**Part A: Consultation process**

**Document checklist for classification of Novel Food status**

This checklist sets out all the information required to establish the Novel Food status of a novel foodstuff or novel traditional foodstuff. It supplements the application form, which must always be completed in full, signed and returned.

This checklist can be used:

* for consultation process requests for determining whether an as yet unclassified foodstuff or an ingredient is a novel foodstuff or novel traditional foodstuff in cases where the FSVO is being asked to establish or confirm Novel Food status;
* as an aid to independently establishing the Novel Food status of a foodstuff or ingredient as a novel foodstuff or novel traditional foodstuff under the legal obligation to ensure self-supervision in accordance with Art. 26 of the Foodstuffs Act (FoodA; SR 817.0).

Please note that you are only required to request a consultation process to establish the Novel Food status of a product in accordance with this checklist if the product is not listed in the Novel Food Catalogue of the European Union (EU) and it has not been officially classified by either the EU or Switzerland. If a request for a consultation process for a foodstuff or ingredient is submitted to the FSVO in accordance with this checklist, all relevant information must be provided and documented.

At the start of each section of this checklist is a paragraph in italics that lists the products (e.g. foodstuffs, extracts, substances, etc. consisting of or manufactured from animal, plant, micro-organism, fungus, algae, material, etc.) for which the section in question has to be completed.

The information and diagrams can be inserted straight into this checklist at the appropriate places. However, you can also insert references to documents and reports in the checklist and enclose the documents and reports separately. Additional information and documents for which the checklist makes no provision, but which may be helpful for classification, should also be listed in this checklist or enclosed with the consultation process request in accordance with this checklist.

This checklist is based largely on [Commission Implementing Regulation (EU) 2018/456](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0456&from=DE) 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 and has been adapted to Swiss requirements. Section 5 of this checklist contains additional questions to help determine the history of consumption for the product, similarly to the EU document «[Human Consumption to a Significant Degree](https://ec.europa.eu/food/system/files/2018-07/novel-food_leg_guide_humn-consumption.pdf)».

**Note:**

* **A separate checklist and application form for novel foodstuffs or application form for novel traditional foodstuffs must be submitted for each product.**
* **All information and documents must refer to the same foodstuff/identical substance manufactured in the same way.**

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

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| **Documents to be submitted for classification by the FSVO** |
| Fully completed application form with handwritten signature.   * **A separate application form must be submitted for each product.** * **The application form must be submitted by post.** |
| Dossier with conclusions, 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.**   **The sections to be submitted/completed are:**   * **For all foodstuffs**: numbers 1 to 7 (= section 1) must be completed in full; * **with the exception of**:   + foodstuffs obtained **by means of a “novel” manufacturing process**, i.e. a process that was not used for food production in Switzerland and/or the European Union prior to 15 May 1997 (Art. 15 let. g and i no. 1 [Foodstuffs and Utility Articles Ordinance (FUAO; SR 817.02)](https://www.admin.ch/opc/de/classified-compilation/20143388/index.html)), in which case numbers 1 to 3 and number 7 of section 1 and number 9 (section 3) have to be completed in full. * For **extracts**, numbers 1 to 7 (= section 1) and number 8 (= section 2) must be completed in full. * For **novel traditional foods (tNF)**, numbers 1 to 7 (= section 1) and number 10 (= section 4) must be completed in full. |
| Enclosures to support information in the dossier (originals)   * **These documents can be submitted by post or electronically.** |

