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## **Information sheet 4**

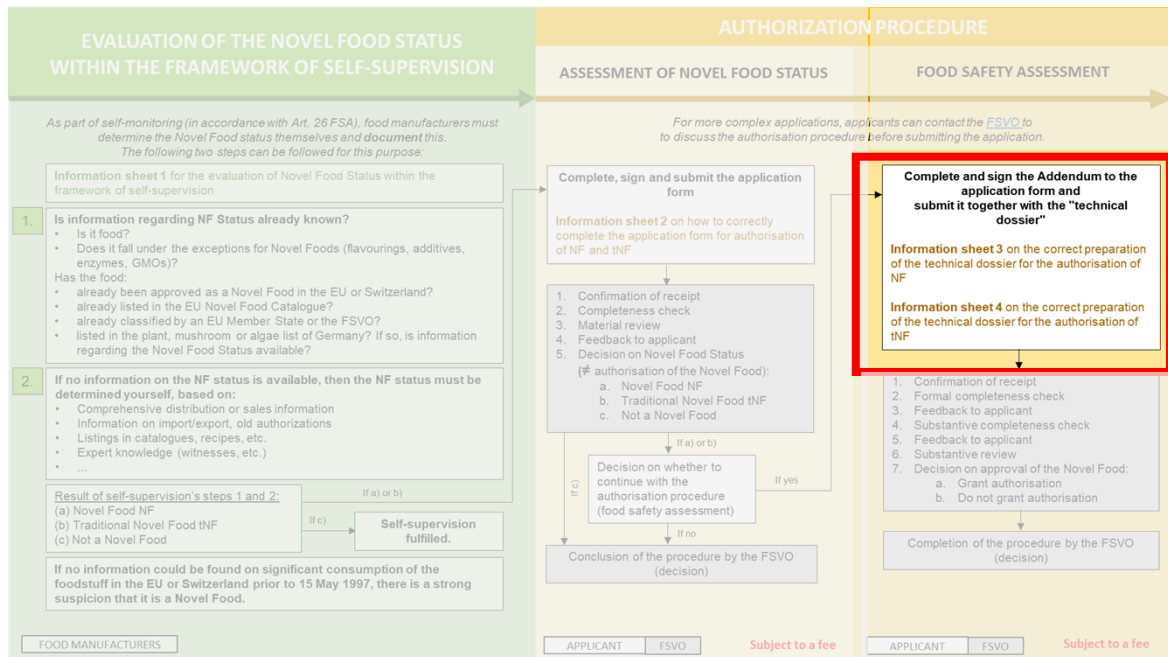
on the correct preparation of the technical dossier  
for the substantive assessment of food safety for  
traditional novel foods

Status: January 2026

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At the latest when the FSVO has assessed the novel food status, food safety must be assessed as part of the authorisation procedure (see Figure 1).

This information sheet supports applicants in preparing a complete and structured technical dossier for the authorisation of **traditional novel foods** from third countries in accordance with Regulation (EU) 2015/2283. It is based on the guidelines of the European Food Safety Authority (EFSA) and the requirements of the Federal Food Safety and Veterinary Office (FSVO). The dossier must contain scientific evidence demonstrating the safety of the product under the intended conditions of use.



**Figure 1** Process for the authorisation of novel foods in accordance with the 'Diagram of the authorisation procedure for novel foods' ([link](#)). This information sheet serves as a guide to the correct preparation of the technical dossier for the substantive assessment of food safety for traditional novel foods.

The technical dossier must be structured in accordance with the requirements of the EFSA guidance document ("[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](#)"). All relevant chapters must be covered in full. If certain chapters or subchapters are not relevant from the applicant's point of view, the reasons why they are considered irrelevant must be clearly explained.

If necessary, the FSVO recommends to reach out at an early stage to clarify any questions regarding the preparation of the technical dossier in a physical or virtual meeting. This can be done by emailing: [lme@blv.admin.ch](mailto:lme@blv.admin.ch) .

In the case of traditional novel foods, the technical dossier must primarily demonstrate a history of safe and continuous use for at least 25 years in a third country outside Switzerland and the EU. The safety of a traditional food should be verifiable on the basis of the data documented in the technical dossier on its composition, experience with its use in a third country outside Switzerland and the EU, and the corresponding conditions of use.

The technical dossier must therefore contain sufficient information and scientific documentation to enable the FSVO to assess the safe use of the traditional food from a third country for the Swiss population.

