

99003021169000

Heruntergeladen am 08.07.2025

<https://fimportal.de/services/99003021169000>

Modul	Sachverhalt
Leistungsschlüssel	99003021169000
Leistungsbezeichnung I	
Leistungsbezeichnung II	Display activities with pathogens
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	Anzeige (169)
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	<p>DIN EN12740 - Guidelines for the treatment, inactivation and testing of waste</p> <p>DIN 30739 - Containers for infectious waste with a nominal volume of 30 l to 60 l</p> <p>DIN 58956-10 - Medical microbiology; medical microbiology laboratories; safety labeling</p> <p>DIN 58956-3 - Medical microbiology; medical microbiology laboratories; requirements for the organization plan</p> <p>DIN 58956-5 - Medical microbiology; medical microbiology laboratories; requirements for the hygiene plan</p> <p>https://www.gesetze-im-internet.de/ifsg/_44.html</p> <p>https://www.gesetze-im-internet.de/ifsg/_45.html</p> <p>https://www.gesetze-im-internet.de/ifsg/_49.html</p> <p>https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRBA/pdf/TRBA-100.pdf?__blob=publicationFile</p> <p>https://www.gesetze-im-internet.de/biostoffv_2013/_4.html</p> <p>https://www.gesetze-im-internet.de/biostoffv_2013/_5.html</p> <p>https://www.gesetze-im-internet.de/biostoffv_2013/_6.html</p> <p>https://www.gesetze-im-internet.de/biostoffv_2013/_7.html</p> <p>https://www.gesetze-im-internet.de/biostoffv_2013/_12.html</p>
Teaser	If you have a permit to work with pathogens and you want to take up this activity for the first time, you must notify the competent authority.
Volltext	The term "pathogens" refers to agents capable of

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reproduction. These include, for example

- viruses
- bacteria
- fungi
- parasites
- or other biologically transmissible agents

These can cause an infection or a communicable disease in humans.

If you, as the responsible person or permit holder, intend to take up activities with pathogens, whether without a permit or subject to a permit, you must notify the competent authority.

The obligation to notify applies to new activities that have not yet been registered. However, it also applies if this activity has already been reported previously by another responsible person or permit holder. The activity is only deemed to have started if the responsible person has never previously worked with the pathogen.

Employees who work under the supervision of a person who has the required permit for activities involving pathogens are not required to notify the authorities.

Activities with pathogens are deemed to be

- Experiments with pathogens capable of reproduction,
- microbiological tests and methods for the detection of pathogens subject to mandatory notification using process steps for the targeted enrichment or multiplication of pathogens.

Even if no permit is required, a person working with pathogens must still report this activity.

Erforderliche Unterlagen

- certified copy of the permit in accordance with the Infection Protection Act, if this was issued by another authority, or information on exemption from a permit
- Information on the nature and scope of the intended activities

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- Information on disposal measures: Listing or naming of the pathogens Description of the disposal routes and disposal procedures for infectious waste
- Information on the presence of an animal house
- Information on the condition of the rooms and facilities: Submission of the floor plan with functional designation of the rooms, i.e. designation of the floor, representation of the access routes, Designation of the laboratory rooms for microbiological work, Description of the function of the laboratory rooms. Description of the boundaries to other areas in which no activities involving biological agents of the specified risk group are carried out. An assessment of the risk and assignment of the activities to a protection level Description of the room equipment and the room layout. A detailed description of the work rooms is required, in particular a description of the surfaces, laboratory benches, installations, ventilation systems, windows, desks. Description of the supply and disposal areas, ancillary rooms, any animal stalls and technical equipment. Preparation of a list of laboratory equipment with location details, in particular a description of the steam sterilizer used for the disposal of biological agents. Information on maintenance, effectiveness checks and description of the waste containers for the disposal of microbiological waste.
- Description of the protective measures: Evidence of protective measures for targeted and non-targeted activities involving biological agents in laboratories Presentation of the labeling of workplaces, in particular the placement of doors, collection containers and furnishings with the biohazard symbol
- Presentation of the operating instructions
- Presentation of the hygiene plan
- Information on the presence of an animal shed

Voraussetzungen

- Permission or exception or exemption
- There is no risk to public health. The main reasons for this are suitable rooms or facilities are available for the type and scope of the activities and the conditions for safe disposal are met.

Kosten

Abgabe: Es fallen keine Kosten an

Verfahrensablauf

You must notify the competent authority of the activity

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	at least 30 days before you intend to take it up.
Bearbeitungsdauer	30 days after submission of the complete documents.
Frist	The activity must be notified at least 30 days before the intended commencement of activities. The activity may only commence if the notification is complete and the activity is permitted after the documents and premises have been checked.
weiterführende Informationen	
Hinweise	All activities involving pathogens, including activities that do not require a permit, must be notified.
Rechtsbehelf	Administrative court action
Kurztext	<ul style="list-style-type: none"> • Activities with pathogens Notification • Activities involving pathogens must be notified to the competent authority before commencement • activities with pathogens that do not require a permit are also subject to notification • Responsible persons or permit holders are subject to the notification requirement • Employees are not subject to notification • Responsible: competent authority
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	