



Information sheet 1

Evaluation of novel food status within the framework of self-monitoring

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Introduction

As part of their self-monitoring, distributors must document how they have determined the novel food (NF) status of a foodstuff. The information sheet provides a decision tree and clarifications on the individual questions that distributors can use as a guide to determine the NF status of a foodstuff.

The information sheet explains the order in which, where, how and in which documents information regarding NF status can be obtained. It is a supporting document and not a requirement. This document does not replace documented self-monitoring, but merely helps to ask the right questions regarding clarifications about NF status and is therefore intended as a guide.

There are no requirements regarding the form of documentation for determining the NF status as part of self-monitoring. Distributors must document their research in such a way that it can be presented to the cantonal enforcement authority upon request. The documents must be comprehensible with regard to the conclusion on the NF status.

The appendix to the [application form](#) and [Information Sheet 2](#) “Supporting document for correctly completing the application form for the authorisation of novel and traditional Novel Foods in accordance with Article 16 of the Ordinance on Food and Utility Articles” can be used as a guide to structure the research in a clear and comprehensible manner.

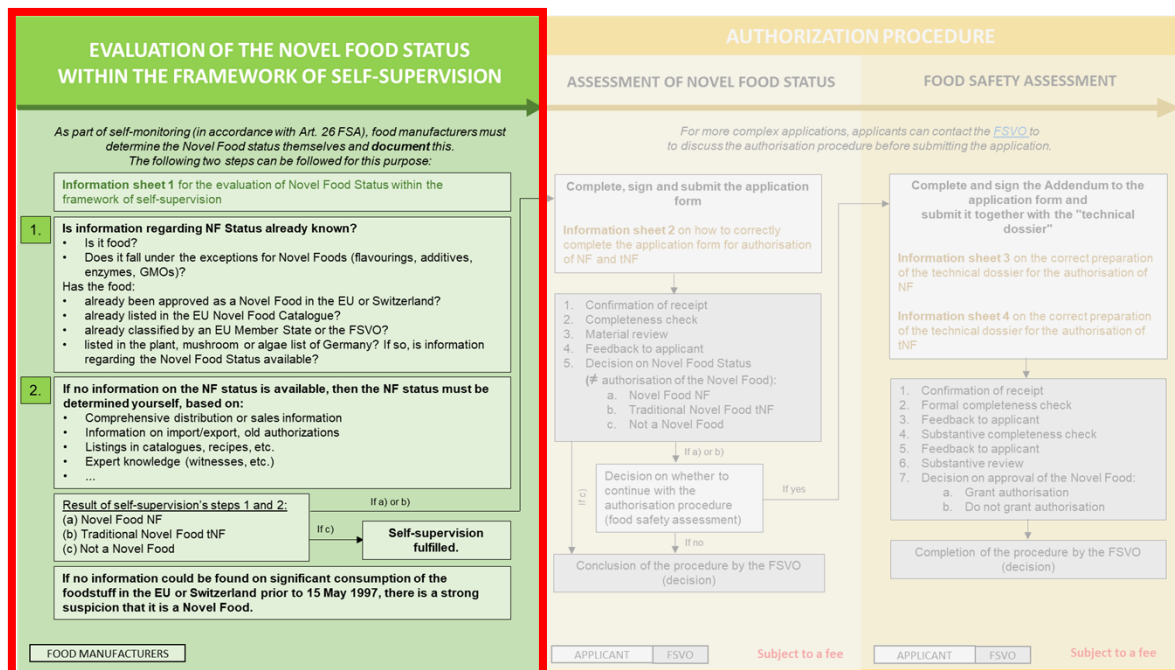


Figure 1 Process for the authorisation of novel foods in accordance with the ‘Diagram of the authorisation procedure for novel foods’ ([link](#)). This information sheet serves as an aid for evaluating novel food status within the framework of self-monitoring (see red box).

A. Decision tree – Overview

The decision tree in Figure 2 provides an overview of the most relevant questions relating to the evaluation of NF status in the context of self-monitoring. [Sections B](#), [C](#) and [D](#) then explain the questions listed in the decision tree.