The dossier must be written in **continuous text** so that the accompanying documents can be explained in a comprehensible manner. A date should be specified so that when amended dossier parts are submitted, it is clear which is the most recent dossier. Dossiers that do not meet the formal requirements will not be processed further.

### **General principles**

- The dossier must contain all relevant data on the safety of the novel traditional food.
- The structure of the dossier should follow the sections specified in this information sheet.
- The sources used (e.g. scientific literature, references to own batch analyses) must be clearly indicated in the text. A document with an appendix overview may also be helpful. The technical dossier should then clearly and unambiguously reference the appendices.
- The applicant should provide an assessment of the data with regard to the safety of the food and explain any uncertainties.
- Any deviations from the requirements of the information sheet must be justified.

The following chapters must be addressed in the technical dossier and should be prepared in accordance with the description and guidance provided for each chapter.

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## Sections for the structure and preparation of the technical dossier

The following sections were created using AI based on the EFSA guidance document ("[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](#)" dated 27 June 2024). This information sheet is a translated summary version and is intended to make the EFSA guidance, which is only available in English, more accessible. The content has been reviewed by the FSVO. In case of uncertainty or for further information, please refer to the EFSA guidance.

### 1. Characterisation of the novel traditional food (technical and scientific data)

#### Brief description (profile) of the novel traditional food:

- Brief description of the food
- Origin of the food
- Description of the production process of the food
- Typical composition of the food
- Intended use of the food
- Intended use of the food

#### Identity of the novel traditional food

Depending on the class(es) to which the traditional foodstuff belongs, the relevant information on the traditional foodstuff must be provided.

- Foods consisting of, isolated from or produced from micro-organisms, fungi or algae: scientific (Latin) name (family, genus, species, strain) according to international nomenclature codes, synonyms that can be used interchangeably with the official/accepted scientific name, other names, origin of the organism, etc.
- Foods consisting of, isolated from or produced from plants or parts of plants: Scientific (Latin) name (botanical family, genus, species, subspecies, variety, with author's name, chemotype if applicable) in accordance with international nomenclature codes, synonyms (botanical names) that can be used interchangeably with the preferred scientific name, common names, parts of the plant used, geographical origin, etc.
- Foods consisting of, isolated from or produced from animals or parts of animals: Scientific (Latin) name (zoological family, genus, species, subspecies, breed, if applicable), synonyms that can be used interchangeably with the preferred scientific name, common names (if a trivial name or common name is used, it should be linked to the scientific name and the part used), parts used, geographical origin, etc.
- Foods consisting of, isolated from or produced from cell cultures or tissue cultures of animals, plants, fungi or algae: Biological source (taxonomic information on family, genus, species, subspecies, variety), origin of organ and tissue, indication of laboratory or culture collection, cell or tissue substrate, etc.

## 2. Manufacturing process

The methods used to produce the traditional food (such as fermentation or isolation from a natural source, etc.) should be described in as much detail as possible. Information must be provided that serves as a basis for assessing bioavailability, nutritional value and safety. The description must also include information on possible by-products, impurities or contaminants.

Information on the handling of raw materials should also be provided, e.g.

- for plants and fungi: the conditions of propagation, growth and harvesting, such as wild or cultivated, cultivation practices, time of harvest in relation to the season and the growth stage of the plant/fungus;
- for farm animals or the hunting, trapping or gathering and killing of wild animals: breeding, rearing, feeding and housing conditions;
- for microorganisms and algae, as well as cell cultures or tissue cultures of plants and animals: the culture conditions.

The description of the breeding of plants, fungi, algae and microorganisms, as well as the rearing of animals, should also include information on the use of pesticides, antimicrobials and antiparasitic agents.

Post-harvest treatment, e.g. transport, drying techniques and storage conditions (duration, light, humidity and temperature) of unprocessed food and raw materials for further processing, should also be described. The parts of the organism used as raw material should be specified and information on other starting materials or materials should be provided if such are used.

For conventional foods consisting of, isolated from or produced from plant, animal or microbiological raw materials, the process by which the raw material is converted into an ingredient or preparation intended for use in food should also be described in detail (e.g. heat treatment, extraction, distillation, pressing, fractionation, purification, concentration, fermentation, etc.). Information must be provided on the substances used in the manufacturing process, such as the identity of the extraction solvents, the ratio between extraction solvent and material, the reagents, the residues remaining in the final product and any special precautions (light and temperature).

