

99118037261000

Zulassung von gesundheitsbezogenen Angaben Entgegennahme

Heruntergeladen am 10.06.2025

<https://fimportal.de/xzufi-services/102889170/B100019>

Modul	Sachverhalt
Leistungsschlüssel	99118037261000
Leistungsbezeichnung I	Zulassung von gesundheitsbezogenen Angaben Entgegennahme
Leistungsbezeichnung II	Apply for approval of health claims on food
Typisierung	1 - Bund: Regelung und Vollzug
Quellredaktion	Bund
Freigabestatus Katalog	fachlich freigegeben (gold)
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	
Verrichtungskennung	Entgegennahme (261)
SDG-Informationsbereich	Vorschriften für und Anforderungen an Erzeugnisse

Modul	Sachverhalt
Lagen Portalverbund	Produkt- und Stoffzulassung (2120200), Verbraucherschutz (2140100)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	29.03.2023
Fachlich freigegeben durch	Federal Ministry of Food and Agriculture (BMEL)
Handlungsgrundlage	https://www.gesetze-im-internet.de/bvla_v/_1.html https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A02006R1924-20141213&qid=1642496527790 https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A02008R0353-20091221
Teaser	Health claims on foods usually require approval. You can apply for this approval via the E-Submission Food Chain (ESFC) platform of the European Commission.
Volltext	<p>Certain requirements apply to the labeling and presentation of foods, as well as to the advertising of foods, in the European Union (EU), which are intended to make a particular contribution to consumer protection.</p> <p>Regulation (EC) No. 1924/2006 serves to harmonize regulations for nutrition and health claims in the labeling and presentation or advertising of foods. So-called voluntary claims on foods must be clear, precise and substantiated in EU countries. This is to enable consumers to make informed and meaningful choices.</p> <p>Applying for approval</p> <p>You can apply for the authorization of a new health claim as well as for the modification of an existing authorization of a health claim electronically via the E-Submission Food Chain (ESFC) platform of the European Commission:</p> <ul style="list-style-type: none"> • In each application, you may only request authorization for the use of a health claim. Furthermore, it is only allowed to show the relationship between a well-defined health effect per advertised

Modul

Sachverhalt

food or food category or a nutrient or substance.

- Notice: EFSA suggests that the application dossier be written in English to avoid delays in the evaluation of the application due to the translation to be arranged there.

Receipt of the application

The Federal Office of Consumer Protection and Food Safety (BVL) is the national competent authority for receiving applications for the authorization of health claims made on foods. The BVL confirms receipt of your application, informs EFSA and is entitled to request supplementary documentation from you within a specified period of time.

Erforderliche Unterlagen

- The application must be prepared according to the requirements of the "Scientific and technical guidance for the preparation and presentation of a health claim application (Revision 3)" (<https://www.efsa.europa.eu/en/efsajournal/pub/6554>)
- The application must include all scientific data (published and unpublished) that support or oppose the health claim, as well as a comprehensive review of data from human studies.
- Summary of the dossier

Voraussetzungen

- You want to use health claims in the labeling and presentation of or advertising for foods that are not yet approved.

Kosten

There are no costs involved.

Verfahrensablauf

You can apply for approval of health claims electronically via the European Commission's E-Submission Food Chain (ESFC) platform.

To do so, proceed as follows:

- Access the European Commission's E-Submission Food Chain (ESFC) platform: <https://webgate.ec.europa.eu/esfc>
- Use the user manual and other training materials for

Modul

Sachverhalt

assistance:

https://ec.europa.eu/food/horizontal-topics/general-food-law/training-and-support_en.

- Create a user account and log in to the portal.
- Select "Food Improvement Agents" from the "Food" domain list. Then select the domain type "Health Claims", the application type, the recipient Member State and the relevant Competent Authority, and then click on "Start process".
- Then create your dossier. Your application must include the following information:
 - Name and address of the person making the application,
 - The name of the nutrient or other substance or the food or food category for which the health claim is to be made and the particular properties involved,
 - a copy of the studies, including, where available, independent and peer-reviewed studies (an examination by experts), on the health claim, and any other available documentation showing that the health claim complies with the criteria of the Regulation,
 - where appropriate, an indication of which information is to be considered proprietary, together with a verifiable justification for this,
 - a copy of other scientific studies relevant to the health claim,
 - a proposal for the wording of the health claim for which authorization is sought, including, where appropriate, specific conditions of use,
 - a summary of the application.
- EFSA suggests that the application dossier be written in English to avoid delays in the evaluation of the application due to the translation to be arranged there.
- Attach any other required documentation to the application.
- Submit the application online.