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| **Dossier** |

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| **Section 1 (numbers 1–7):**   * *This section must be completed in full for:*    + ***all*** *foodstuffs and substances;*   + *only numbers 1 to 3 and number 7 for foodstuffs obtained by means of a “novel” manufacturing process.* |
| 1. **Description of the foodstuff** |
| **1.1.** Name of the foodstuff |
| Click or start typing here to enter text. |
| * 1. Detailed description of the foodstuff.   Please also provide information on whether the foodstuff consists of engineered nanomaterials as referred to in Article 2 paragraph 1 number 30 [FUAO](https://www.admin.ch/opc/de/classified-compilation/20143388/index.html)**.** |
| Click or start typing here to enter text. |
| **1.3.** Proposed category of the novel foodstuff in accordance with Article 15 para. 1 FUAO.  **Note:**  If the category “Art. 15 para. 1 let. k FUAO: novel traditional food” is ticked, one of the categories of Art. 15 para. 1 let. b, d, e and f FUAO must also be ticked.  Foodstuff with new or specifically modified molecular structure (Art. 15 para. 1 let. a FUAO)  Foodstuff manufactured from or with or isolated from microorganisms, fungi or algae (Art. 15 para.1 let. b FUAO)  Foodstuff manufactured from or with or isolated from materials of mineral origin (Art. 15 para.1 let. c FUAO)  Foodstuff manufactured from or with or isolated from plants or parts of plants (Art. 15 para.1 let. d FUAO)  Foodstuff manufactured from or with or isolated from animals or parts of animals (Art. 15 para.1 let. e FUAO)  Foodstuff manufactured from or with or isolated from cell or tissue cultures of animals, plants, microorganisms, fungi or algae (Art. 15 para.1 let. f FUAO)  Foodstuff manufactured using a process that was not conventionally used prior to 15 May 1997 (Art. 15 para.1 let. g FUAO)  Foodstuff manufactured from engineered nanomaterials (Art. 15 para. 1 let. h FUAO)  Vitamins, minerals and other substances from cell or tissue cultures of animals, plants, microorganisms, fungi or algae or which contain or consist of engineered nanomaterials (Art. 15 para.1 let. i FUAO)  Prior to 15 May 1997, foodstuff was used exclusively in food supplements and will now be used in other foodstuffs than just these (Art. 15 para.1 let. j FUAO)  Novel traditional food (Art. 15 para. 1 let. k FUAO), wi**th additional cross by the applicable category of** Art. 15 para. 1 let. b, d, e or f (above). |
| **1.4. Current classification of identical foodstuff/substance** |
| **In the EU:** |
| |  |  |  |  | | --- | --- | --- | --- | | Not novel (not NF) | Not novel in/as food supplement(s) (FS) | | Not yet classified | | Novel (NF)  For the food category | | Please specify | All |   Comments (optional)  Click or start typing here to enter text.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **In Switzerland:** | | | | | | Not novel (not NF) | Not novel in/as food supplement(s) (FS) | | Not yet classified | | Novel (NF)  For the food category | | Please specify | All |   Comments (optional)  Click or start typing here to enter text |
| **2. Further characterisation of the foodstuff and/or source of the foodstuff (where relevant)** |
| **A. Organisms (microorganisms, fungi, algae, plants, animals)**   * *This section must be completed in full for**foodstuffs consisting of, obtained from or isolated from microorganisms, fungi, algae, plants or animals.* |
| **2.1.** Taxonomic name (full Latin name with author name) |
| Click or start typing here to enter text. |
| **2.2.** Synonyms, other names, where applicable |
| Click or start typing here to enter text. |
| **2.3.** Where relevant, specify precisely which part of the microorganisms, fungi, algae, plants or animals the use for consumption by humans in Switzerland or the European Union before 15 May 1997 refers to |
| Click or start typing here to enter text. |
| **2.4** Specification regarding purity/concentration |
| Click or start typing here to enter text. |
| **B. Chemical substances**   * *This section only needs to be completed in full for chemical substances.* |
| **2.5.** CAS number(s) (if attributed) |
| Click or start typing here to enter text. |
| **2.6.** Chemical name(s) according to IUPAC nomenclature rules |
| Click or start typing here to enter text. |
| **2.7.** Synonyms, trade name, common name, where applicable |
| Click or start typing here to enter text. |
| **2.8.** Molecular and structural formulae |
| Click or start typing here to enter text. |
| **2.9.** Specification regarding purity/concentration |
| Click or start typing here to enter text. |
| **3. Conditions of use**   * *This section must be completed in full for* ***all*** *foodstuffs and substances.* |
| **3.1.** How is the foodstuff intended to be used? |
| Click or start typing here to enter text. |
| **3.2.** Type of product(s) in which the foodstuff is intended to be used |
| Click or start typing here to enter text. |
| **3.3.** Level/concentration (or range of levels) in the product(s) in which the foodstuff is intended to be used |
| Click or start typing here to enter text. |
| **4. Production process**   * *This section must be completed in full for* ***all*** *foodstuffs and substances* ***except*** *foodstuffs obtained using a “novel” manufacturing process.* |
| **4.1.** Detailed description of the production process. Include a process flow chart to describe the production process. |
| Click or start typing here to enter text. |
| **5. Current consumption of the foodstuff in Switzerland and/or the European Union prior to 15 May 1997**  **Not relevant: exclusive use e.g. as a food additive, flavouring, non-food uses such as medicinal products, cosmetics, etc.**   * *This section must always be completed in full for all foodstuffs, substances and extracts* ***except*** *foodstuffs obtained using a “novel” manufacturing process. Please comment on any points that do not apply to the product.* * ***The searches carried out and methodological approaches used (what words were used to search what sources) must always be disclosed even if the results were negative. The information and documents must be drawn from different sources to permit inferences to be drawn.*** |
| **5.1.** To what extent was the foodstuff consumed to a significant degree **throughout Switzerland and/or the European Union** (EU) before 15 May 1997? Details should be provided. |
