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Aufnahme eines Primärprodukts in die Gemeinschaftsliste zugelassener Primärprodukte Entgegennahme

Heruntergeladen am 12.07.2025

<https://fimportal.de/xzufi-services/102889172/B100019>

Modul	Sachverhalt
Leistungsschlüssel	99118038261000
Leistungsbezeichnung I	Aufnahme eines Primärprodukts in die Gemeinschaftsliste zugelassener Primärprodukte Entgegennahme
Leistungsbezeichnung II	Apply for inclusion of a smoke flavoring primary product in the Community list of authorized primary products.
Typisierung	1 - Bund: Regelung und Vollzug
Quellredaktion	Bund
Freigabestatus Katalog	fachlich freigegeben (gold)
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung

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Leistungsgruppierung	
Verrichtungskennung	Entgegennahme (261)
SDG-Informationsbereich	Vorschriften für und Anforderungen an Erzeugnisse
Lagen Portalverbund	Produkt- und Stoffzulassung (2120200), Verbraucherschutz (2140100)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	02.03.2022
Fachlich freigegeben durch	Federal Ministry of Food and Agriculture (BMEL)
Handlungsgrundlage	https://eur-lex.europa.eu/legal-content/de/ALL/?uri=CELEX%3A32003R2065 https://eur-lex.europa.eu/legal-content/de/ALL/?uri=CELEX%3A32003R2065 https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A32013R1321&qid=1644220274731 https://www.gesetze-im-internet.de/bvla_v/BJNR097200008.html
Teaser	If you want to use a new smoke flavoring in or on food, you must have it approved at the European level . If approved, the smoke flavoring will be placed on the EU Community List of Primary Products.
Volltext	<p>Smoking is one of the oldest methods of food treatment. It is used both for preservation and seasoning. However, if the flavor advantage of smoking is to be used above all, smoke flavorings can also be used for food processing nowadays. However, smoke flavorings are used exclusively for flavoring foods such as meat, soups and snacks. According to current knowledge, it is not possible to extend shelf life by spraying smoke flavorings or dipping foods in smoke flavorings.</p> <p>If you use smoke flavorings, you should first check which smoke flavorings are approved in the European Union. The authorized smoke flavorings are on a Community list of the European Community. Because smoke flavorings are made from smoke that is</p>

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subjected to fractionation and purification, the use of smoke flavorings is generally considered to pose less of a health risk than the traditional smoking process. However, if you wish to use a previously unapproved smoke flavoring, you must first apply for its approval from the Federal Office of Consumer Protection and Food Safety (BVL).

What are smoke flavorings

As with conventional smoking, smoke is used to produce smoke flavorings. For this purpose, hardwoods are smoked under controlled conditions. The smoke is then used and processed to produce the so-called primary products. When these primary products are supplemented with carriers, smoke flavorings are created that can be incorporated directly into food or applied to its surface.

Why approval is needed

Since smoke flavorings are complex mixtures of many chemical substances, special regulations apply to their use as food flavorings. Therefore, a smoke flavoring requires an authorization that demonstrates that it does not pose a risk to human health.

Legal basis

In principle, only smoke flavorings that are on the EU list of authorized smoke flavorings and primary products can be used for processing in or on foods. It is specified how primary products are uniformly

- evaluated,
- approved
- and used

are to be used. All authorized primary products and smoke flavorings in the European Community are listed in this Community list. This ensures a high level of consumer safety.

Submitting an application for authorization

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If you would like another smoke flavoring or its primary product to be authorized and thus added to the EU Community List, you must submit an application to the Federal Office of Consumer Protection and Food Safety. Based on the data submitted, the European Food Safety Authority (EFSA) will then evaluate the safety of the product. This will include an assessment of whether there are any risks to human health or the environment from the use proposed in the application.

Please note that smoke flavorings are in principle only approved for 10 years. If you have already received authorization for a smoke flavoring in the past, you must submit a new application at least 18 months before the existing authorization expires.

Erforderliche Unterlagen

If you wish to submit an application for an authorization for smoke flavourings, you must submit the following documents in accordance with Article 7(3) of Regulation (EC) No 2065/2003:

- Name and address of the applicant;
- the information listed in Annex II to Regulation (EC) 2065/2003;
- a substantiated statement that the product complies with Article 4(1), first indent (that the use does not present risks to human health);
- a summary of the dossier;
- where appropriate, a request for confidentiality of certain information in accordance with Article 15 of Regulation (EC) 2065/2003.

The application shall be prepared according to the requirements of the "Scientific Guidance for the preparation of applications on smoke flavouring primary products" (EFSA Journal 2021;19(3):6435).

Voraussetzungen

The use of smoke flavourings in or on foods will only be authorised if the applicant company can demonstrate that this does not present a risk to human health and that consumers will not be misled.