If you have applied for approval of health claims, the receipt of your application by the Federal Office of Consumer Protection and Food Safety (BVL) is as follows:

Modul	Sachverhalt
	<p>The BVL</p> <ul style="list-style-type: none"> • confirms receipt of your application in writing within 14 days of receipt. • The date of receipt of the application will be noted in the confirmation. • will inform EFSA without delay, • may, if necessary, request you as the applicant to supplement the documents relating to the application within a specified period.
Bearbeitungsdauer	<p>8 - 24 Monat(e)</p> <p>The subsequent request for documents leads to an extension of the processing deadlines.</p>
Frist	<p>1 Monat(e)</p> <p>Pursuant to Section 70 of the Administrative Court Rules (VwGO), the objection must be lodged in writing, in electronic form pursuant to Section 3a (2) of the Administrative Procedure Act (Verwaltungsverfahrensgesetz) or in writing with the authority that issued the administrative act within one month of the administrative act being notified to the person complained of. The time limit shall also be observed by filing the appeal with the authority that issued the notice of appeal. §§ Sections 58 and 60 (1) to (4) shall apply mutatis mutandis.</p>
weiterführende Informationen	<p>https://www.bvl.bund.de/DE/Arbeitsbereiche/01_Lebensmittel/04_AntragstellerUnternehmen/01_HealthClaims/lm_healthClaims_node.html</p> <p>https://www.bmel.de/DE/themen/ernaehrung/lebensmittel-kennzeichnung/pflichtangaben/naehrwertinformationen-health-claims.html</p> <p>https://www.efsa.europa.eu/de/applications/nutrition/regulationsandguidance#health-claims</p> <p>https://www.bvl.bund.de/DE/Arbeitsbereiche/01_Lebensmittel/04_AntragstellerUnternehmen/01_HealthClaims/lm_healthClaims_Grundsatzliche_Hinweise_Antragstellung_basepage</p> <p>https://ec.europa.eu/food/food-feed-portal/screen/home?event=search</p> <p>https://www.bvl.bund.de/SharedDocs/Downloads/01_Lebensmittel/healthclaims/guidance_claim.html</p>
Hinweise	

Modul	Sachverhalt
Rechtsbehelf	<ul style="list-style-type: none"> • Appeal. For more information on how to lodge an appeal, please refer to the instructions on appealing in the notification of your application. • Lawsuit before the administrative court. For more information on how to file a lawsuit, see the appeal instructions in the notice of appeal.
Kurztext	<ul style="list-style-type: none"> • Authorization of health claims Receipt • Health claims on food must be approved according to EU regulation <ul style="list-style-type: none"> • a "health claim" is any claim which states, suggests or implies that there is a relationship between a food category, a food or one of its constituents, on the one hand, and health, on the other hand • Application for approval of health claims via the E-Submission Food Chain (ESFC) platform of the European Commission • Federal Office of Consumer Protection and Food Safety (BVL) is the competent national authority for receiving applications for the authorization of health claims made on foods as well as applications for the inclusion of a health claim in the list according to Article 13 of the EU Regulation <ul style="list-style-type: none"> • BVL checks the validity of the application and makes it available to the European Food Safety Authority (EFSA) for scientific assessment • BVL may, if necessary, request applicants to supplement documents relating to the application within a specified period of time • responsible: Federal Office of Consumer Protection and Food Safety (BVL)
Ansprechpunkt	
Zuständige Stelle	
Formulare	<ul style="list-style-type: none"> • Forms available: No • Written form required: No • Informal application possible: No • Personal appearance required: No • Online services available: Yes
Ursprungsportal	Zulassung von gesundheitsbezogenen Angaben Entgegennahme, Zulassung von gesundheitsbezogenen Angaben Entgegennahme