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Konsultationsverfahren zur Bestimmung des Status als neuartiges Lebensmittel Durchführung

Heruntergeladen am 29.06.2025

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Modul	Sachverhalt
Leistungsschlüssel	99118033058000
Leistungsbezeichnung I	Konsultationsverfahren zur Bestimmung des Status als neuartiges Lebensmittel Durchführung
Leistungsbezeichnung II	Request consultation procedure for novel foods
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	Durchführung (58)

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SDG-Informationsbereich	Vorschriften für und Anforderungen an Erzeugnisse
Lagen Portalverbund	Erlaubnisse und Genehmigungen (2010400), Produkt- und Stoffzulassung (2120200), Verbraucherschutz (2140100)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	02.12.2024
Fachlich freigegeben durch	Federal Ministry of Food and Agriculture (BMEL)
Handlungsgrundlage	https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A02015R2283-20210327 https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A32018R0456 https://www.gesetze-im-internet.de/nlv_2018/index.html
Teaser	<p>Would you like to launch a food on the German market and are unsure whether it is to be classified as a novel food? Then you can apply to the Federal Office of Consumer Protection and Food Safety (BVL) for a consultation procedure.</p>
Volltext	<p>In the European Union (EU), foodstuffs may generally be placed on the market without prior authorization. Novel foods are an exception to this rule. These must first undergo a health assessment and be approved before being placed on the market.</p> <p>If you are unsure whether your food is to be classified as a novel food, you can consult the competent authority of the EU Member State in which you intend to place the food on the market first. In Germany, the Federal Office of Consumer Protection and Food Safety (BVL) is responsible.</p> <p>With your application to initiate such a consultation procedure, the BVL requires documents and information from you which, among other things, show the production, composition and intended use of your food. In your application, you can request confidential treatment of the food information you have submitted if its disclosure could harm your competitive position.</p>

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Please note that your application to the BVL alone initiates the consultation procedure in which the BVL assesses whether your food is to be classified as a novel food. You must apply separately to the European Commission for the actual authorization to place a novel food on the market.

In order to determine the novel food status, the BVL consults the food control authorities of the federal states and exchanges information with the authorities of other EU member states and the European Commission. If you submit your application documents in English, this will speed up the procedure as they no longer need to be translated before being forwarded to the European Commission and the EU Member States.

Erforderliche Unterlagen

The consultation procedure can be applied for online via the federal portal or by e-mail.

The following documents are required for all types of application:

- technical documents A corresponding template can be found in Annex II of Implementing Regulation (EU) 2018/456 or on the BVL website
- Documents to support your request for consultation, if available Evidence of significant consumption of the food in the EU before 15.05.1997, for example: Evidence of import and sales figures Evidence of actual availability on the market as a foodstuff labels Technical literature, if applicable
- Note in which you explain the purpose and relevance of the documents submitted
- if you are submitting the request by e-mail: Cover letter for a request for consultation with information on the company in accordance with the model cover letter in Annex I to Implementing Regulation (EU) 2018/456 if you submit the request online but are not registered, you can generate your completed request as a PDF file and send it to the BVL by email, for example
- if you request confidential treatment of the information submitted with the application:

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	<p>corresponding statement</p> <ul style="list-style-type: none"> • if the application is made by proxy: Power of attorney • if necessary, further documents, depending on the circumstances, for example study results product illustrations • Note: You can find out from the BVL which additional documents you may have to submit.
Voraussetzungen	<ul style="list-style-type: none"> • You cannot independently determine beyond doubt whether your food falls under the EU Novel Food Regulation. • You want to place your food on the market in Germany first, not in another EU member state.
Kosten	<p>Gebühr: 680€ - 7.800€</p> <p>Fees have been charged for processing a consultation request since 01.10.2021. The amount of the fee depends on the processing effort.</p>
Verfahrensablauf	<p>First of all, you are responsible for checking whether or not your food falls under the EU Novel Food Regulation. If you cannot identify the food in question with certainty, you can consult the BVL.</p> <p>You can apply for the consultation procedure online via the federal portal or by e-mail.</p> <p>Apply for the consultation procedure online via the federal portal:</p> <ul style="list-style-type: none"> • Call up the online application on the federal portal verwaltung.bund.de. This will guide you step by step through the necessary information, which you can enter electronically. • Upload the required documents as a file and submit the application. • You will receive confirmation that your application has been received. • If you are not registered, you can generate your completed application as a PDF file and send it to the BVL by e-mail. • The BVL will check your details and documents and coordinate with the authorities of the federal states and EU member states. • The BVL will contact you if further documents or

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information are required.

