



Fact sheet concerning the submission of an application for the authorisation of a health claim not specified in Annex 14 Food IO

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Introduction

In accordance with article 31, paragraph 3 of the FDHA Ordinance on Information on Foodstuffs (FoodIO; SR 817.022.16), health claims that are not specified in Annex 14 of this ordinance are subject to authorisation by the Federal Food Safety and Veterinary Office (FSVO). This fact sheet is intended for those who would like to submit such an application for authorisation.

Please note that authorisations are granted only to those who are domiciled or authorised to reside in Switzerland. Applicants living abroad must be represented in Switzerland; the representative submits the application for authorisation and undertakes to comply with the regulations (article 4 of the Ordinance on Foodstuffs and Utility Articles [FUAO; SR 817.02]).

The FSVO deals only with applications for the authorisation of health claims that concern the effect of a foodstuff in accordance with the Swiss legislation on foodstuffs or of an authorised substance in foodstuffs. New types of foodstuffs (novel food) must have been authorised before an application is submitted for the authorisation of a health claim concerning such foodstuffs.

Services connected with the processing of the application for authorisation will be invoiced in accordance with art. 108 and 109 of the Ordinance on the Implementation of Foodstuffs Legislation (FLIO; SR 817.042). Fees will be charged regardless of the authorisation decision.

To submit an application for authorisation, a duly completed and signed application form for the authorisation of a health claim¹ together with the necessary supporting documents should be sent to the FSVO. An authorisation application dossier in accordance with the requirements of the European Food Safety Authority (EFSA) is always included as part of the supporting documentation.

To a large extent the FSVO refers to the EFSA guidelines when assessing the dossiers for the authorisation of a health claim. These guidelines can be viewed on the internet via the following link under the heading "Scientific guidance":

[Nutrition applications: regulations and guidance | European Food Safety Authority \(europa.eu\)](https://eufsa.europa.eu/nutrition-applications-regulations-and-guidance)

¹ Application form for the authorisation of a health claim not specified in Annex 14 FoodIO; SR 817.022.16

Procedure

- 1) Complete and sign the application form for the authorisation of a health claim, which can be found on the FSVO website via the following link: <https://www.blv.admin.ch/blv/en/home/lebensmittel-und-ernaehrung/rechts-und-vollzugsgrundlagen/bewilligung-und-meldung/health-claims.html>.

This form should be completed in accordance with the requirements stated in the Annex section of this fact sheet. In accordance with article 32, FoodIO, the application form for the authorisation of a health claim can be completed in English or in one of the official languages of the Swiss Confederation.

- 2) Attach an authorisation dossier for a health claim to the application form for the authorisation of a health claim. In accordance with article 32, paragraph 1, FoodIO, the dossier can also be supplied in English or in one of the official languages of the Swiss Confederation. It should be structured as shown in the EFSA document "[Scientific and technical guidance for the preparation and presentation of a health claim application \(Revision 2\)](#)". It should contain the information described in this template and retain the same numbering.

However, the following sections of the EFSA "[Scientific and technical guidance for the preparation and presentation of a health claim application \(Revision 2\)](#)" are either not applicable in Switzerland, applicable in a different manner or are replaced by the application form for the authorisation of a health claim:

- 1.2. Applicant
This part is replaced by sections 2 to 5 of the application form for the authorisation of a health claim.
- 1.3. Specifications
No distinction is currently made in Switzerland between the various types of health claims. However this section can be completed by way of information.
- 1.4. Proprietary data
This part is replaced by section 7 of the application form for the authorisation of a health claim.
- 1.7.3 Provide a proposal for the wording of the health claim
This section is replaced by section 1 of the application form for the authorisation of a health claim. However, the proposed wording for the claim can be provided in this section in one of the official languages of the Swiss Confederation or in English. Please note that, before an authorisation is granted, the wording will have to be provided in the three official languages of the Swiss Confederation.
- 1.7.4 Conditions of use
The specific conditions of use for the claim can be provided in this section in one of the official languages of the Swiss Confederation or in English. Please note that, before an authorisation is granted, the specific conditions of use will have to be provided in the three official languages of the Swiss Confederation.
- 1.8. Application Form and summary of the application
This section refers to "Appendix A" and "Appendix B", which are not applicable in Switzerland. Section 1.8 can therefore be disregarded.
- Appendix A
"Appendix A" is replaced by the application form for the authorisation of a health claim.

