Click or start typing here to enter text. |
| **2.2.4 Food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, fungi or algae**  This section concerns cultures of multicellular origin (animals, plants, multicellular algae and mushrooms).  Foods originating from cultures of unicellular origin should be addressed under Section 2.2.2. |
| 1. Biological source (taxonomic information on family, genus, species, subspecies, variety) |
| Click or start typing here to enter text. |
| 1. For plants5, algae1 and fungi2, verification of the identity according to internationally recognised databases and methodology |
| Click or start typing here to enter text. |
| 1. Origin of organ and tissue or part of the organism |
| Click or start typing here to enter text. |
| 1. Laboratory or culture collection sourced |
| Click or start typing here to enter text. |
| 1. Information on the identity of cells |
| Click or start typing here to enter text. |
| 1. Cell or tissue substrate used as a traditional food |
| Click or start typing here to enter text. |
| 1. Type of cultures |
| Click or start typing here to enter text. |

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| **2.3. Production process** |
| **2.3.1. Detailed description of the production process – Notes on the information to be submitted:**  The process(es) employed to produce the traditional food (e.g. fermentation, isolation from a natural source, etc.) should be described in as much detail as possible. The information that will form the basis for the evaluation of bioavailability, nutritional value and safety should be provided. The description should include information on potential by-products, impurities or contaminants.  Information should also be provided on the handling of the sources, for example:   * for plants and fungi: the propagation, growth and harvesting conditions e.g. wild or cultivated, cultivation practices, time of harvest in relation to both season and stage of growth; * for farmed animals or the hunting, catching, collecting and killing of wild living animals:   the breeding, rearing, feeding and farming conditions;   * for microorganisms and algae, and cell culture or tissue culture from plants and animals: the culture conditions.   Descriptions of the cultivation of plants, fungi, algae and microorganisms, and the rearing of animals, should include information on the use of pesticides, antimicrobials and antiparasitic agents.  Post-harvest handling, e.g. transport, drying techniques and storage conditions (duration, light, moisture and temperature) of unprocessed foods and the raw materials for further processing should be described. The parts of the organism used as a raw material should be specified and information on other starting substances or materials, if used, should be provided.  For traditional foods consisting of, isolated from or produced from plant, animal or microbiological sources, the applicant should describe in detail the process by which the raw material is converted into an ingredient or a preparation intended for a food product (e.g. heat treatment, extraction, distillation, squeezing, fractionation, purification, concentration, fermentation, etc.). Information on substances used in the manufacturing process, e.g. identity of extraction solvents, ratio of extraction solvent to material, reagents, residues remaining in the final product, and any special precautions (light and temperature) should be provided.  Operational limits and key parameters of the production process should be given.  Where the traditional novel food contains undesirable ingredients or contaminants, the influence of the production process on their levels should be documented.  Measures implemented for production control and quality and safety assurance should be described (e.g. HACCP, GMP, ISO). A production flow chart should be provided, including quality and safety control checks. Standardisation criteria (e.g. chemical markers for the traditional food) should be provided.  For traditional foods consisting of, isolated from or produced from plants, specific considerations and complementary information are provided in the EFSA guidance on safety assessment of botanicals and botanical preparations (EFSA Scientific Committee, 2009)4. |
| **Detailed description of the production process:**  Click or start typing here to enter text. |

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| **2.4. Compositional data – Notes on the information to be submitted:**  The information should include qualitative and quantitative data on the composition, physicochemical and biochemical properties and the microbiological characterisation of the traditional food.  Validated methods should be used for the analyses, preferably applying nationally or internationally recognised methods (e.g. Association of Analytical Communities, American Chemical Society, European Pharmacopoeia). The respective methods of analysis should be described together with relevant references. The information on analyses for substances of toxicological concern should include their limit of detection and limit of quantification. If in-house methods are employed, they should be described (including results of the respective validation procedures). If the analyses are not performed in accredited laboratories, justification should be provided.  