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Zulassung von Ausnahmen und Allgemeinverfügungen bei Tabakerzeugnissen Erteilung

Heruntergeladen am 05.07.2025

<https://fimportal.de/xzufi-services/102889190/B100019>

Modul	Sachverhalt
Leistungsschlüssel	99003057001000
Leistungsbezeichnung I	Zulassung von Ausnahmen und Allgemeinverfügungen bei Tabakerzeugnissen Erteilung
Leistungsbezeichnung II	Applying for approval of exemptions and issuing general rulings for tobacco and related products
Typisierung	1 - Bund: Regelung und Vollzug
Quellredaktion	Bund
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	
Verrichtungskennung	Erteilung (1)
SDG-Informationsbereich	Vorschriften für und Anforderungen an Erzeugnisse

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Lagen Portalverbund	Produkt- und Stoffzulassung (2120200)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	15.03.2023
Fachlich freigegeben durch	Federal Ministry of Food and Agriculture (BMEL)
Handlungsgrundlage	https://www.gesetze-im-internet.de/tabakerzg/_39.ht ml https://www.gesetze-im-internet.de/tabakerzg/_40.ht ml
Teaser	If you want to produce or place on the market tobacco and related products that do not meet the requirements applicable in Germany, you can apply for an exemption or a general ruling under certain conditions.
Volltext	<p>Derogation for tobacco and related products</p> <p>In principle, economic operators are responsible for compliance with the legal requirements for tobacco products and related products as part of their business activities.</p> <p>In individual cases, exemptions from the applicable tobacco law requirements can be approved under certain conditions. If you intend to manufacture, handle or place on the market a tobacco product or a related product whose composition deviates from the legal requirements applicable in Germany, you can apply for a derogation from the Federal Office of Consumer Protection and Food Safety (BVL).</p> <p>A derogation has no general effect, but is only valid in individual cases. It is limited to certain products. If the product range is extended, a corresponding extension of the exemption must be applied for.</p> <p>Exemptions may only be granted if it can be assumed that no increased health risk is to be expected and the results may be relevant for amending or supplementing the tobacco regulations. Exceptions to the regulations on adequate labeling may not be</p>

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permitted.

Once an exemption has been granted, the authorities of the federal state in which your company is based will monitor the production and distribution process. Among other things, they check the labeling, proper production and compliance with the requirements, maximum quantities and formulation on which the exemption is based. The official monitoring of the exemption is carried out at the applicant's expense.

General ruling for tobacco and related products imported from other European countries

Tobacco products and related products that are legally on the market in an EU or EEA member state may be brought into other member states and sold there, even if they do not comply with the national regulations applicable there. With one restriction: If a product does not meet the requirements for German consumer health protection, you as an import company must apply for a general ruling from the Federal Office of Consumer Protection and Food Safety (BVL).

Decisions on whether to issue a general ruling are made on a case-by-case basis.

Erforderliche Unterlagen

Please inform the BVL about the deviation of your product from the legal requirements applicable in the Federal Republic of Germany and enclose the following documents:

- Precise description of the facts including the specific deviation from the legal tobacco requirements in Germany.
- Details of all parties involved, such as manufacturer, distributor, user. If the application is submitted by a person authorized to represent the company, corresponding powers of attorney.
- For the application for a special authorization additionally: Evidence that there is no risk to human health beyond the typical risks associated with the consumption of products. Explanation of what results are expected from the exemption that may be of significance for amending or supplementing the

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	<p>tobacco regulations.</p> <ul style="list-style-type: none"> • For applications for general rulings, additional evidence that the product is lawfully manufactured or marketed in another EU or EEA country, for example by means of official proof.
Voraussetzungen	<p>Exemption</p> <ul style="list-style-type: none"> • It is not expected that there is a risk to human health beyond the typical dangers of tobacco consumption. • Results are expected that may be of significance for amending or supplementing the tobacco regulations. <p>General ruling</p> <ul style="list-style-type: none"> • The product applied for is legally manufactured or marketed in another EU or EEA country. • There are no concerns with regard to health protection.
Kosten	<p>Gebühr: 2.300€ - 4.800€</p> <p>First-time granting of the exceptional approval https://www.gesetze-im-internet.de/bmelbgebv/anlage.html</p> <p>Gebühr: Es fallen keine Kosten an</p> <p>General ruling</p>
Verfahrensablauf	<p>You can apply for the derogation or general ruling online via the federal portal or informally in writing to the BVL.</p> <p>Apply for an exemption or general ruling 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. • The BVL will check your information and documents and will contact you if further documents or information are required. Please note that the processing time will be longer if the application documents are incomplete. Processing is only possible

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once all relevant information has been submitted.

