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Zulassung von neuen Stoffen für Kunststoffe im Lebensmittelkontakt gem. Verordnung (EU) Nr. 10/2011 Erteilung

Heruntergeladen am 10.06.2025

<https://fimportal.de/xzufi-services/102889174/B100019>

Modul	Sachverhalt
Leistungsschlüssel	99118039001000
Leistungsbezeichnung I	Zulassung von neuen Stoffen für Kunststoffe im Lebensmittelkontakt gem. Verordnung (EU) Nr. 10/2011 Erteilung
Leistungsbezeichnung II	Apply for approval of new substances for plastics in food contact materials
Typisierung	1 - Bund: Regelung und Vollzug
Quellredaktion	Bund
Freigabestatus Katalog	fachlich freigegeben (gold)
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	

Modul	Sachverhalt
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	
Verrichtungskennung	Erteilung (1)
SDG-Informationsbereich	Vorschriften für und Anforderungen an Erzeugnisse
Lagen Portalverbund	Produkt- und Stoffzulassung (2120200)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	01.09.2022
Fachlich freigegen durch	Federal Ministry of Food and Agriculture (BMEL)
Handlungsgrundlage	https://eur-lex.europa.eu/legal-content/DE/ALL/?uri=CELEX%3A32011R0010 https://eur-lex.europa.eu/legal-content/de/ALL/?uri=CELEX%3A32004R1935
Teaser	You want to use a new substance for the production of food contact plastics? Then you need an authorization. You can submit the application online on the portal E-Submission Food Chain Platform of the European Commission.
Volltext	Materials that come into contact with food are subject to European legislation. In good manufacturing practice and under normal conditions, they must not release constituents into the food in quantities which • endanger human health • lead to an unacceptable change in the composition of the food, or • cause a deterioration in the organoleptic properties of the food, such as taste or odor. As a manufacturer of plastic food contact materials, you are responsible for compliance with these requirements. You must ensure that the contact materials are harmless to health.

Modul

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For finished products made of plastic for food contact, such as packaging, there is no obligation for approval in Germany. However, there is one for the substances and materials that your company uses in the manufacture of the individual materials. The basis for this is an EU-wide coordinated and valid procedure.

You can submit the application for approval of a new substance for use in food contact plastics exclusively via the European Commission's online portal "E-Submission Food Chain Platform" (ESFC).

The Federal Office of Consumer Protection and Food Safety (BVL) is the national contact point in Germany. If you select the BVL as your point of contact, the BVL formally checks the application for completeness and relevance of the documents. The BVL then forwards it to the European Food Safety Authority (EFSA).

EFSA reviews your application on the basis of scientific findings. The European Commission decides on the actual approval. Even in the event of non-approval, the European Commission will inform you and give reasons for its decision.

If the substance complies with all food law requirements, it will be added to the so-called Union list of substances permitted in plastics for food contact in accordance with Regulation (EU) No.10/2011. This means that you and, if applicable, other companies may use the substance for the manufacture of plastic materials with food contact.

You must inform the EU Commission immediately if you have new scientific or technical knowledge that may affect the assessment of the safety of the substance in relation to human health.

Erforderliche Unterlagen

- You have to submit the application documents according to the requirements of the so-called Guideline document of EFSA.

Voraussetzungen

- The content and form of your application and the accompanying documents must comply with the requirements of EFSA's guidance.

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Kosten	There are no costs involved.
Verfahrensablauf	You can apply for the authorization of new food contact plastics substances exclusively online via the ESFC portal of the European Commission. The process goes through different phases with different stakeholders and responsibilities: • Upload your application, prepared according to EFSA's specifications, directly to the platform. Follow the procedure described in the so-called UserGuide of the platform. • The BVL will receive the application if you select it as the national point of contact. • After successful completion of the formal review, the BVL forwards the application within the platform to the responsibility of EFSA. • EFSA takes over the scientific review and publishes information on received applications in scientific opinions. • Via the Open EFSA Portal, you and other interested parties can follow the status of applications up to the publication of the scientific opinion. • The European Commission, with the involvement of the EU member states, decides on the actual authorization.
Bearbeitungsdauer	• You will receive a confirmation of receipt within 14 days. • The BVL usually needs no more than 4 weeks for the initial review of your application. Queries or additional requests as well as your reaction times may influence the duration. Only when the documents are complete, the BVL forwards them to EFSA.
Frist	There is no deadline for submission.
weiterführende Informationen	https://ec.europa.eu/food/safety/chemical-safety/food-contact-materials_en https://www.efsa.europa.eu/de/applications/foodcontactmaterials/regulationsandguidance https://www.efsa.europa.eu/de/applications/foodcontactmaterials/regulationsandguidance https://www.efsa.europa.eu/de/applications/foodcontactmaterials/regulationsandguidance https://ec.europa.eu/food/safety/chemical-safety/food-contact-materials_en

Modul	Sachverhalt
	contact-materials_en https://ec.europa.eu/food/horizontal-topics/general-food-law/training-and-support_en https://open.efsa.europa.eu/ https://ec.europa.eu/food/horizontal-topics/general-food-law/training-and-support_en https://www.bvl.bund.de/LM-Kontaktmaterialien-Zulassung https://www.bvl.bund.de/FAQs_FCM_Zulassung
Hinweise	There are no clues or specifics.
Rechtsbehelf	• You file an appeal against a decision directly with the authorizing body, i.e. the European Commission.
Kurztext	• Authorization of new substances for plastics in contact with food according to Regulation (EU) No. 10/2011 Granting • relevant for manufacturers of plastics for contact with foodstuffs • new substances for the production of plastics used as food packaging have to be approved • application only electronically via ESubmission Food Chain Platform (ESFC) • Objective: food safety • Food contact materials must not release ingredients into food in quantities that would • are likely to endanger human health, or • cause an unacceptable change in the composition of food or • cause an impairment of the organoleptic properties of food, e.g. taste or odor. • Manufacturers of food contact materials are responsible for compliance with the requirements of food legislation • they must ensure that contact materials are safe for human health • Application for approval of a new food contact material must be submitted exclusively via the online portal E-Submission Food Chain Platform (ESFC). • in Germany, the Federal Office of Consumer Protection and Food Safety (BVL) is the national contact point • the BVL confirms receipt of your dossier within 14 days

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- EFSA reviews the applications on the basis of scientific evidence
- the European Commission decides on the approval
- if the substance meets all food law requirements, it is included in the so-called Union list.
- The substance may only be used for the manufacture of plastic materials that come into contact with foodstuffs once it has been included in the Union list.
- costs: none
- responsible: Federal Office of Consumer Protection and Food Safety

Ansprechpunkt

Zuständige Stelle

Formulare

Ursprungsportal

Zulassung von neuen Stoffen für Kunststoffe im Lebensmittelkontakt gem. Verordnung (EU) Nr. 10/2011 Erteilung, Zulassung von neuen Stoffen für Kunststoffe im Lebensmittelkontakt gem. Verordnung (EU) Nr. 10/2011 Erteilung