

99003021005000

Heruntergeladen am 08.07.2025

<https://fimportal.de/services/99003021005000>

Modul	Sachverhalt
Leistungsschlüssel	99003021005000
Leistungsbezeichnung I	
Leistungsbezeichnung II	Activities with pathogens - apply for a permit
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Baustein Leistungen
Freigabestatus Katalog	fachlich freigegeben (gold)
Freigabestatus Bibliothek	fachlich freigegeben (gold)
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Health (individuell, 003)
Verrichtungskennung	Erlaubnis (005)
SDG-Informationsbereich	Erlangung von Lizenzen, Genehmigungen oder Zulassungen im Hinblick auf die Gründung und Führung eines Unternehmens
Lagen Portalverbund	Anmeldepflichten (2010100), Erlaubnisse und Genehmigungen (2010400)

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Einheitlicher Ansprechpartner	
Fachlich freigegeben am	27.06.2024
Fachlich freigegeben durch	Federal Ministry of Health (BMG)
Handlungsgrundlage	https://www.gesetze-im-internet.de/ifsg/_44.html https://www.gesetze-im-internet.de/ifsg/_45.html https://www.gesetze-im-internet.de/ifsg/_46.html https://www.gesetze-im-internet.de/ifsg/_47.html https://www.gesetze-im-internet.de/ifsg/_49.html
Teaser	If you want to import pathogens into Germany, export them, store them, dispense them or work with them, you need a permit from the competent authority.
Volltext	<p>You require a permit in accordance with the Infection Protection Act if you are the person responsible for</p> <ul style="list-style-type: none"> • import pathogens into Germany, • export them from Germany, • store them, • dispense them or • want to work with them. <p>The following are considered pathogens</p> <ul style="list-style-type: none"> • viruses, • bacteria, • fungi, • parasites and • other agents that can cause an infection or transmissible disease in humans. <p>Activities involving pathogens include in particular</p> <ul style="list-style-type: none"> • Tests with pathogens capable of reproduction, • microbiological and serological tests to identify reportable pathogens using procedures for the targeted enrichment or multiplication of pathogens; <p>Certain activities or persons who carry out microbiological tests for diagnostic purposes for the direct treatment of their own patients are exempt from</p>

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the licensing requirement. These include

- Doctors,
- dentists and
- veterinarians;
- Persons who carry out microbiological quality assurance work and have the necessary expertise and the competent authority exempts them from the permit requirement upon request;
- Employees who work under the supervision of a person who has a permit or is exempt from the permit requirement;
- certain procedures, for example sterility tests;

If you belong to one of the above-mentioned groups, please contact the authority responsible for you before starting work. You must register your activity there.

Erforderliche Unterlagen

Proof of a degree:

- Proof of completion of a degree course in human, dental or veterinary medicine, pharmacy or
- Proof of completion of a natural science course at a university of applied sciences or university with microbiological content by means of semester certificates, examination certificates, license to practice medicine or final examination or exam

Proof of employment:

- Proof of two years of full-time work with pathogens under the supervision of a person with a license or
- Proof of another two years of full-time professional work in bacteriology, mycology, parasitology or virology, if equivalent expertise was acquired in the process

Proof of reliability:

- Police clearance certificate (document type O)

Voraussetzungen

- You have the necessary expertise and can demonstrate this through
- one of the following degrees: Human, dental or veterinary medicine pharmacy a degree in natural

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sciences from a university of applied sciences or university with microbiological content and at least two years of full-time work with pathogens

- You have proven to be reliable in dealing with pathogens.

Note: Other full-time professional activities of at least two years in the fields of bacteriology, mycology, parasitology or virology also count as proof of expertise. The prerequisite is that you have acquired equivalent expertise.

Kosten

Verfahrensablauf

- You apply for a permit from the authority responsible for you.
- The authority checks your documents. You will then receive the desired permit or a notice of refusal.
- To prevent communicable diseases, it may restrict the permit to certain activities or certain pathogens, or attach conditions to it.

Bearbeitungsdauer

3 Monat(e)
The competent authority decides within three months.

Frist

You need permission from the authorities in good time before the start of your activity in order to be able to report your activity 30 days before the planned start.

weiterführende Informationen

Hinweise

All activities involving pathogens, including activities that do not require a permit, must be notified.

Rechtsbehelf

Administrative court action

Kurztext

- Activities with pathogens Permit
- Importing, exporting, storing, dispensing or working with pathogens requires a permit under the Infection Protection Act
- there are exemptions from the permit requirement for certain groups of people or activities
- personal permits are issued if the required expertise and reliability are present
- Responsible: competent authority

Modul	Sachverhalt
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	