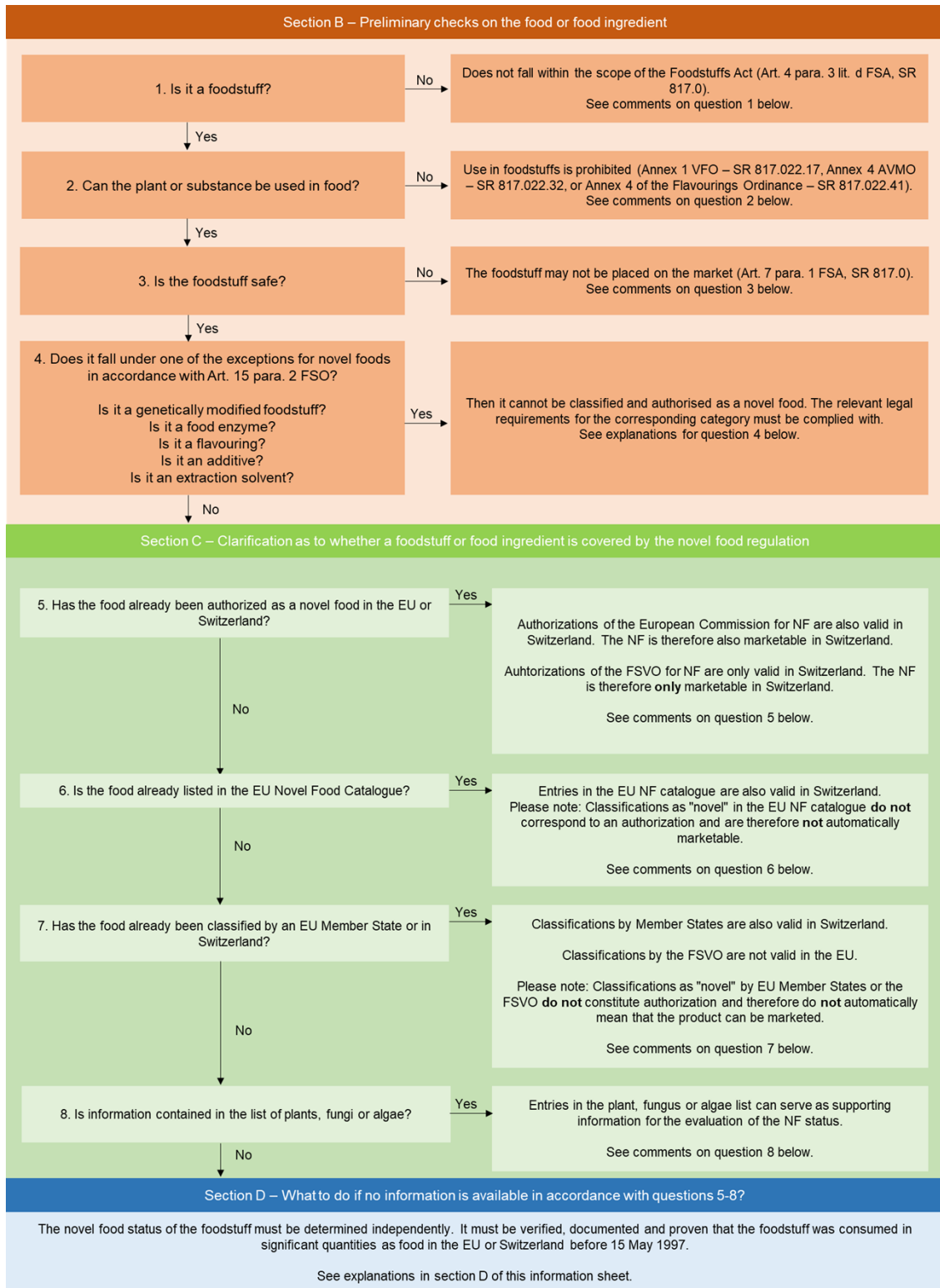


Figure 2 Decision tree with the most important questions that may be helpful in evaluating NF status as part of self-monitoring. Each question is then explained in [sections B](#), [C](#) and [D](#) of this information sheet.

B. Preliminary checks regarding the food or food ingredient

1. Is it a foodstuff?

The requirements for NF only apply to foodstuffs. These are defined in the Foodstuffs Act ([FSA](#), SR 817.0) in [Article 4, paragraphs 1 and 2](#).

Substances that are not foodstuffs according to [Art. 4 para. 3](#) FSA cannot be assessed as NF. These include medicinal products, narcotics and psychotropic substances.