Analytical data from publications can also be used if the publications provide sufficient information on the laboratory where analyses were carried out and the methods utilised, and whether the studies were performed on representative samples of the traditional food. Available published data can also provide information on the variability of the composition of the traditional food.  Data on composition and its variability should support the setting of specifications for the traditional food as it is intended to be placed on the market (Section 2.5). The analytical information should be provided on at least five representative batches of the traditional food that have been separately produced (i.e. using separate batches of raw materials). Where several production processes are proposed, such data should be provided for each process.  Especially for potentially toxic substances, the levels documented in the batch analysis should be compared with previous/traditional levels or levels from literature research. |
| **2.4.1. General requirements (required for all** **traditional foods)**  Accurate information should be provided on the identities and quantities of impurities or by-products, residues and chemical and microbiological contaminants (e.g. heavy metals, mycotoxins, PCBs/dioxins, pesticides, etc.). The type and spectrum of potential target analytes should be considered in the light of the sources and the production process. For example, for foods produced by microbial fermentation, the presence of undesirable metabolites should be investigated; for foods isolated by extraction, data on residues of the solvent used should be provided. |
| Click or start typing here to enter text. |
| **2.4.2. Complex mixtures and whole foods**  Complex mixtures (e.g. extracts, protein hydrolysates) and whole foods (e.g. milk, meat, fruits, seeds) are defined as those where all constituents cannot be fully chemically characterised and/oridentified.   * If not all components can be fully chemically characterised and/or identified, a qualitative and quantitative characterisation of the main components and toxicologically relevant constituents should be performed and documented. * In the case of whole foods, the qualitative and quantitative characterisation should include ash, moisture, protein, fat and carbohydrates. On the basis of these data, a mass balance should be calculated. The amount of unidentified components should be indicated and should be as low as possible.   For the classes of components that characterise the nature of the traditional food (e.g. peptides, phospholipids, carotenoids, phenolics, sterols), comprehensive qualitative and quantitative data should be provided.  Qualitative and quantitative data on nutritionally relevant inherent constituents (e.g. micronutrients) should also be given.  Depending on the origin of the traditional food, qualitative and quantitative data on inherent substances of possible concern for human health (e.g. toxic, addictive, psychotropic, allergenic) should be provided.  In addition to analytical data on composition, a literature search should be performed to retrieve published compositional data for the source and the part used in/as traditional food. The methodology developed by EFSA (EFSA, 2010; section 3.2) may be useful in this respect.  Information on the keywords and inclusion/exclusion criteria used for the literature search should be provided.  Any substances of concern derived from plants should be classified according to their chemical structure. Levels at which the constituents are present in the respective part of the botanical or botanical preparation should be given where available. It is recommended that chemical fingerprinting of the botanical material is undertaken for this purpose.  Particular attention should be given to the possible presence of genotoxic and/or carcinogenic substances.  The following non-exhaustive list of resources can help in identifying possible substances of concern in a botanical material:  - The EFSA Compendium of Botanicals which provides information on naturally occurring substances that may be of concern for human health (EFSA, 2012)[[6]](#footnote-6),  - The EFSA Chemical Hazard Database (S-IN, 2015)[[7]](#footnote-7). |
| Click or start typing here to enter text. |
| **2.4.3. Stability**  The stability of the traditional food should be evaluated in order to identify hazards which might arise during storage and transport. The nature of degradation products in the food during storage/transport should be characterised.  Stability tests should therefore focus on those constituents and parameters of the traditional food that may be susceptible to changes during storage and may directly affect its safety or serve as indicators of changes that could have an impact on the safety of the food.  Depending on the nature and type of the traditional food, the stability testing should address the physicochemical, biochemical and microbiological stability of the traditional food under normal conditions of storage, including the effects of packaging, storage temperature and environmental conditions (light, oxygen, moisture, relative humidity). Information should be provided on the normal storage conditions of traditional food, and on the storage conditions under which the stability testing was performed. The stability testing should be provided on preferably at least five representative batches of the traditional food that have been separately produced (i.e. using separate batches of raw materials).  The duration of the stability testing may depend on the type of the traditional food and its proposed uses and should cover at least the end of the shelf-life. Accelerated conditions (usually at a higher temperature) may be used as an alternative to stability testing under normal conditions.  Information should be provided on ingredients added to the traditional food to improve its stability. |