Kosten

There are no costs involved.

Verfahrensablauf

You can apply for smoke flavoring authorization electronically through the European Commission's

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E-Submission Food Chain (ESFC) platform. To do so, proceed as follows:

- Access the European Commission's E-Submission Food Chain (ESFC) platform.
- Use the user manual and other training materials for assistance.
- Create a user account and log in to the portal.
- Select "Food Improvement Agents" from the "Food" domain list. Then select the domain type "Smoke Flavourings", the application type, the recipient Member State and the relevant Competent Authority, then click "Start process".
- Then, create your dossier. Your application must include, but is not limited to, the following information: the type of wood used for the production of the primary product; detailed information on the production methods of the primary products and the further processing used in the production of derived smoke flavourings; the qualitative and quantitative chemical composition of the primary product and the characterization of the unidentified portion. Of particular importance are the chemical specifications of the primary product and information on the stability and degree of variability of the chemical composition. The unidentified portion, i.e., the portion of substances whose chemical structure is not known, should be as low as possible and characterized by appropriate analytical methods, such as chromatographic or spectrometric methods; A validated analytical procedure for sampling, identification and characterization of the primary product; Information on intended use levels in or on specific foods or food categories; toxicological data in accordance with the opinion of the Scientific Committee on Food in its report on smoke flavourings of 25 June 1993 or its latest update. 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 a primary product,

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the receipt of your application by the Federal Office of Consumer Protection and Food Safety (BVL) is as follows:

The BVL

- Acknowledges receipt of your application in writing within 14 days of its receipt. The date of receipt of the application is noted in the confirmation.
- informs EFSA without delay,
- may, if necessary, request you as the applicant to supplement the documents relating to the application within a specified period.
- The European Food Safety Authority shall immediately inform the other Member States and the Commission of the application and make all application documents available to them.
- The European Food Safety Authority shall examine the application and publish its opinion.
- Within 3 months of publication of the opinion, the European Commission shall prepare a draft regulation adding the primary product applied for to the list of authorized primary products or a draft decision addressed to the applicant refusing authorization.

Bearbeitungsdauer

Duration: 9 months to several years. The subsequent request for documents with a deadline of up to one year in each case can lead to a considerable extension of the processing time

Frist

There is no deadline for the application for a new smoke flavoring. The validity of an existing authorization is 10 years. An application for renewal of an authorization must be submitted at least 18 months before the expiry of the existing authorization.

weiterführende Informationen

<https://aromenverband.de/informationenleitlinien/was-sind-raucharomen/>
https://www.bfr.bund.de/de/fragen_und_antworten_zu_raucharomen-200385.html
<https://www.efsa.europa.eu/de/topics/topic/smoke-flavourings>
<https://www.efsa.europa.eu/en/efsajournal/pub/6435>
https://ec.europa.eu/food/horizontal-topics/general-food-law/training-and-support_en

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<https://www.efsa.europa.eu/en/efsajournal/pub/6435>
https://ec.europa.eu/food/horizontal-topics/general-food-law/training-and-support_en
https://ec.europa.eu/food/safety/food-improvement-agents/flavourings/smoke-flavouring-renewals-existing_en

Hinweise

There are the following indications:

An approval is granted for 10 years. An extension for a further 10 years is possible. For this purpose, the authorization holder must submit a corresponding application to the European Commission at least 18 months before the authorization expires.

Previously approved primary products are authorized until January 1, 2024. Applications to extend the authorization must be submitted by June 30, 2022.

Rechtsbehelf

Kurztext

- Inclusion of a primary product in the Community list of authorised primary products Reception
- Smoke flavorings are subject to their own legal regulation due to their special chemical composition
- EU regulation therefore governs the Evaluation, authorization and Use of smoke flavourings.
- Authorization of smoke flavourings/primary products for use in and on foods must be applied for Competent national authority: Federal Office of Consumer Protection and Food Safety Approval takes place on European level
- The applicant has to prove that the corresponding smoke flavourings do not pose a health risk (e.g. specification of species, intended use and quantity)
- Upon authorization, the primary product is included in the Community list of authorized primary products
- Authorization of smoke flavourings is valid for 10 years 18 months before expiry of the authorization, a new application must be submitted
- Competent national authority: Federal Office of Consumer Protection and Food Safety

Ansprechpunkt

Zuständige Stelle

Modul	Sachverhalt
Formulare	Forms available: No Written form required: No Informal application possible: No Personal appearance required: No Online services available: Yes
Ursprungsportal	Aufnahme eines Primärprodukts in die Gemeinschaftsliste zugelassener Primärprodukte Entgegennahme, Aufnahme eines Primärprodukts in die Gemeinschaftsliste zugelassener Primärprodukte Entgegennahme