Some substances are toxicologically harmful or have a pharmacological effect that, according to the legal definition, is reserved exclusively for medicinal products. Such substances may not be used in foodstuffs (Art. 2 para. 4 lit. d FSA). Such products cannot therefore be classified as NF, as they are not foodstuffs.

Support in distinguishing between medicinal products and foodstuffs can be found on the following website: [Differentiation criteria](#)

Information on narcotics and psychotropic substances can be found here: [Das Betäubungsmittelgesetz](#) (available in German, French and Italian) and [Federal Act on Narcotics and Psychotropic Substances](#) (NarcA, SR 812.121).

2. Plants, plant parts or preparations thereof that are prohibited in foodstuffs and substances that may not be added to foodstuffs

Swiss law prohibits the use of certain products in foodstuffs. These products may therefore not be used in the preparation and manufacture of foodstuffs, regardless of their NF status.

Examples:

- Prohibited plants: [Annex 1](#) of the FDHA Ordinance on Foodstuffs of plant Origin, Fungi and Table Salt (VFO SR 817.022.17 – *available in German, French and Italian*): List of plants and parts of plants, as well as preparations and substances produced from them, whose use in foodstuffs is not permitted
- Prohibited substances:
 - [Annex 4](#) to the FDHA Ordinance on the Addition of Vitamins, Minerals and other Substances to Foodstuffs (AVMO, SR 817.022.32 – *available in German, French and Italian*): substances that may not be added to foodstuffs
 - [Annex 4, Section 1](#) of the FDHA Ordinance on Flavourings and Food Ingredients with Flavouring Properties in or on Foodstuffs (Flavourings Ordinance, SR 817.022.41 – *available in German, French and Italian*)

3. Foodstuffs or food ingredients that are not safe.

If the product clearly contains critical ingredients that could be relevant to food safety, this issue must be addressed before the NF status is evaluated.

Certain botanicals in foodstuffs may pose a safety risk. Plants that contain pharmacologically active substances, exhibit toxic properties in the dosages used, may have side effects or are not suitable for certain consumers (contraindications) are particularly problematic. The production and dosage are also particularly relevant for the assessment of botanicals as food or food ingredients. For example, extracts can vary considerably in their composition and nutritional, pharmacological and toxicological properties depending on the manufacturing process and the extraction agents used.

A search in the [EFSA Database](#) could also help to find out whether the EFSA has already carried out a scientific assessment of a particular substance or product.

4. Does the foodstuff fall under one of the exceptions for novel foods?

According to [Art. 15 para. 2](#) of the Ordinance on Foodstuffs and Utility Articles ([FSO](#), SR 817.02 – *available in German, French and Italian*), the following foodstuffs are **not** considered NF:

1. Genetically modified foodstuffs (the requirements set out in [Section 6](#) of the FSO and the FDHA Ordinance on Genetically Modified Foodstuffs ([GMFO](#), SR 817.022.51 – *available in German, French and Italian*) apply here)
2. Food enzymes (the requirements of the FDHA Ordinance on Technical Procedures and Technical Auxiliaries for the Treatment of Foodstuffs ([TPAFO](#), SR 817.022.42 – *available in German, French and Italian*) apply here)
3. Additives (the requirements of the FDHA Ordinance on Additives permitted in Foodstuffs ([FoodAO](#), SR 817.022.31 – *available in German, French and Italian*) apply here)
4. Flavourings (FDHA Ordinance on Flavourings and Food Ingredients with Flavouring Properties in or on Foodstuffs ([Flavourings Ordinance](#), SR 817.022.41) apply here)
5. Extraction solvents (the requirements of the FDHA Ordinance on Technical Procedures and Technical Auxiliaries for the Treatment of Foodstuffs ([TPAFO](#), SR 817.022.42 – *available in German, French and Italian*) apply here)

C. Clarification as to whether a foodstuff or food ingredient is covered by the novel food regulation

5. Has the food already been authorized as a novel food in the EU or Switzerland?

a. Union list in the EU

Foodstuffs that fall under the definition of NF in the EU and have been authorized by the EU Commission are listed in the [EU Commission's Union list](#). This consists of two tables:

- I. **Table I "Authorized novel foods"** contains all authorized NFs in the EU and also includes the conditions under which the NF may be used. This table also specifies maximum levels and specific labelling requirements, among other things.
- II. **Table II "Specifications"** contains the specifications for each NF. If the product currently being evaluated for its NF status does not exactly match the specification, it will not be authorized.