The operating limits and the most important parameters of the production process should also be specified.

If the traditional novel food contains undesirable ingredients or contaminants, the influence of the manufacturing process on their levels should be documented.

The measures taken to control production and ensure quality and safety should be described (e.g. HACCP, GMP, ISO). A **production flow diagram** should be provided, which also includes quality and safety controls. Standardisation criteria (e.g. chemical markers for the traditional food) should be specified.

For traditional foods consisting of, isolated from or produced from plants, the EFSA guidance on the safety assessment of plant substances and plant preparations contains specific considerations and additional information.

### 3. Information on composition<sup>1</sup>

The information must include qualitative and quantitative data on the composition, as well as the physicochemical and biochemical properties and microbiological characterisation of the traditional food.

Validated methods must be used for the analyses, preferably using nationally or internationally recognised methods (e.g. Association of Analytical Communities, American Chemical Society, European Pharmacopoeia). The respective analytical methods should be described together with the relevant references. Information on analyses of substances of toxicological concern (e.g. heavy metals, mycotoxins) must also include their limits of detection and determination. If in-house methods are used, these should be described (including the results of the respective validation procedures). If the analyses are not carried out in accredited laboratories, this should be justified.

Analysis data from scientific publications may also be used if they contain sufficient information about the laboratory where the analyses were carried out and the methods used, and if the study is representative of the traditional food. Available published data may also provide information on the variability of the composition of the traditional food.

The data on composition and its variability should support the establishment of specifications for the traditional food as it is to be placed on the market. The analytical information should be provided for at least **five representative batches** of the traditional food, produced independently of each other (i.e. with independent batches of raw materials). If several manufacturing processes are proposed, this data must be provided for each individual process.

In particular for potentially toxic substances, the levels documented in the batch analysis should be compared with previous/traditional levels or levels from the literature search.

A table containing all average data from analyses of nutrients and undesirable substances (heavy metals, mycotoxins, etc.) should be created. This table should clearly show which data was obtained from analyses and which was derived from the literature.

#### General information

Precise information should be provided on the identity 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 taken into account, considering the sources and the production process. For example, in the case of foodstuffs produced by microbial fermentation, the presence of undesirable metabolites should be investigated, and in the case of foodstuffs isolated by extraction, data on residues of the solvent used should be provided.

#### Mixtures and whole foods

In mixtures (e.g. extracts, protein hydrolysates, etc.) and whole foods (e.g. milk, meat, fruit, seeds), it is not always possible to completely chemically characterise and/or identify all components.

- If not all components can be fully chemically characterised and/or identified, a qualitative and quantitative characterisation of the main components and toxicologically relevant ingredients should be carried out and documented.
- For whole foods, the qualitative and quantitative characterisation should include, in particular, ash, moisture, protein, fat and carbohydrates. A mass balance should be established on the

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<sup>1</sup> The following EFSA assessment for a traditional novel food can be used as an example/guidance (Chapter 3.4): [Technical Report on the notification of roasted seeds of \*Dipteryx alata\* Vogel as a traditional food from a third country pursuant to Article 14 of Regulation \(EU\) 2015/2283](#)

basis of these data. The quantity of unidentified components should be specified and should be as low as possible.

For classes of components such as peptides, phospholipids, carotenoids, phenols and sterols, which characterise the nature of the traditional food, comprehensive qualitative and quantitative information must be provided.

Qualitative and quantitative information on nutritionally relevant ingredients (e.g. micronutrients) should also be provided.

Depending on the origin of the traditional food, qualitative and quantitative data should be provided on substances contained therein that may be of concern to human health (e.g. toxic, addictive, psychotropic, allergenic).

In addition to the analytical data on composition, a literature search should be conducted to find published data on the composition of the food.

Information on the keywords used and the inclusion/exclusion criteria applied for the literature search must be provided.

All substances of concern derived from plants should be classified according to their chemical structure. Where available, the quantities in which the ingredients are contained in the respective part of the plant or herbal preparation should be specified. It is recommended that a chemical fingerprint of the herbal material be created for this purpose.

Particular attention should be paid to the possible presence of genotoxic and/or carcinogenic substances.

