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Zulassung von aktiven und intelligenten Substanzen im Lebensmittelkontakt gem. Verordnung (EG) Nr. 450/2009 Erteilung

Heruntergeladen am 10.06.2025

<https://fimportal.de/xzufi-services/102889176/B100019>

Modul	Sachverhalt
Leistungsschlüssel	99118040001000
Leistungsbezeichnung I	Zulassung von aktiven und intelligenten Substanzen im Lebensmittelkontakt gem. Verordnung (EG) Nr. 450/2009 Erteilung
Leistungsbezeichnung II	Apply for approval of active and intelligent substances in food contact materials
Typisierung	1 - Bund: Regelung und Vollzug
Quellredaktion	Bund
Freigabestatus Katalog	fachlich freigegeben (gold)
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	

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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	20.07.2022
Fachlich freigegen durch	Federal Ministry of Food and Agriculture (BMEL)
Handlungsgrundlage	https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=celex%3A32009R0450 https://eur-lex.europa.eu/legal-content/de/ALL/?uri=CELEX%3A32004R1935
Teaser	Do you want to use active and intelligent substances for materials that come into contact with food? Then you need to apply for approval on the European Commission's online portal E-Submission Food Chain Platform.
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 food contact materials, you are responsible for compliance with the legal requirements. You must ensure that the contact materials are safe for human health.

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****What are active and intelligent food contact substances?****

Active materials absorb or release substances to improve the quality of packaged food or extend its shelf life.

Smart materials monitor the condition of packaged food or the environment surrounding it. For example, they provide information about the freshness of the food.

Applications for approval of active and intelligent substances in food contact can only be submitted 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 point of contact 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 and evaluates your application based on scientific evidence. 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 active and intelligent materials or articles meet the legal and scientific requirements, they will be added to the corresponding EU list of permitted substances. They may then be used as food contact materials.

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

Erforderliche Unterlagen

\- You have to submit the application documents according to the requirements of the so-called

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	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.
Kosten	There are no costs involved.
Verfahrensablauf	You can apply for the approval of active and intelligent substances in food contact 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 user guide of the platform. • The BVL will receive the application if you select it as the national contact point. • 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	0 - 4 Woche(n) \- 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 are no deadlines for submission.
weiterführende Informationen	https://ec.europa.eu/food/safety/chemical-safety/food-contact-materials_en https://www.efsa.europa.eu/en/efsajournal/pub/1208

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https://ec.europa.eu/food/horizontal-topics/general-food-law/training-and-support_en
<https://www.efsa.europa.eu/de/applications/foodcontactmaterials/regulationsandguidance>
<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

Rechtsbehelf

\- You file an appeal against a decision directly with the authorizing body, i.e. the European Commission.

Kurztext

- Approval of active and intelligent substances in contact with food according to Regulation (EC) No. 450/2009
 - Active and intelligent substances that are to be used in food packaging, for example, must be approved.
 - Application only electronically via the E-Submission Food Chain Platform (ESFC)
 - Goal: Food safety
 - Food contact materials must not release components into food in quantities that are likely to endanger human health or cause
 - cause an unacceptable change in the composition of food or
 - cause an adverse effect on the organoleptic properties of food, such as taste or odor.
 - Manufacturers of the materials are responsible for compliance with food law requirements
 - Manufacturers must ensure that contact materials are safe for human health
 - Active materials: absorb or release substances to improve quality of packaged foods or extend shelf life
 - Intelligent materials: monitor the condition of packaged food or the surrounding environment, for example, provide information on food freshness
 - in Germany, the Federal Office of Consumer Protection and Food Safety (BVL) is the national contact point
 - the BVL confirms receipt of your documents within 14 days

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- the European Food Safety Authority (EFSA) examines the applications on the basis of scientific findings
- the European Commission decides on approval
- If the active and intelligent substances meet all food law requirements, they are included in the so-called Community list.
- Substances and materials included in the Community list may be used in food contact materials in accordance with the restrictions set out in the list, if applicable
- Cost: none
- responsible: Federal Office of Consumer Protection and Food Safety (BVL)

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 aktiven und intelligenten Substanzen im Lebensmittelkontakt gem. Verordnung (EG) Nr. 450/2009 Erteilung, Zulassung von aktiven und intelligenten Substanzen im Lebensmittelkontakt gem. Verordnung (EG) Nr. 450/2009 Erteilung