| Data available:  Yes (see enclosed explanations and documented searches)  No  No information available on this point (see enclosed documented searches)  Supplementary information:  It was consumed as a normal part of the diet  Evidence (see below for explanations)  Click or start typing here to enter text.  It was available for purchase in Switzerland and/or the EU, particularly in nationwide food stores  Evidence (see below for explanations)  Click or start typing here to enter text.  It has been consumed for a long period of time  Evidence (see below for explanations)  Click or start typing here to enter text.  It has been consumed in quantities typical for similar products in the specific food category  Evidence (see below for explanations)  Click or start typing here to enter text.  Supplementary information  Click or start typing here to enter text. |
| **5.2.** To what extent was the foodstuff consumed to a significant degree **throughout Switzerland and/or one Member State of the EU** before 15 May 1997? Details should be provided. |
| Data available:  Yes (see enclosed explanations and documented searches)  No  No information available on this point (see enclosed documented searches)  Supplementary information:  It was consumed as a normal part of the diet  Evidence (see below for explanations)  Click or start typing here to enter text.  It was available for purchase in Switzerland and/or the EU, particularly in food stores  Evidence (see below for explanations)  Click or start typing here to enter text.  It has been consumed for a long period of time  Evidence (see below for explanations)  Click or start typing here to enter text.  It has been consumed in quantities typical for similar products in the specific food category  Evidence (see below for explanations)  Click or start typing here to enter text.  Supplementary information  Click or start typing here to enter text. |
| **5.3.** Was the foodstuff consumed **only regionally/on a small local scale** in Switzerland and/or the European Union before 15 May 1997? Details should be provided. |
| Data available:  Yes (see enclosed explanations and documented searches)  No  No information available on this point (see enclosed documented searches)  Supplementary information  It was consumed as a normal part of the diet  Evidence (see below for explanations)  Click or start typing here to enter text.  It could be purchased **regionally/locally** in Switzerland and/or the EU, primarily in food stores (not only in pharmacies, health shops or specific restaurants, etc.)  Which region/locality  Click or start typing here to enter text.  Evidence (see below for explanations)  Click or start typing here to enter text.  It has been consumed for a long period of time  Evidence (see below for explanations)  Click or start typing here to enter text.  It has been consumed in quantities typical for similar products in the specific food category  Evidence (see below for explanations)  Click or start typing here to enter text.  Supplementary information  Click or start typing here to enter text. |
| **5.4.** Was the foodstuff available before 15 May 1997 in Switzerland and/or the European Union **as an ingredient designed for a specific target population** (e.g. foodstuff for a special medical purpose, foodstuff for athletes, food supplements)? Details should be provided. |
| Data available:  Yes (see enclosed explanations and documented searches)  No  No information available on this point (see enclosed documented searches)  Supplementary information:  Target population group  Click or start typing here to enter text.  Evidence (see below for explanations)  Click or start typing here to enter text.  It was on the market in Switzerland and/or the EU and was available for the target group(s) to purchase  Evidence (see below for explanations)  Click or start typing here to enter text.  Use was restricted to individuals with an underlying medical condition  Evidence (see below for explanations)  Click or start typing here to enter text.  It was used in food supplements only. (If yes: Only relevant for use in food supplements. Authorisation for use in other foodstuffs required)  Evidence  Click or start typing here to enter text.  Supplementary information  Click or start typing here to enter text. |
| **Explanations of evidence:**   |  |  |  | | --- | --- | --- | | Type of evidence | | Possible weighting | | Comprehensive sales information | Invoices, etc. detailing sales of foodstuff, including evidence of large-volume sales in the EU | Good evidence if purpose (foodstuff use) is indicated | | Sales information | Invoices, etc. detailing sales of foodstuff | Good evidence if purpose (foodstuff use) is indicated | | Government/official import/export information | Official documents | Supporting evidence if purpose (foodstuff use) is indicated | | Sales information | Catalogues, sales brochures. | Supporting evidence if purpose (foodstuff use) is indicated | | Listed in recognised catalogues/ documents |  | Supporting evidence | | Expert knowledge | Personal testimonies | Supporting evidence | | Supporting information | Magazine articles, recipe books, sales receipts, etc. | Supporting evidence | | Other |  |  | |
| **6. Consultations on availability in Switzerland and/or the European Union**  **Where food business operators are unsure whether the information in their possession is sufficient to prove that the foodstuff concerned has been used for human consumption to a significant degree in Switzerland and/or within the European Union before 15 May 1997, they may consult other food business operators or food business operator federations in order to gather sufficient information.**   * *This section must always be completed in full for* ***all*** *foodstuffs, substances and extracts* ***except*** *foodstuffs obtained using a “novel” manufacturing process.* |
| **6.1.** Have other food business operators or food business operator federations been consulted? Details should be provided**.** |
| Click or start typing here to enter text. |
| **6.2.** Is the foodstuff currently available on the market within the European Union (EU)? Details should be provided. |
| Click or start typing here to enter text. |
| **7. More information**   * *This section must always be completed in full for* ***all*** *foodstuffs and substances.* |
| **7.1.** Is there any information that the product concerned is used in Switzerland and/or within the European Union as a medicinal product in accordance with the Therapeutic Products Act or Directive 2001/83/EC[[1]](#footnote-1)? |
| Click or start typing here to enter text. |
| **7.2.** Is there any other information which would assist in determining the Novel Food status? Any relevant information must be submitted even if it is not specifically requested. |
| Click or start typing here to enter text. |

