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| Federal Food Safety and Veterinary Office  FSVO |
| Department of Food and Nutrition |
| Sector Market Access |
| Schwarzenburgstrasse 155 |
| 3003 Bern |

**Application according to Article 16 letter b of the Ordinance on Foodstuffs and Utility Articles (FUAO; SR 817.02) in regard to placing on the market a novel foodstuff pursuant to Article 15 paragraph 1 letters a-j of the FUAO**

This form must be filled in and signed, and physically submitted to the address cited above. Supporting documents for the application may be submitted electronically ([lme@blv.admin.ch](mailto:lme@blv.admin.ch)).

It is possible, in a first step, to submit only the documents pertaining to Part A (consultation process). In this case the FSVO will then request the required documentation for Part B (substantive assessment of the application), insofar as the consultation process requirements have been met.

**First approval**

**Modification of an existing approval**

The approval will be granted only to persons who are resident or have their place of business in Switzerland. Foreign applicants must appoint a representative in Switzerland to request the approval on their behalf and who assumes the responsibility to ensure compliance with the standards (Art. 4 FUAO).

Please note that the application will only be substantively considered if the foodstuff to be approved is classified as a novel food. This evidence is deemed sufficient if the foodstuff either:

**is listed in the Novel Food Catalogue of the EU (**<http://ec.europa.eu/food/safety/novel_food/catalogue/search/public/index.cfm>) **with the status “Novel Food”**,

or

**the FSVO, in the context of the consultation process of the application, has confirmed the Novel Food status of the foodstuff.**

The undersigned note(s) that:

* services called upon by this application are invoiced in accordance with Articles 108-109 of the Ordinance on the Implementation of Foodstuffs Legislation (SR 817.042).
* all information is subject to professional secrecy in accordance with Article 94 of the Federal Personnel Ordinance (FpersO; SR 172.220.111.3).

Date, place

Signature

Name and first name of the authorised signatory

**Documents to be submitted:**

The following documents are to be submitted in all cases.

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|  | **Applicant:**  Full address, incl. telephone number and email |
|  | **Optional legal representation (please attach signed power of attorney):**  Full address, incl. telephone number and email |
|  | **Swiss representative (only for foreign applicants):**  Full address, incl. telephone number and email Required attachments: - Power of attorney of the foreign applicant to the domestic representative - Declaration by the domestic representative that he or she assumes responsibility to ensure compliance with all standards |
|  | **Contact person:**  Full address, incl. telephone number and email |
|  | **Billing address:**  Full address, incl. telephone number and email |
|  | **Name of the novel foodstuff:** |
|  | **Specific designation:** |

**Part A: Consultation Process**

**Documents to be submitted in regard to the Novel Food status of the foodstuff:**

These documents are only to be submitted if the foodstuff is not listed in the Novel Food Catalogue of the EU and it has not been officially classified by either the EU or Switzerland.

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|  | **Dossier, prepared** prepared in accordance with the «**Document Checklist for classification of Novel Food status**» (CL).  This CL is based on and structured in accordance with the[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](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0456&from=DE) Under number 5 of this CL, additional questions for clarifying the history of human consumption have been included in line with the EU guidance document [«Human Consumption to a Significant Degree»](https://ec.europa.eu/food/sites/food/files/safety/docs/novel-food_guidance_human-consumption_en.pdf). |
|  | **Documents to number 5 of the CL that demonstrate that the foodstuff had been used prior to 15 May 1997 for human consumption to a significant degree in Switzerland or in the EU include notably:**   * Consumption as food, * For a long period of time and continued up to the present, * by a large section of the population, * part of the normal diet, * commercially availability.   **Important: Research by the methodical procedure has to be presented in its entirety to the FSVO, independently of whether it results in useable information or not.** |

**Part B: Documents for a substantive assessment of the application**

**Documents to be submitted:**

These documents shall be submitted if the consultation process has confirmed the status as a novel food or that the foodstuff is listed as a novel food in the catalogue of the EU.

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|  | **Proof in accordance with the Novel Food Catalogue of the EU that it concerns a foodstuff pursuant to Article 15 paragraph 1 letters a-j of the FUAO:** |
|  | **Statement that it concerns a foodstuff and not a medicinal product:** |
|  | **Optionally: has an application been submitted outside Switzerland for an authorisation of the novel foodstuff? What is the status of the application?** |
|  | **Documents relating to:**   * Composition and specification, * Analytical methods, * The scientific data, the documentation corresponds to the novel foodstuff Article 17 paragraph 1 FUAO, * Purpose of use and conditions for use, and * The production process or the propagating or breeding practices,   are prepared and submitted following the "[Administrative guidance on the submission of applications for authorisation of a novel food pursuant to Article 10 of Regulation (EU) 2015/2283](https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2018.EN-1381)".  **Important: The application will only be processed if all required documents have been prepared by the applicants and structured according to the abovementioned guidance, and presented to the FSVO.** |