The following tools may help to identify the substances of concern that may be present in a botanical material (incomplete):

- The EFSA Compendium of Botanicals, which contains information on naturally occurring substances that may be of concern to human health [Compendium of botanicals | EFSA](#) ,
- the EFSA Chemical Hazard Database: (Open Food Tox) [Chemical hazards | EFSA](#)

### **Stability**

The stability of the traditional food should be assessed to identify hazards that may arise during storage and transport. The nature of the degradation products in the food during storage/transport should be characterised.

Stability tests should therefore focus on those components and parameters of the traditional food that may change during storage and that may directly affect the safety of the food or serve as indicators of changes that could affect the safety of the food.

Depending on the nature and type of the traditional food, the stability test should cover the physicochemical, biochemical and microbiological stability of the traditional food under normal storage conditions, including the effects of packaging, storage temperature and environmental conditions (light, oxygen, humidity, relative humidity). Information on the normal storage conditions for traditional foods and on the storage conditions under which the shelf life test was carried out must be provided. The shelf life test should preferably be carried out on **at least five representative batches** of the traditional food, which have been produced independently of each other (i.e. with independent batches of raw materials).

The duration of the shelf life test may depend on the type of traditional food and its intended use and should cover at least the end of the shelf life. Accelerated conditions (usually at higher temperatures) may be used as an alternative to stability testing under normal conditions.

Information should be provided on the ingredients added to the traditional food to improve its stability.

#### 4. Specifications<sup>2</sup>

The specifications of the traditional food must be submitted.

The specifications shall, in principle, set out the main parameters that characterise and prove the identity of the traditional food, as well as limits for these parameters and for other relevant physicochemical, biochemical and microbiological properties. The specifications are used, alongside other composition data, as key parameters to assess whether the data submitted to demonstrate the "history of safe use" is relevant to the traditional food to be placed on the Swiss market. In addition, the limit values specified in the specifications for toxicologically and/or nutritionally relevant components are taken into account in the risk assessment.

Based on the analytical data on the traditional food listed in Chapter 3, the specifications should contain the limits and information on the exact method for each of the selected parameters in the form of a table.

The specifications should refer to nutritional or biologically active components or, if these are not known, to selected chemical markers. The specifications should also include the concentrations of the most important groups of components of the food, e.g. amino acids and proteins, lipids, carbohydrates, inorganic ions, polyphenols, alkaloids, terpenes, alkenylbenzenes, lignin, saponins, chitin, as well as the most important substances within these classes.

A justification for the selected parameters in the specifications should be provided. The specification must include at least the levels and/or limits of the parameters for the identity of the product, the minimum purity and the permissible limits for contaminants and degradation products, in particular those of toxicological or nutritional significance. Maximum levels for contaminants (e.g. microorganisms, mycotoxins, heavy metals, pesticide residues, polycyclic aromatic hydrocarbons) should also be specified, even if there may be no legal requirements for these in Switzerland or the EU.

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<sup>2</sup>The following EFSA assessment for a traditional novel food can be used as an example/guidance (Chapter 3.5): [Technical Report on the notification of roasted seeds of \*Dipteryx alata\* Vogel as a traditional food from a third country pursuant to Article 14 of Regulation \(EU\) 2015/2283](#)

## **5. Data from experience of continuous use**

This section should contain all data from experience of continuous use over 25 years that are relevant to the safety assessment of the traditional food.

References may include scientific publications, scientific reports, monographs, information from international or national organisations, government documents, figures on cultivation/harvesting, sales and trade. Further information may be obtained from cookbooks, recipes and anecdotal data. The reliability and weight of the data shall be assessed taking into account their source and their qualitative and quantitative nature.

It is important to characterise traditional use patterns as far as possible in terms of preparation methods, extent of use and duration of exposure. A food that is traditionally consumed only on special occasions or exclusively in combination with another food/substance may raise health concerns/adverse effects if consumed in larger quantities, over a longer period of time, or in a different combination or context. It is possible that consumers in Switzerland use, prepare and consume the food differently than in its country of origin.

### **Experience with the use of the food in its country of origin**

The evidence of experience with the use of the food must include a description of the extent of use of the traditional food, the population group for which the traditional food was 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 must be prepared.

Information must also be provided on the search strategy, including the sources used to find relevant data (databases, other sources) and the terms and restrictions used (e.g. publication dates, publication types, languages, population, standard tags).

Ideally, the published literature should be reviewed in accordance with the principles of systematic literature review. Information on the search strategy for data in non-peer-reviewed literature ("grey literature") should also be provided. If available, please submit complete study reports.