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| **Section 2:**  **Extracts** |
| **8. Extracts**   * *This section must always be completed in full for* ***all extracts****.* |
| **8.1.** Any further details of the source material for the extract, if not provided in section 1. Details should be provided. |
| Click or start typing here to enter text. |
| **8.2.** Specification of the extract. Details should be provided**.** |
| Click or start typing here to enter text. |
| **8.3.** If extracted from a food source, will the intake of any extract components in the foodstuff be higher than the intake of these components in the food source? Details should be provided. |
| Click or start typing here to enter text. |

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| **Section 3:**  **Foodstuffs resulting from a production process not used for food production in Switzerland and/or within the European Union before 15 May 1997 (“new” technological process)**   * *This section must always be completed in full for all foodstuffs resulting from a “novel” manufacturing process (Art. 15 para. 1 let. g and i no. 1 FUAO).* |
| **9. Production process** |
| **9.1.** Detailed description of the production process. Include a process flow chart to describe the production process. |
| Click or start typing here to enter text. |
| **9.2.** Does the structure or composition of the foodstuff affect its nutritional value, metabolism or level of undesirable substances because of the process by which the foodstuff has been prepared?  Details should be provided. |
| Click or start typing here to enter text. |
| **9.3.** Is the foodstuff produced from a source that in itself is not normally consumed as part of the diet?  Details should be provided. |
| Click or start typing here to enter text. |
| **Enclosures:**  Please list all enclosures that are being submitted separately from this dossier as evidence in support of the information provided. |
| Click or start typing here to enter text. |

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| **Section 4:**  **Novel traditional foods** |
| **10. Novel traditional foods**   * *This section must additionally be completed in full for* ***all*** *novel traditional foods.* |
| **10.1 Description of the novel traditional food**  (Only if different from the information in 1.1, 1.2 and 2.A)  Click or start typing here to enter text. |
| **10.2 Origin (country) of the novel traditional food:**  (Country of origin, for which the information and evidence, especially evidence of traditional consumption, is also submitted)  Click or start typing here to enter text. |
| **10.3 Typical composition of the novel traditional food**  (Qualitative and quantitative data on composition (nutritional value, nutrients, micronutrients, physico-chemical, biochemical and microbiological properties, impurities or by-products, residues and contaminants (e.g. heavy metals, mycotoxins, PCBs/dioxins, pesticides), etc.))  Click or start typing here to enter text. |
| **10.4 Evidence, based on the history of use, that this foodstuff has been shown in the country of origin as stated in point 10.2, a country outside Switzerland and the EU, to be safe as part of the normal diet of a significant number of people over the last 25 years (continuous use).**  (Including 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)  Click or start typing here to enter text. |

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| **Conclusion on Novel Food status:** |
| On the basis of the above information, this product is  not a novel (traditional) foodstuff  a novel (traditional) foodstuff  **Reasons**:  Click or start typing here to enter text. |

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| **Sources quoted:** |
| Click or start typing here to enter text. |

1. [Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32001L0083&from=DE) [↑](#footnote-ref-1)