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| **2.5. Specifications**  The specifications of the traditional food must be submitted.  The specifications define the key parameters which characterise and substantiate the identity of the traditional food, as well as limits for these parameters and for other relevant physicochemical,biochemical and microbiological properties. The specifications will be used as key parameters, among other compositional data, to evaluate whether the data provided to substantiate the «history of safe food use» are relevant to the traditional food intended to be placed on the Swiss market. In addition, the limits set in the specifications for toxicologically and/or nutritionally relevant components will be considered in the risk assessment.  On the basis of the analytical data on the traditional food provided in Sections 2.2–2.4, the applicant should propose specifications, in the form of a table, which include the limits and information on the exact method for each of the selected parameters.  The specifications should include nutritional or biologically active components or, if these are not known, selected chemical markers. The specifications should also include concentrations of the major groups of constituents present in the food, e.g. amino acids and proteins, lipids, carbohydrates, inorganic ions, polyphenols, alkaloids, terpenes, alkenylbenzenes, lignin, saponins and chitin, as well as the main substances within these classes.  A rationale for the parameters selected in the specifications should be provided. As a minimum, the specification should include contents and/or limits for the parameters on the identity of the product, the minimum purity and limits acceptable for impurities and degradation products, in particular those of toxicological or nutritional relevance. Maximum levels of contaminants (e.g. microorganisms, mycotoxins, heavy metals, pesticide residues, polycyclic aromatic hydrocarbons) should be included, even in the absence of legal requirements in Switzerland or the EU. |
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| **2.6. Data from experience of continued use**  This section should provide all data from the experience of continued use for 25 years which are pertinent to the safety assessment of the traditional food.  The type of references could include scientific publications, scientific expert opinions, monographs, information from international or national organisations, governmental documentation and figures on cultivation/harvesting, sales and trade. Further information might be obtained from cookbooks, recipes and anecdotal data. The reliability and weight of the data will be assessed in the light of their source and their qualitative and quantitative nature.  It is important to characterise as much as possible the traditional modalities of use in terms of preparation type, extent of use and duration of exposure. A food traditionally consumed only on special occasions or exclusively in combination with another food/substance may cause health concerns/adverse effects if consumed in larger quantities, for a longer duration or in a different combination or context. It is possible that the food could be used, cooked and consumed differently by consumers in Switzerland, as compared to the country of origin. |
| Click or start typing here to enter text. |
| **2.6.1. Experience of continued food use in the country of origin (i.e. in a country outside Switzerland and the EU)**  The supporting documentation on the experience of continued food use should provide a description of the extent of use of the traditional food, the population group for which the traditionalfood has been a part of their diet, information on its preparation and handling, its role in the diet and information on precautions. A comprehensive literature review of human studies related to the consumption of the traditional food should be performed.  Information on the search strategy, including the sources used to retrieve pertinent data (databases, other sources), the terms and limits used (e.g. publication dates, publication types, languages, population, default tags) should be reported.  Where applicable, the published literature should be reviewed by taking into account systematic review principles (EFSA, 2010)7. Information on the search strategy for data in the non-peerreviewed literature («grey literature») should also be provided. Full study reports should be provided if available.  The documentation provided should relate to the traditional food as it is intended to be placed on the Swiss market. |
| Click or start typing here to enter text. |
