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Zulassung von neuen Stoffen für Zellglasfolien im Lebensmittelkontakt gem. Richtlinie 2007/42/EG Erteilung

Heruntergeladen am 10.06.2025

<https://fimportal.de/xzufi-services/102889180/B100019>

Modul	Sachverhalt
Leistungsschlüssel	99118042001000
Leistungsbezeichnung I	Zulassung von neuen Stoffen für Zellglasfolien im Lebensmittelkontakt gem. Richtlinie 2007/42/EG Erteilung
Leistungsbezeichnung II	Apply for approval of new substances for regenerated cellulose film in contact with foodstuffs
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	

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Verrichtungskennung	Erteilung (1)
SDG-Informationsbereich	Vorschriften für und Anforderungen an Erzeugnisse
Lagen Portalverbund	Produkt- und Stoffzulassung (2120200)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	20.07.2022
Fachlich freigegeben durch	Federal Ministry of Food and Agriculture (BMEL)
Handlungsgrundlage	https://eur-lex.europa.eu/legal-content/DE/ALL/?uri=CELEX%3A32007L0042 https://eur-lex.europa.eu/legal-content/de/ALL/?uri=CELEX%3A32004R1935
Teaser	You want to use new substances for the production of regenerated cellulose films in food contact? To do so, you need to submit an application for approval on the European Commission's online portal E-Submission Food Chain Platform.
Volltext	<p>Materials that come into contact with food are subject to European coordinated legislation.</p> <p>In good manufacturing practice and under normal conditions, they must not release constituents into the food in quantities which</p> <ul style="list-style-type: none"> • endanger human health • lead to an unacceptable change in the composition of the food, or • cause an impairment of the organoleptic properties - e.g. taste or odor - of the food. <p>As a manufacturer of plastic food contact materials, you are responsible for compliance with these requirements. You must ensure that the contact materials are safe for human health.</p> <p>Food contact materials are materials and articles that are</p>

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- are intended to come into contact with foodstuffs
- Are already in contact with food and are intended to be, or
- reasonably foreseeable to come into contact with food or to transfer their constituents to food during normal or foreseeable use.

In the European Union, and thus also in Germany, no approval is required for the finished food contact material, i.e. the finished product.

However, this does not apply to new substances to be used in the manufacture of food contact plastics. Therefore, if your company wants to use new substances for the production of appropriate regenerated cellulose films, you will need an approval.

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).

If the Federal Office of Consumer Protection and Food Safety (BVL), as the national point of contact in Germany, has been selected by the applicant as the point of contact, the BVL will formally check the application, i.e. for completeness and relevance of the documents. The BVL then forwards the application to the European Food Safety Authority (EFSA).

EFSA publishes detailed specifications on the required documents and content requirements in guidance documents on its website.

EFSA reviews your application on the basis of scientific findings. The European Commission decides on the actual approval.

Even in the case of non-authorization, the European Commission will inform you and you will receive a justification.

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	<p>If the substance meets all the requirements of food law, it is placed on the so-called Union list of authorized substances of the European Union (EU). This means that you and, if applicable, other companies may use the substance for the manufacture of plastic materials that come into contact with food.</p> <p>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 with regard to human health.</p>
Erforderliche Unterlagen	<ul style="list-style-type: none"> You must submit your application documents according to the requirements of EFSA's Guideline document. Details can be found on the EFSA website.
Voraussetzungen	<p>The content and form of your application and the accompanying documents must comply with the requirements or EFSA guidance. Details can be found on the EFSA website.</p>
Kosten	<p>There are no costs involved.</p>
Verfahrensablauf	<p>You must submit the application via the European Commission's online portal ESFC:</p> <ul style="list-style-type: none"> Upload your application, prepared according to EFSA's specifications, directly to the ESFC platform. Details on the procedure are described in the platform manual (user guide). The BVL will receive the application if you select it as national contact point. The BVL formally checks the application. Afterwards, BVL forwards the application within the platform to the responsibility of EFSA. EFSA carries out the scientific review. The European Commission decides on the actual authorization with the involvement of the EU member states.
Bearbeitungsdauer	<p>The BVL usually needs no more than 4 weeks for the initial review of your application. However, queries or additional requests as well as your response times may influence the duration. Only when the documents are complete, the BVL forwards the application to EFSA.</p>
Frist	<p>There is no deadline.</p>

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weiterführende Informationen	<p> https://ec.europa.eu/food/safety/chemical-safety/food-contact-materials_en https://food.ec.europa.eu/system/files/2023-11/gfl_train_supp_esfc_e-sub_user-guide.pdf https://www.efsa.europa.eu/de/applications/foodcontactmaterials/regulationsandguidance 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 </p>
Hinweise	There are no clues or specifics.
Rechtsbehelf	<ul style="list-style-type: none"> • No legal remedies are provided against the BVL. • An appeal against a decision must be filed directly with the European Commission.
Kurztext	<ul style="list-style-type: none"> • Authorization of new substances for food contact regenerated cellulose films according to Directive 2007/42/EC Granting <ul style="list-style-type: none"> • Authorization required for new substances to be used in the manufacture of regenerated cellulose film for food contact applications • Application only electronically via the E-Submission Food Chain Platform (ESFC) • Goal: Food safety • Food contact materials are not allowed to release ingredients to food in quantities that would <ul style="list-style-type: none"> • are likely to endanger human health, or • bring about unacceptable changes in the composition of food, or • adversely affect the organoleptic properties of food - e.g. taste or odor. • Manufacturers of food contact materials are responsible for compliance with food law requirements. They must ensure that contact materials are harmless to health. • Procedure: <ul style="list-style-type: none"> • In Germany, the Federal Office of Consumer Protection and Food Safety (BVL) is the national point

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of contact.

- The BVL confirms receipt of the dossiers within 14 days.
- the EFSA examines the applications on the basis of scientific findings
- the European Commission decides on authorization
- if the substance complies with all food law requirements, it is included in the so-called Union list.
- The substance may only be used for the manufacture of regenerated cellulose film with food contact once it has been included in the Union list.
- Costs: none
- responsible: Contact point for Germany: Federal Office of Consumer Protection and Food Safety (BVL), approval is granted by the European Commission.

Ansprechpunkt

Zuständige Stelle

Formulare

Forms available: No

Written form required: No

Informal application possible: No

Personal appearance required: No

Online services available: Yes

Ursprungsportal

Zulassung von neuen Stoffen für Zellglasfolien im Lebensmittelkontakt gem. Richtlinie 2007/42/EG Erteilung, Zulassung von neuen Stoffen für Zellglasfolien im Lebensmittelkontakt gem. Richtlinie 2007/42/EG Erteilung