Both tables must be checked to obtain information about the authorized NF.

If a foodstuff has been approved as an NF in the EU, it is marketable in both the EU and Switzerland. However, the relevant specifications must be complied with.

As the Union list is only updated 3 to 4 times a year, it is not always up to date. The fact that a foodstuff is not listed in the Union list does not therefore mean that the foodstuff is not novel or has not been authorized.

The FSVO therefore supplements the Union list by listing all novel foods approved in the EU with the corresponding implementing regulation (authorization) ([link](#)).

Please note

- Applicants in the EU can apply for a data protection clause for scientific studies submitted and conducted as part of the NF authorisation procedure. Whether the EU Commission has granted the application for data protection is recorded in the relevant implementing regulation and in the Union list. In this case, the NF can only be placed on the market by the applicant for 5 years.

b. Switzerland: Authorizations by the FSVO

The FSVO can also authorize novel foods as part of an authorization procedure in accordance with [Art. 17](#) FSO. These are listed on the FSVO website. The FSVO maintains a [list](#) of submitted applications and their status, as well as a [list](#) of classified and (depending on the status of the procedure) authorized NF or tNF in Switzerland.

Please note

- Authorizations granted in Switzerland for NF are not valid in the EU. Authorisation from the European Commission is still required.
- [The annex](#) to the FDHA Ordinance on Novel Foods (SR 817.022.2) lists foods that may be placed on the market without further authorisation from the FSVO.

Has the food not yet been authorized as a novel food in the EU or Switzerland? If so, question 6 should be considered.

6. Is the food already listed in the EU Novel Food Catalogue?



The [Novel Food Catalogue](#) is a non-exhaustive list of foods of animal and plant origin, algae species, food cultures and other substances whose NF status has been determined. It is a non-binding document that serves as a guide to whether a product requires authorization under the NF Regulation.

The foods listed in the EU Novel Food Catalogue are arranged alphabetically. A search engine helps with the search. For each application, the name (scientific name for animals, plants, algae and fungi), description, update date and classification can be found. The catalogue is only available in English.

The screenshot shows the EU Novel Food Catalogue interface. At the top, there is a navigation bar with letters A through Z and 'ALL'. Below this is a search bar containing 'Dimorphandra mollis Benth.' with a 'Clear' button. To the left of the search bar is a list of search results. Four arrows point to specific parts of the entry: a red arrow points to the 'Name' field, a yellow arrow points to the 'Description' field, a blue arrow points to the 'Classification' field, and a green arrow points to the 'Update' date field. The 'Update' field shows 'Latest update: 30/01/2025'. The 'Description' field contains text about the use of Dimorphandra mollis Benth. and quercetin extraction. The 'Classification' field shows a 'NOVEL FOOD' status with a red 'X' icon and a detailed explanation of why pre-market authorization is required.

Figure 3 Excerpt from the EU Novel Food Catalogue for an example product. The arrows indicate the most important information for the entry: name of the food/substance (red), description of the food to which the entry refers (yellow), classification (blue) and update date (green).

Several assessments are possible for classification:

Symbol		Meaning
	NOT NOVEL IN FOOD	Not novel: Food is not subject to the Novel Food authorisation procedure
	NOT NOVEL IN FOOD SUPPLEMENTS	Not novel in food supplements: Food may be used in food supplements, but the NF status for use in non-food supplements must be further clarified <i>See section "Please note" below</i>




	NOVEL FOOD	Food is novel and subject to authorization
	AUTHORISED NOVEL FOOD	The food is novel , but has already been authorized in the EU (see question 3).
	SUBJECT TO A CONSULTATION REQUEST	A novel food status determination is ongoing or has been completed in a Member State (see question 5).

Table 1 Key for the classifications used in the EU Novel Food Catalogue.

Although the EU Novel Food Catalogue is not legally binding, it is considered a strong indicator when evaluating the novel food status of a foodstuff. The Novel Food Catalogue is updated regularly and is also used as strong evidence in court decisions.

