

99003095011000

Permission to trade in commodities Amendment

Heruntergeladen am 10.06.2025

<https://fimpportal.de/xzufi-services/106189848/B100019>

Modul	Sachverhalt
Leistungsschlüssel	99003095011000
Leistungsbezeichnung I	Permission to trade in commodities Amendment
Leistungsbezeichnung II	Change permission to handle basic substances
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	Änderung (11)
SDG-Informationsbereich	nicht SDG-relevant
Lagen Portalverbund	Erlaubnisse und Genehmigungen (2010400), Import und Export (2070200)
Einheitlicher	

Modul	Sachverhalt
Ansprechpartner	Nein
Fachlich freigegeben am	13.12.2024
Fachlich freigegeben durch	Federal Ministry of Health (BMG)
Handlungsgrundlage	https://eur-lex.europa.eu/legal-content/DE/ALL/?uri=CELEX%3A32004R0273 https://eur-lex.europa.eu/legal-content/DE/ALL/?uri=CELEX%3A32015R1011 https://eur-lex.europa.eu/legal-content/DE/ALL/?uri=CELEX%3A32005R0111 https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX%3A32015R1013&from=DE
Teaser	<p>If you wish to change your authorization to trade in category 1 precursors, you can submit an application. This may concern the precursors, the processes, the business premises or the responsible representative(s).</p>
Volltext	<p>The handling of precursors that can potentially be converted into drugs is subject to strict controls, especially if they are category 1 precursors that can be used to produce drugs with a high potential for dependence and abuse.</p> <p>You require a permit for any handling of these precursors. This is the case if you</p> <ul style="list-style-type: none"> • possess • manufacture • process • store them • trade with them • arrange transactions with them • carry out drop shipments, even if the raw materials do not touch the territory of the European Union (EU) • import into the EU • export from the EU <p>If you already have a permit to handle precursors but wish to change it, you must apply for a new permit. This may be the case if</p>

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- another basic substance is added
- a new process is to be included
- the location of your premises where you carry out the operations changes.

If the responsible representative or the name of the company changes, you must also inform the BfArM.

You can submit all applications informally in writing.

Erforderliche Unterlagen

- Your complete details:
 - Name
 - your address
 - telephone number
 - Fax number, if available
 - e-mail address
- Description and Combined Nomenclature (CN) code of the required raw materials and their salts
- For mixtures:
 - the name of the mixture
 - the name and CN codes of all the basic substances contained in the mixture
 - Indication of the maximum possible content of such basic substances in the mixture
 - a description of the operations envisaged, for example
 - Trade in the European Union
 - further processing
 - import
 - export
 - Brokerage
 - Intermediary transactions
- completed declaration form for the appointment of the responsible agent(s)
 - current police clearance certificate of the appointed responsible agent(s)
 - certified extract
 - from the commercial register or
 - certified copy of the business registration

Voraussetzungen

- You must be resident in Germany.
- The application must be complete and plausible.

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- There must be no reasonable grounds for doubting the suitability and reliability of the applicant or the designated responsible representative(s).

Kosten

Abgabe: 110€
For a new or change application per raw material and per operating site
<https://www.gesetze-im-internet.de/bmgbgebv/index.html>

Abgabe: 55€
For a new or change application for a basic substance for scientific or analytical purposes without a commercial purpose per basic substance and per operating site
<https://www.gesetze-im-internet.de/bmgbgebv/index.html>

Verfahrensablauf

You can apply online or informally in writing to the BfArM for a permit to handle category 1 precursors.

Apply for a permit online:

- Go to the website of the federal portal and call up the online application. This will guide you step by step through the necessary information, which you can enter electronically.
 - You will need the following for the application:
 - an Elster company account
 - an Elster certificate.
 - Upload the required documents as a PDF, PNG or JPEG file with a maximum size of 10 megabytes each and send the application.
 - If any of your details or documents are incomplete, you will receive a request to submit them within a deadline set by the BfArM.
 - If you are granted a license, the BfArM will send you the license certificate by post together with a notification of fees.

Apply for a permit informally in writing:

- Draw up an application with all the required information, print it out and sign it.

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	<ul style="list-style-type: none"> • Send your informal application to the BfArM by post. <p>If any of your details or documents are incomplete, you will receive a request to submit them within a deadline set by the BfArM. If you are granted a license, the BfArM will send you the license certificate and a fee notice by post.</p>
Bearbeitungsdauer	42 Tag(e)
Frist	<p>3 Jahr(e)</p> <p>The BfArM can either limit the validity of the license to a maximum period of 3 years or require you to prove at regular intervals of no more than 3 years that you still meet the requirements for the license.</p> <p>The application for a license must be submitted before you start working with category 1 precursors. If any of your details or documents in your application for authorization are incomplete, you will be asked to submit them within a deadline set by the BfArM. If the name or legal form of your company changes, if you appoint a new responsible representative or if their name or address changes, you must inform the BfArM within 10 working days by e-mail or in writing.</p>
weiterführende Informationen	<p>https://www.bfarm.de/DE/Bundesopiumstelle/Grundstoffe/Erlaubnis/_node.html</p> <p>https://www.bfarm.de/DE/Bundesopiumstelle/_FAQ/Grundstoffe/Erlaubnis-und-Registrierungspflicht/faq-liste.html?nn=471312</p>
Hinweise	There are no indications or special features.
Rechtsbehelf	<ul style="list-style-type: none"> • Contradiction <ul style="list-style-type: none"> • You will find detailed information on how to lodge an objection in your notification of your application for a change of permit.
Kurztext	<ul style="list-style-type: none"> • A permit is required for handling category 1 precursors <ul style="list-style-type: none"> • Basic substances are also known as: <ul style="list-style-type: none"> • scheduled substances • drug precursors • Category 1 includes precursors that can potentially

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be converted into drugs with a high potential for dependence and abuse

- a license is required for precursors:
 - possesses
 - manufactures
 - processes
 - stores
 - trades with them
 - arranges transactions with them
 - carries out drop shipments, even if the raw materials do not touch the territory of the European Union (EU)
- imports into the EU
- exports from the EU
- anyone who already has a permit but wishes to change it must apply for a new permit
 - This may be the case if:
 - another basic substance is added,
 - a new process is to be included or
 - the location of the premises where the operations are carried out changes.
 - the BfArM must be notified of any changes to the responsible authorized representative or the name of the company
 - all applications are made informally in writing.
 - Processing time: on average around 42 days
 - Responsible: Federal Institute for Drugs and Medical Devices (BfArM)

Ansprechpunkt
Zuständige Stelle
Formulare
Ursprungsportal

Erlaubnis für den Handel mit Grundstoffen Änderung,
 Permission to trade in commodities Amendment