| **2.6.1.1. Extent of use**  The extent of use of the traditional food must be described. Points a–e below should be completed in full. |
| 1. The place of production and volume of the traditional food produced per year in the country of origin. |
| Click or start typing here to enter text. |
| 1. The geographical areas (e.g. region, country, continent) where the food is consumed. |
| Click or start typing here to enter text. |
| 1. The quantity of consumption, information on the serving size(s), the average, high and if available maximum intake levels per person should be provided. If available, intake estimates based on food consumption surveys or other estimates should be provided. |
| Click or start typing here to enter text. |
| 1. A clear distinction should be made between the intakes of a part of a botanical as such, derived preparations (e.g. tea), or e.g. an intake of essential oil. |
| Click or start typing here to enter text. |
| 1. The length and continuity of use over time |
| Click or start typing here to enter text. |
| **2.6.1.2. Characteristics of the population group(s) of consumers in the country of origin**  Documentation should be provided on whether a food has been consumed by the general population or whether its consumption was largely or wholly confined to specific subpopulations defined by, for example, their age, sex, ethnic background, physiological and/or medical condition.  Information should be provided on the size of the population or population groups which have consumed the traditional food. |
| Click or start typing here to enter text. |
| **2.6.1.3. Role in the diet**  Documentation should be provided on the consumption pattern including the frequency, context and consumption habits (e.g. for specific purposes, ceremonies, combined consumption with other foods), the type of dish or meal for which the food is used (e.g. as a snack, main dish, ingredient or spice for specified foods or meals). Information on the contribution of the food to the overall macro- and micronutrient intake of the population may be helpful. |
| Click or start typing here to enter text. |
| **2.6.1.4. Information on the handling and preparation of the food (prior to consumption)**  This section should provide documentation concerning the handling, including storage, and preparation of the food prior to its consumption, e.g. breakup or milling, peeling, removing or using only specific parts of the food, any kind of heat treatment (cooking method), or any other type of treatment. |
| Click or start typing here to enter text. |
| **2.6.1.5. Precautions for preparation and restrictions of use**  Information should be provided on any prohibition or restrictions imposed in respect of the food in the country of origin, precautions to be taken during its preparation, any kind of treatment or methods to reduce levels of toxic, allergenic or antinutritional substances or to improve digestibility, as well as information on reported limitations and restrictions for sensitive/specific population groups. |
| Click or start typing here to enter text. |
| **2.6.1.6. Human data**  The applicant should document their comprehensive literature search for available human data related to the safety of the traditional food (e.g. kinetic data, toxicological, nutritional, microbiological, allergenic, tolerability, interaction with medicines). These could include human intervention and observational studies, case reports and information from surveillance reports.  The applicant should not only consider and limit their literature search to the traditional food itself, but should also search for studies with specific and typical components of the traditional food and for studies with similar foods from the same or other closely related sources (e.g. other varieties or subspecies or related species of the same genus or family). |
| Click or start typing here to enter text. |
| **2.6.2. Other information**  All other available information relevant for the safety assessment of the traditional food should be provided. This could include non-food uses (e.g. cosmetic, medical, feed) and animal studies (e.g. toxicity studies). |
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| **2.7. Proposed conditions of use for the Swiss market**  In principle, a food can be approved for the Swiss market only if it is the same food, for the same population group, that has already been consumed as a traditional food for at least 25 years in a country outside Switzerland and the EU.  A rationale for the target population, proposed uses and use levels, precautions and restrictions of use should be provided with cross-referencing to relevant data on the «history of safe food use». |
| **2.7.1. Target population**  The applicant should unambiguously specify the intended target population, e.g. the general population or certain defined population subgroups.  **Note:** The target population for this novel traditional food in Switzerland must be the same population group that has consumed the same food as a safe food in the country of origin for more than 25 years (see point 2.6.1.2). |