- The BVL will inform you of the provisional result of the consultation procedure.
- You comment on the preliminary result of the consultation procedure.
- You will receive a notification of approval digitally via the feedback channel function of the federal portal or by post.
- In this notification, you will be informed whether your foodstuff novel, not novel or non-novel only in food supplements.
- You will also receive a separate notification of fees. You then pay the fees.

Request a consultation procedure by e-mail:

- Formulate an application using, for example, the sample cover letter in Annex I of Implementing Regulation (EU) 2018/456. Alternatively, access the online application on the federal portal verwaltung.bund.de. Complete the application online and save it as a print preview.
- Attach all required documents.
- Send your application to the BVL by e-mail.
- You will receive confirmation that your application has been received.
- The BVL will check your details and documents and coordinate with the authorities of the federal states and EU member states.
- The BVL will contact you if further documents or information are required.
- The BVL will inform you of the provisional result of the consultation procedure.
- You comment on the preliminary result of the consultation procedure.
- The BVL will inform you by official decision whether your food is novel, not novel or non-novel only in food supplements.
- You will also receive a separate notification of fees. You will then pay the fees.

Bearbeitungsdauer

4 Monat(e)

The BVL must decide on complete applications within 4 months. In justified cases, this period may be extended by a maximum of 4 further months.

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Frist	<p>4 Woche(n) After the BVL has informed you of the provisional result of the consultation procedure, you have 4 weeks to comment on it.</p> <p>1 Monat(e) After the BVL has informed you of the result of the consultation procedure by means of a decision, you have 1 month to lodge an objection.</p>
weiterführende Informationen	<p>https://www.bvl.bund.de/novelfood https://ec.europa.eu/food/safety/novel-food_en https://ec.europa.eu/food/food-feed-portal/screen/novel-food-catalogue/search https://ec.europa.eu/food/food-feed-portal/screen/novel-food-catalogue/search https://www.bvl.bund.de/SharedDocs/Downloads/01_Lebensmittel/novelfood/Muster_technische_Unterlagen_gem_Anhang_II_DVO.html</p>
Hinweise	<p>The BVL does not carry out the actual authorization procedure for novel foods. The authorization of novel foods is carried out by the European Commission and must be applied for separately. The consultation procedure is about determining whether a food is novel and whether there is a need to submit an application to the European Commission.</p>
Rechtsbehelf	<ul style="list-style-type: none"> • Contradiction Further information on how to lodge an appeal can be found in the information on legal remedies in the notification of your application. • Appeal to the administrative court You can find further information on how to lodge a complaint in the legal remedies information in the notice of objection.
Kurztext	<ul style="list-style-type: none"> • Consultation procedure for determining novel food status Implementation • Companies that want to launch a food on the German market and are unsure whether it is a novel food can consult the Federal Office of Consumer Protection and Food Safety (BVL) by submitting an application. • Background: Novel foods require approval before they can be placed on the market. • Consultation procedure: Responsible food business operators are responsible for classifying whether a food is a novel food. In case of doubt regarding the

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classification, the BVL assesses whether the food in question falls within the scope of the Novel Food Regulation of the European Union. BVL does not carry out the actual authorization procedure. Authorization of novel foods is carried out by the European Commission and must be applied for separately.

- Documents required for the consultation procedure: technical documentation Supporting documents to substantiate the consultation request Note explaining the objective, relevance and composition of the documents submitted if the request is made by e-mail or post: Cover letter
- Note: Documents in English speed up the procedure.
- Fees for consultation procedure: EUR 680 to EUR 7,800
- Processing time: 4 months after submission of the complete application
- Applications can be submitted: online via the federal portal by e-mail
- responsible: Federal Office of Consumer Protection and Food Safety

Ansprechpunkt

Zuständige Stelle

Formulare

Ursprungsportal

Konsultationsverfahren zur Bestimmung des Status als neuartiges Lebensmittel Durchführung,
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