However, the following must also be noted:

- Swiss law takes precedence. This means that if Swiss legislation prohibits the use of certain substances in foodstuffs, these substances may not be used in foodstuffs, even if they are classified as "not novel" in the EU Novel Food Catalogue. Examples:
 - Melatonin is prohibited under Art. 2 para. 4 and [Annex 4](#) of the FDHA Ordinance on the Addition of Vitamins, Minerals and other Substances to Foodstuffs (AVMO, SR 817.022.32).
 - Extracts from the seeds of the plant *Griffonia simplicifolia* are prohibited under Art. 3 and [Annex 1](#) of the VFO; this also applies to 5-HTP produced from these extracts.

An entry in the Novel Food Catalogue does not constitute authorization of the foodstuff.

Please note:

- If a plant, fungus or algae is classified as non-novel in foodstuffs or food supplements, this classification does not apply to extracts obtained from it. If, for example, components are isolated or purified by means of extraction processes for the production of a foodstuff, the composition of the products no longer corresponds to their natural composition.
 - However, according to the unanimous opinion of the EU Member States, the same status applies to non-concentrated aqueous extracts from non-novel foods for use as tea.
 - In the case of alcoholic extractions – even if the extraction process is conventional – a shift in the proportions of the plant's substances is usually unavoidable, which in principle means that the novel food status must be determined for each individual extract.
- If parts of plants or fungi are classified as non-novel, this classification does not automatically apply to all or other parts of the plants and fungi. Different parts of plants and fungi can vary considerably in terms of their composition.

- Even in the case of preparations made from plants, fungi and algae that are classified as non-novel, the novel food status cannot be transferred to other preparations made from them, as these may also differ significantly in their composition.
- If parts of plants, fungi or algae or preparations are classified as non-novel only for specific food categories, the status does not automatically apply to all food categories and manufacturing methods.
- In the case of classifications as "not novel in food supplements", it is still necessary to check in what form parts of plants, fungi or algae or preparations were placed on the market in food supplements before 1997. The classification "not novel in food supplements" does not mean that all preparations are not novel as food supplements.
- The fact that a foodstuff is not listed in the NF catalogue does not mean that the food is not novel. If it is not in the catalogue, the clarification of the novel food status must be continued. Furthermore, entry in the EU Novel Food Status Catalogue does not constitute authorization of the food. It only provides an indication of the novel food status of the food in the EU.
- In principle, EU classifications also apply in Switzerland, unless it can be proven that a foodstuff was used for human consumption to a significant extent in Switzerland (as opposed to an EU Member State) before 15 May 1997. In this case, the foodstuff may be considered non-novel in Switzerland, unlike in the EU.

Is the food not listed in the EU Novel Food Catalogue? Then question 7 should be considered.

7. Has the foodstuff already been classified by an EU Member State or in Switzerland?

Although the EU Novel Food Catalogue is continuously updated, the classifications of individual Member States may not be included in the catalogue. It is therefore worth checking whether a particular food has already been classified by a Member State.

The database can be found here: [Consultation process on novel food status – European Commission](#)

Consultation process on novel food status

PAGE CONTENTS						
Search		Name and description of the food concerned	Date of publication	Statement on the food concerned	Reasons justifying the statement	Where the food is novel, the most appropriate food category under which it falls in accordance with Article 3(2) of Regulation (EU) 2015/2283
A		A				
B						
C						
D						
E						
F						
G						
H						
I		A plant protein concentrate that is fermented with the mycelium of shiitake (<i>Lentinus edodes</i>).	25 February 2019	Classification	View document	Category 3(2)(a)(ii)
K		Agaricus blazei dehydrated mycelium powder	29 October 2019	Novel Food	View NF Category	Category 3(2)(a)(ii)
L						
M						
N						
O						
Q	Name	Albizia julibrissin Durazz. - flowers	8 August 2019	Novel Food	View document	Category 3(2)(a)(iv)

Figure 4 Excerpt from the database. The arrows indicate the most important information for using the database: search function for foods listed alphabetically (red), name of the classified food/substance (blue), link to the document explaining the classification (yellow), and reference to the category under which the novel food falls (green).

Please note:

- The fact that the NF status of a foodstuff has not been determined by an EU Member State does not mean that the foodstuff is not novel. If it is not included in the list, the clarification of the NF status must be continued.
- Classifications do not always include specifications. It is therefore necessary to continue to check whether a particular product falls under the published classification or not.
- A classification by a Member State does not constitute an authorization of the foodstuff.

The FSVO has the authority to determine the novel food status of a foodstuff. Like the FSVO's novel food authorizations, this classification is only valid in Switzerland.