The documents submitted should refer to the traditional foodstuff as it is to be marketed in Switzerland.

### **Extent of use**

The extent of use of the traditional food must be described. To this end, the following information must be provided in full:

- The place of manufacture and the quantity of the traditional food produced per year in the country of origin
- The geographical areas (e.g. region, country, continent) where the food is consumed
- The amount consumed, information on portion size(s), the average, high and, if available, maximum amount consumed per person should be provided. If available, intake estimates based on food consumption surveys or other estimates should be provided
- A clear distinction should be made between the intake of a part of a plant as such, preparations made from it (e.g. tea) or, for example, the intake of essential oil
- The duration and continuity of use over time

### **Characteristics of the consumer population(s) in the country of origin**

It must be documented whether a food was consumed by the general population or whether its consumption was/is rather or entirely limited to specific subgroups defined, for example, by their age, gender, ethnic background, physiological and/or disease status.

Information should be provided on the size of the population or population groups that have consumed the traditional food.

### **Role in the diet**

Consumption habits, including 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 course, ingredient or condiment for certain foods or meals). Information on the contribution of the food to the overall intake of macro- and micronutrients in the population may be helpful.

### **Information on the handling and preparation of the food (before consumption)**

This section should document the handling, including storage, and preparation of the food before consumption, e.g. chopping or grinding, peeling, removing or using only certain parts of the food, any type of heat treatment (cooking method) or any other type of treatment.

### **Precautions for preparation and restrictions on use**

Information should be provided on possible prohibitions or restrictions relating to the food in the country of origin, precautions for preparation, treatments or processes to reduce the content of toxic, allergenic or nutrient-damaging substances or to improve digestibility, and reported restrictions and limitations for sensitive/specific population groups.

### **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 data, tolerability, interactions with medicinal products). This could include intervention and observational studies in humans, case reports and information from surveillance reports.

The applicant should not limit their literature search to the traditional food itself, but should also search for studies on specific and typical components of the traditional food and for studies on similar foods from the same or a closely related source (e.g. other varieties or subspecies or related species of the same genus or family).

## **6. Proposed conditions for use on the Swiss market**

In principle, only the same foodstuff and for the same population group that has already been consumed as a traditional foodstuff for at least 25 years in a country outside Switzerland and the EU can be authorised for the Swiss market.

Justification for the target population, the proposed uses and amounts of use, precautions and restrictions on use should be provided with cross-references to relevant data on the "history of safe food use".

### **Target population**

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

Please note: The target population for this novel traditional food in Switzerland must correspond to the population group that has been consuming the same food as a safe food for more than 25 years in the country of origin.

### **Proposed uses**

It is important that the information provided in this section is accurate, complete and unambiguous. All available information on safety should be taken into account when proposing uses and amounts of use. Points a – e must be completed in full:

Please note: The proposed use (e.g. form and quantity of use) for this novel traditional food in Switzerland must correspond to its traditional use in the country of origin and must not exceed that use (see section 2.6.1.1).

- Form of use (e.g. as a whole food or ingredient)
- Food category(ies) in which the traditional food is to be used (if it is an ingredient)
- Indication of whether the traditional food is intended to replace another food
- The proposed maximum amount(s) and concentration(s) of use in the final product(s)
- Where appropriate, the proposed daily intake for different age and gender groups

### **Intended role in the diet**

If a traditional food is to replace another food in Switzerland, it should be demonstrated that it does not differ from that food in a way that would be nutritionally disadvantageous to the consumer.

### **Precautionary measures and restrictions on use**

If precautions and restrictions on use are proposed, all available information on safety should be taken into account.

The applicant should specify the population (sub)groups (including populations with specific physiological conditions) that should avoid consumption of the traditional food and give reasons for this. The applicant should also specify any other restrictions on use and precautions relating to the handling, preparation and consumption of the traditional food.

Any effects of possible excessive consumption on the population or population groups should be described.

## **7. Conclusions**

The information on the composition and experience of use (continuous over 25 years in the country of origin) must be summarised here. A brief overall assessment must also be provided of how the composition and experience of use demonstrate the safe use of the traditional food in the past and how this relates to the proposed conditions of use on the Swiss market.

If potential health risks have been identified on the basis of the composition and/or data from experience of use, these must be discussed.

## **8. Annexes to the dossier**

All documents enclosed must be clearly labelled, clearly referenced in the report at the appropriate place and listed in an appendix overview by chapter.