- You will receive a notification of approval digitally via the federal portal or by post.
- In the case of an exemption permit, you will receive a notification of fees with a request for payment.

Apply for an exemption or general ruling informally in writing:

- Formulate an informal application and attach all the documents listed under "Required documents".
- Send your application to the BVL. The application documents can be sent on a CD-ROM or DVD.

Please note: USB data carriers or links for downloads from other platforms will not be accepted for reasons of data security.

- The BVL will check your information and documents and will contact you if further documents or information are required. Please note that the processing time will be longer if the application documents are incomplete. As processing is only possible once all relevant information has been submitted, you will be asked to submit additional documents if necessary.
- You will then receive notification of your admission.
- In addition, you will receive a separate notification of fees with a request for payment in the case of an exemption.

Bearbeitungsdauer

3 - 12 Stunde(n)

Applies to both exceptional approvals and general rulings. The processing time can be shortened for follow-up applications for uncomplicated matters, e.g. renaming a product.

Frist

0 - 3 Jahr(e)

The approval of an exemption is valid for a maximum of 3 years. It can be extended 3 times upon request for a maximum of 3 years each time, provided that the conditions for approval are still met.

1 Monat(e)

0 - 90 Tag(e)

A decision on your application for general rulings

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	should be made within 90 days. If this is not possible, the BVL will inform you of the reasons for this.
weiterführende Informationen	https://www.bvl.bund.de/DE/Arbeitsbereiche/03_Verbraucherprodukte/03_AntragstellerUnternehmen/07_Ausnahmegenehmigungen/bgs_ausnahmeGenehm_node.html https://www.bvl.bund.de/DE/Arbeitsbereiche/03_Verbraucherprodukte/03_AntragstellerUnternehmen/06_Allgemeinverfuegungen/bgs_allgVerf_node.html?cms_the_ma=Allgemeinverf%C3%BCgungen+nach+%C2%A7+40+TabakerzG https://www.bvl.bund.de/tabakrecht https://www.bvl.bund.de/Ueberblick_Tabak
Hinweise	
Rechtsbehelf	<ul style="list-style-type: none"> • Appeal. Further information on how to lodge an appeal can be found in the notification of your application. • Appeal to the administrative court
Kurztext	<ul style="list-style-type: none"> • Approval of exemptions and general rulings for tobacco products Issuance • In principle, economic operators are responsible for compliance with the legal requirements for tobacco products and related products as part of their business activities. • In individual cases, exemptions from the applicable tobacco law requirements may be approved under certain conditions. • Tobacco products and related products that are lawfully manufactured or marketed in another EU or EEA country may, in principle, also be marketed in Germany. Exceptions are products that do not comply with consumer health protection regulations. In this case, a general ruling must be applied for. In individual cases, it is checked whether the requirements for issuing a general ruling are met. • Exemptions and general rulings must be applied for. • Notification of the products in the European Commission's online portal, the EU Common Entry Gate (EU-CEG), is required in all cases • Fees: Exceptional approval: EUR 2,300 to EUR 4,800 General ruling: free of charge • Processing time: usually 3 to 12 months

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	<ul style="list-style-type: none"> • Applications can be submitted: online via the federal portal informally by post • Responsible: Federal Office of Consumer Protection and Food Safety in agreement with the Federal Office of Economics and Export Control
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	Zulassung von Ausnahmen und Allgemeinverfügungen bei Tabakerzeugnissen Erteilung, Zulassung von Ausnahmen und Allgemeinverfügungen bei Tabakerzeugnissen Erteilung