- Appendix B
"Appendix B" is not applicable in Switzerland.

The inapplicable sections or sections replaced by the application form for the authorisation of a health claim mentioned above do not therefore have to be included in the authorisation dossier. However, the numbering must still correspond to that in the EFSA document.

- 3) Send the duly completed and signed application form for the authorisation of a health claim by post to the following address:

**Federal Food Safety and
Veterinary Office FSVO**
Food and Nutrition
Market Access
Schwarzenburgstrasse 155
3003 Bern

- 4) Send the supporting documents, including the authorisation application dossier per the EFSA requirements, either
 - a. by post with the application form for the authorisation of a health claim as hard copy or in electronic form, or
 - b. by e-mail to the address lme@blv.admin.ch

Annex

The application form for the authorisation of a health claim not specified in Annex 14 FoodIO should be completed in accordance with the following requirements:

1) Health claim:

State the precise wording of the health claim forming the subject of this authorisation application. The wording should, in particular, satisfy the requirements of the FUAO and the Food IO. The requirements mentioned in the scientific guidance documents of the EFSA should also be taken into account ([Nutrition applications: regulations and guidance | European Food Safety Authority \(europa.eu\)](https://www.efsa.europa.eu/en/nutrition)).

The definitive wording of the health claim will need to be formulated in the three official languages of Switzerland at the latest by the end of the authorisation procedure.

2) Applicant:

State the full address of the applicant.

3) Legal representative if applicable:

If applicable, state the full address of the legal representative and attach a power of attorney.

4) Swiss representative (only for applicants domiciled abroad):

In accordance with article 4 FUAO, the authorisation is granted only to those who are domiciled or authorised to reside in Switzerland. Applicants living abroad must be represented in Switzerland; the representative submits the application for authorisation and undertakes to comply with the regulations.

The full address of the Swiss representative must be provided.

Supporting documents to be provided if applicable:

- Power of attorney of the applicant domiciled abroad to its Swiss representative*
- Declaration of the Swiss representative that it undertakes to comply with Swiss legislation and to assume responsibility in the event of a violation of this legislation.*

5) Contact person:

Indicate the full details of the contact person (company, surname, first name, postal address, e-mail address, phone number).

Communication during the authorisation procedure will be exclusively with the contact person indicated here (letters, e-mails, phone contacts).

If the contact person changes during the course of the procedure, please send the details of the new contact person to the FSVO by letter or e-mail.

6) Billing address:

State the full billing address.

7) Applicant's proprietary data:

Indicate whether the authorisation application contains proprietary data of the applicant. In accordance with article 38, paragraph 4, FUAO, the scientific data and information used for authorising a health claim cannot be used by another applicant without the consent of the owner for a period of five years from the date of authorisation if the three following conditions are satisfied:

- a) the authorisation holder has designated the scientific data and information as protected in the submitted application.*
- b) on the date of application submission, the authorisation holder had an exclusive right to the use of the data and information.*

c) *the health claims would not have been authorised without the submission of this data.*

The applicant must also provide a justification that, on the date of application submission, the applicant had an exclusive right to the use of the data and information (justification for the proprietary claim on the protected data and information) and an explanation justifying that the health claim could not have been authorised without the submission of this data and information (explanation of the need for the protected data and information).

8) Assessment of the claim by the EFSA:

State whether the health claim for which an application for authorisation has been submitted has already been assessed by the EFSA. If so, state the reference for the EFSA assessment. In the event of a negative assessment by the EFSA, state the reason, or reasons, and provide a description of the changes made to the dossier.

9) Supporting documents:

List the documents attached to the application form for the authorisation of a health claim.

The following documents should be attached to the authorisation application form:

- *Application dossier for the authorisation of a health claim according to the EFSA requirements "[Scientific and technical guidance for the preparation and presentation of a health claim application \(Revision 2\)](#)" (in all cases)*
- *Power of attorney (if applicable)*
- *Power of attorney of the applicant domiciled abroad to its Swiss representative (if applicable)*
- *Declaration of the Swiss representative that it undertakes to comply with Swiss legislation and assume responsibility in the event of a violation of this legislation (if applicable)*
- *Justification for the proprietary claim on the protected data and information (article 38, paragraph 4, letter b, FUAO, if applicable)*
- *Explanation of the need for the protected data and information (article 38, paragraph 4, letter c, FUAO, if applicable)*