

99003059001000

Zulassung von neuartigen Tabakerzeugnissen Erteilung

Heruntergeladen am 10.06.2025

<https://fimportal.de/xzufi-services/102889198/B100019>

Modul	Sachverhalt
Leistungsschlüssel	99003059001000
Leistungsbezeichnung I	Zulassung von neuartigen Tabakerzeugnissen Erteilung
Leistungsbezeichnung II	Applying for approval of novel tobacco 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
Lagen Portalverbund	Produkt- und Stoffzulassung (2120200), Verbraucherschutz (2140100)
Einheitlicher	

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Ansprechpartner	Nein
Fachlich freigegeben am	15.03.2023
Fachlich freigegeben durch	Federal Ministry of Food and Agriculture (BMEL)
Handlungsgrundlage	Section 12 of the Tobacco Products Act in conjunction with Section 9 of the Tobacco Products Ordinance https://www.gesetze-im-internet.de/tabakerzg/_12.html https://www.gesetze-im-internet.de/tabakerzv/_9.html
Teaser	Novel tobacco products, for example heated tobacco products, may only be placed on the market if they have been approved. You can apply for approval from the Federal Office of Consumer Protection and Food Safety (BVL).
Volltext	<p>In Germany, novel tobacco products may only be placed on the market if they have been approved. The legislator defines novel tobacco products as tobacco products that</p> <ul style="list-style-type: none"> • do not fall into one of the following categories: <ul style="list-style-type: none"> • Cigarettes, • roll-your-own tobacco, • pipe tobacco, • water pipe tobacco, • cigars, • cigarillos, • chewing tobacco, • snuff and • tobacco for oral use; • and which are placed on the market after May 19, 2014. <p>E-cigarettes and herbal smoking products, for example herbal cigarettes, are not tobacco products and therefore not novel tobacco products within the meaning of this definition.</p> <p>If your company produces novel tobacco products or imports them to Germany and intends to place them</p>

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on the market in Germany, you must apply for approval for these products from the Federal Office of Consumer Protection and Food Safety (BVL).

The authorization also includes a statement as to whether the novel tobacco product is a smoking tobacco product or a smokeless tobacco product.

The authorization can be revoked if your tobacco product no longer meets the legal requirements.

The authorization does not release you from fulfilling the legal requirements, including the notification of the products in the EU Common Entry Gate (EU-CEG) notification portal.

Erforderliche Unterlagen

Please enclose the following documents in electronic form with your German-language application in accordance with Section 9 (2) of the Tobacco Products Ordinance:

- Name, address and electronic contact details of the manufacturer or importer,
- Description of the novel tobacco product, instructions for use and information on ingredients and emissions as well as the analytical methods and measurement procedures used,
- available scientific studies on toxicity, addictive effects and attractiveness of the novel tobacco product, in particular with regard to its ingredients and emissions
- available studies on market research and on the preferences of the consumer groups concerned with regard to ingredients and emissions, as well as summaries of the market studies they carry out on the occasion of the launch of new tobacco products; and
- other available information, including a risk-benefit analysis of the novel tobacco product, its expected impact on tobacco cessation and initiation, and expected consumer perceptions.

The listed annexes to the application are also accepted in English.

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If there are changes in the composition, if new studies are available or if the BVL requests further information, you must submit this immediately.

Voraussetzungen

- You apply for authorization for a novel tobacco product, i.e. a tobacco product,
 - that does not fall into one of the following categories:
 - Cigarettes,
 - roll-your-own tobacco,
 - pipe tobacco,
 - water pipe tobacco,
 - cigars,
 - cigarillos,
 - chewing tobacco,
 - snuff and
 - tobacco for oral use;
 - and which is placed on the market after May 19, 2014.
- The application must be submitted by the manufacturer or importer.

The product subject to the application must meet the requirements of tobacco law.

Kosten

Verfahrensablauf

You can apply for admission online via the federal portal.

Apply for admission online via the federal portal:

- 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 contact you if further documents or information are required. Please note that the processing time will be longer if the application documents are incomplete.

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	<p>As processing is only possible after all relevant information has been submitted, you will be asked to submit additional documents if necessary.</p> <ul style="list-style-type: none"> • You will receive a notification of admission digitally via the federal portal or by post. • You will also receive a separate notification of fees with a request for payment. <p>If you are unable to submit the application via the federal portal, please contact the BVL at poststelle@bvl.bund.de.</p>
Bearbeitungsdauer	<p>6 - 12 Monat(e)</p> <p>The approval of novel tobacco products is a case-by-case examination that can take some time. The processing time also depends on the completeness of the documents.</p>
Frist	1 Monat(e)
weiterführende Informationen	<p>https://www.bvl.bund.de/Tabakrecht</p> <p>https://www.bvl.bund.de/Ueberblick_Tabak</p>
Hinweise	<p>The following information is available:</p> <p>An application for authorization does not replace the legal requirements generally applicable to tobacco products, including notification requirements (EU-CEG). The notification of a product in EU-CEG as a novel tobacco product does not constitute an application for authorization.</p> <p>To ensure a smooth process, make sure that the application documents, including the notification in the EU-CEG, are complete at the time of application.</p>
Rechtsbehelf	<ul style="list-style-type: none"> • Appeal. You will find further information on how to lodge an objection in the notification of your application. • Appeal to the administrative court. You can find more information on how to lodge a complaint in the notification of your objection.
Kurztext	<ul style="list-style-type: none"> • Authorization of novel tobacco products Issue

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- Novel tobacco products may only be placed on the market if they have been authorized
- Authorization requirement applies to each individual product or variety
- Authorization is subject to compliance with the legal requirements
- Authorization must be applied for
- Fees: EUR 8,500 to EUR 11,200
- Processing time: usually 6 to 12 months
- Applications can be submitted:
 - online via the federal portal
- 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 neuartigen Tabakerzeugnissen
Erteilung, Zulassung von neuartigen
Tabakerzeugnissen Erteilung