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| **2.7.2. Proposed uses**  It is important that the information provided in this section is precise, complete and free of ambiguity. When proposing uses and use levels, all available information on safety should be taken into consideration. Points a–e should be completed in full:  **Note:** The proposed use (e.g. form and quantity of use) for this novel traditional food in Switzerland must be the same as the traditional use in the country of origin and must not go further than included there (see point 2.6.1.1). |
| 1. The form of use (e.g. as a whole food or as an ingredient) |
| Click or start typing here to enter text. |
| 1. The food category (or categories) in which the traditional food (if an ingredient) is to be used. |
| Click or start typing here to enter text. |
| 1. Whether the traditional food is intended to replace another food |
| Click or start typing here to enter text. |
| 1. The proposed maximum use level(s) and concentration(s) in the final product(s) |
| Click or start typing here to enter text. |
| 1. The proposed daily intakes for different age/gender groups as appropriate |
| Click or start typing here to enter text. |
| **2.7.3. Intended role in the diet**  Where a traditional food is intended to replace another food in Switzerland, the applicant should demonstrate that it does not differ from that food in a way that would be nutritionally disadvantageous for the consumer. |
| Click or start typing here to enter text. |
| **2.7.4. Precautions and restrictions of use**  When proposing precautions and restrictions of use, all available information on safety should be taken into consideration.  The applicant should specify the population (sub)groups (including population groups with certain physiological conditions) which should avoid consumption of the traditional food and include therationale. The applicant should also indicate any other restrictions of use and precautions related to the handling, preparation and consumption of the traditional food.  Any effects of potential overconsumption on the population or population subgroups should be described. |
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| **2.8. Concluding remarks**  The information on composition and experience of use (continuously over 25 years in the country of origin) must be summarised here. The applicant must also provide a concise overall consideration on how this substantiates the history of safe use of the traditional food and how this relates to the proposed conditions of use for the Swiss market.  Where potential health hazards have been identified on the basis of the composition and/or data from the experience of use, they should be discussed. |
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| **Part 3:**  **Annexes to the dossier** |
| 1. The glossary or abbreviations of terms quoted throughout the dossier |
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| 1. Certificates (on the accreditation of laboratories, certificates of analyses) |
| Click or start typing here to enter text. |
| 1. Full copies/print-outs of all pertinent scientific data (published and unpublished) |
| Click or start typing here to enter text. |
| 1. Full study reports |
| Click or start typing here to enter text. |
| 1. Scientific opinions of national/international regulatory bodies |
| Click or start typing here to enter text. |
| 1. Full texts of all cited non-scientific references («grey literature»). |
| Click or start typing here to enter text. |

1. For algae species: The Algae database ([www.algaebase.org](http://www.algaebase.org)) [↑](#footnote-ref-1)
2. For the identification of fungi: The *Index fungorum*: <http://www.indexfungorum.org/names/names.asp> for identification of fungi. [↑](#footnote-ref-2)
3. EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2016b. General scientific guidance for stakeholders on health claim applications. EFSA Journal 2016;14(1):4367, 38 pp. doi:10.2903/j.efsa.2016.4367, General scientific guidance for stakeholders on health claim applications - - 2016 - EFSA Journal - Wiley Online Library [↑](#footnote-ref-3)
4. These requirements are in line with the [EFSA Scientific Committee guidance on the safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements](https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2009.1249) (EFSA Scientific Committee, 2009). [↑](#footnote-ref-4)
5. The Plant List ([www.theplantlist.org](http://www.theplantlist.org)), resulting from the collaboration between the Royal Botanic Gardens, Kew and Missouri Botanical Garden; The USDA-ARS Germplasm Resources Information Network (GRIN) database <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysimple>) if The Plant List does not provide the required information; The International Plant Names Index (<http://www.ipni.org/>) if the two above sources do not provide the required information. [↑](#footnote-ref-5)
6. EFSA (European Food Safety Authority), 2012. Compendium of botanicals reported to contain naturally occurring substances of possible concern for human health when used in food and food supplements. EFSA Journal 2012;10(5):2663, 60 pp. [doi:10.2903/j.efsa.2012.2663](https://www.efsa.europa.eu/en/efsajournal/pub/2663) [↑](#footnote-ref-6)
7. S-IN (Soluzioni Informatiche), 2015. Further development and update of EFSA’s Chemical Hazards Database NP/EFSA/EMRISK/2012/01. EFSA supporting publication 2014:EN-654, 103 pp. Available online: [www.efsa.europa.eu/publications](http://www.efsa.europa.eu/publications) [↑](#footnote-ref-7)