It should be checked whether an application for a specific product has already been submitted to the FSVO and whether the FSVO has already carried out a classification for a product ([list of applications submitted to the FSVO](#) and the [FSVO NF Catalogue](#)).

Has the foodstuff already been classified by an EU Member State or the FSVO? If not, question 8 should be considered.

8. Is the food listed in the plant, mushroom or algae list of Germany? If so, is information regarding the novel food status available?

The [substance lists of the federal government and the federal states](#) facilitate the classification of plants and plant parts, fungi and algae as food or food ingredients. They also simplify the delimitation from medicinal products.

These lists of substances serve as **a guide** in Germany, Austria and Switzerland for the assessment of plants and plant parts, fungi and algae as food or food ingredients. If information regarding their use as food is known, this has been recorded in the list accordingly. This information can help in the evaluation of novel food status. More information on the use and interpretation of the substance lists can be found in the foreword to the substance lists and in information letter 2021/4.1.

It is possible that individual classifications in Switzerland may differ from the substance lists. This applies in particular to the prohibition lists in [Annex 1 VFO](#), the classification as a novel food and the delimitation from narcotics and medicinal products acts. In any case, the relevant legal provisions of Switzerland are decisive.

Here are the most important links:

- I. [FSVO website substance lists](#)
- II. [Foreword to the list of substances](#)
- III. [Plant list A-K](#), [plant list L-Z](#), [mushroom list](#) and [algae list](#)
- IV. [Information letter 2021/4.1](#) (available only in German, French and Italian) Use of "substances" in the categories plants, fungi, lichens and algae, as well as preparations made from them, as foodstuffs or food ingredients. *This information letter describes the assessment of substances*

within the framework of self-monitoring (see in particular chapters 4 and 5 of the information letter) and recommends the substance lists (plant, mushroom and algae lists) from Germany as a guide for the assessment of "substances".

- V. [Information letter 2020/2.1](#) (available only in German, French and Italian) Marketability of fungi as foodstuffs

Please note:

- The substance lists from Germany serve as guidance for the assessment of "substances" as food or food ingredients. These substance lists are not legally binding and do not claim to be exhaustive. They are updated periodically to reflect new scientific findings and market developments. They serve as supporting information in the novel food status question.
- A decision tree in the foreword to the substance lists serves as the basis for classifying "substances". This can also be used to classify other "substances" that are not included in the lists. In individual cases, it must be checked whether the classification of a "substance" can be transferred to a preparation made from it. In particular, the classification of a "substance" with regard to its novel food status is not applicable to extracts obtained from it.
- References to country lists of EU Member States are elements that can be taken into account as supporting information when assessing novel food status. However, these alone do not provide sufficient evidence of significant consumption in food supplements prior to 15 May 1997 and are not sufficient for classification of NF status.
- Notification in an EU Member State does not mean that the novel food status has been assessed by the authority. In Belgium, for example, only in certain cases does the notification require the submission of evidence for the evaluation of novel food status so that it can be assessed. Nevertheless, proof of whether or not these products are novel must be provided at the latest during the inspection by the enforcement authorities. The fact that a product has been notified and the plant is listed in the positive list is therefore not sufficient to prove novel food status in the context of self-monitoring.
- If no information can be found in the substance lists of the federal government and the federal states, the clarification of novel food status must be continued.

Is there no information on the foodstuff in the substance lists? Then section D should be taken into account.

D. What to do if no information is available according to questions 5-8?

If there is no clear information regarding the NF status of a food or ingredient in the above-mentioned documents ([questions 5-8, section C](#)), the NF status must be clarified independently and comprehensively by the person placing the food on the market as part of their self-monitoring and documented accordingly.

The correct classification of substances is becoming increasingly complex and poses a major challenge for manufacturers, distributors, authorities and consumers alike. **A final assessment of products must always be made on a case-by-case basis**, taking into account all relevant and available criteria. These include, for example, the manufacture and dosage of a substance. Different manufacturing processes or extraction agents can result in significant differences in the composition of preparations (e.g. extracts) and their nutritional, pharmacological and toxicological properties.

Research must be carried out to determine whether the foodstuff was consumed **by humans to a significant extent** in the EU or Switzerland **before 15 May 1997**.

This section is available to distributors for this purpose, based on the provisions of [Commission Implementing Regulation \(EU\) 2018/456 of 19 March 2018 on the procedural steps of the consultation process for determination of novel food status in accordance with Regulation \(EU\) 2015/2283 of the European Parliament and of the Council on novel foods](#). This includes questions for clarifying the history of consumption as food, analogous to the EU document "[Human Consumption to a Significant Degree](#)".

The following criteria must be taken into account in order to determine whether a food is to be classified as novel:

- Firstly, there must be a **history of use as a foodstuff** in the EU or Switzerland prior to 15 May 1997.
- The **use** must have been significant, as determined by factors such as widespread and general distribution within an EU country or Switzerland, continuous market presence and integration into local or regional traditions.
- The **amount of food used** and the **type of use** (e.g. as part of a normal diet or only on certain occasions) are also important considerations.
- **The way in which the food is available on the market** (e.g. in normal food shops or only in pharmacies) and the duration of availability are also important.
- Changes in **composition** due to different manufacturing conditions must therefore also be taken into account. In the case of extracts, it must be ensured that the evidence relates to precisely this extract: this means that the manufacture, composition and concentration of the ingredients, the consumption pattern (e.g. comparable amount in a food supplement), etc. must be the same.
- Not only the sales, but also the **geographical and temporal availability** of the food prior to 1997 must be ascertained during the assessment. If a food was sold, this does not necessarily mean that it was available in significant quantities and consumed.

Robust and reliable information from documented sources is required to assess novel food status. This includes details about

- the food itself, such as its composition, origin, processing and intended conditions of use
- evidence of its use as a food before 15 May 1997 (in the form of sales data, invoices, recipes, cookbooks, catalogues and other relevant documents, see table below)

In the case of extracts, it must be ensured that the evidence relates to the identical or comparable extract: this means that the composition, concentration of ingredients, consumption pattern, etc. must be the same.

Type of evidence of its use as a foodstuff before 15 May 1997	Possible weighting	
Comprehensive distribution information	Invoices, etc. with detailed information on the sale of foodstuffs, including evidence of large quantities sold in the EU or Switzerland	Good evidence if the purpose (food use) is stated
Sales information	Invoices, etc., detailing the sale of food	Good evidence if the purpose (food use) is stated
Information on import/export by the government/authority	Official documents	Supporting evidence if the purpose (food use) is stated
Sales information	Catalogues, sales brochures	Supporting evidence if the purpose (food use) is stated
Consultation with the food business operator or relevant associations	Reports, internal information	Supporting evidence
Listed in recognised catalogues/documents		Supporting evidence
Expert knowledge	Personal testimonials	Supporting evidence
Supporting information	Articles in journals and magazines, cookery and recipe books, purchase receipts, etc.	Supporting evidence
Old legal texts	Legal regulations Old positive lists of foods in Switzerland and in EU member states	Supporting evidence (Information on whether certain foods or substances have already been on the market for human consumption)
Documents at the Federal Archives (BAR)	Business-related documents from the Federal Administration (old permits or information sheets)	Supporting evidence in case of doubt Support from the new chatbot of the Swiss Federal Archives. Possibility of providing certain documents in digital form
Other		

Traditional novel foods

Foods that have a history of safe consumption in a third country (outside Switzerland and the EU) over the last 25 years may be considered novel traditional foods. The history of consumption must also be comprehensive, traceable and verifiable by means of concrete evidence. Sales data, literature sources, authorizations in a third country, expert knowledge, etc. should also clearly demonstrate consumption in the third country over the last 25 years.

The most important thing you need to prove is the proven safe use of this food in the third country. Specifically, you need evidence that demonstrates the following:

- History of use: The food must have been safely used in the third country for at least 25 years as part of the normal diet of a significant number of people.
- Evidence of safe use:
 - Composition data: Information on the composition of the traditional food.
 - Conditions of use: The typical conditions under which it is consumed (e.g. processing, quantity, frequency).
 - Experience in the third country: Credible, scientifically sound data and evidence demonstrating safe use over the last 25 years. This includes, for example:
 - Publications in scientific literature.
 - Reports or data from research institutes.
 - Statistical data on consumption.
 - Information on production and sales.
 - No reports of adverse health effects.
- Manufacturing process: It must be demonstrated that the characteristics of the food have not been significantly altered by the manufacturing process (insofar as it differs from that traditionally used in the third country) and that no additional safety concerns arise.
- Comparison with another food: Where appropriate, comparison with a food already on the market and if the food has a similar structure or composition.