

99003021169000, 99003021169000

Display activities with pathogens

Heruntergeladen am 08.07.2025

<https://fimportal.de/xzufi-services/218499226/L100038>

Modul	Sachverhalt
Leistungsschlüssel	99003021169000, 99003021169000
Leistungsbezeichnung I	Display activities with pathogens
Leistungsbezeichnung II	Display activities with pathogens
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Thüringen
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	fachlich freigegeben (gold)
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Gesundheit (003)
Verrichtungskennung	Anzeige (169)
SDG-Informationsbereich	Erlangung von Lizzenzen, Genehmigungen oder Zulassungen im Hinblick auf die Gründung und Führung eines Unternehmens
Lagen Portalverbund	Erlaubnisse und Genehmigungen (2010400), Anmeldepflichten (2010100)

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Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	23.02.2024
Fachlich freigegeben durch	Thuringian Ministry of Labor, Social Affairs, Health, Women and Family
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 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/_49.html https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRBA/pdf/TRBA-100.pdf?__blob=publicationFile https://www.gesetze-im-internet.de/biostoffv_2013/_4.html https://www.gesetze-im-internet.de/biostoffv_2013/_5.html https://www.gesetze-im-internet.de/biostoffv_2013/_6.html https://www.gesetze-im-internet.de/biostoffv_2013/_7.html https://www.gesetze-im-internet.de/biostoffv_2013/_12.html 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/_49.html https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRBA/pdf/TRBA-100.pdf?__blob=publicationFile</p>

Modul**Sachverhalt**

blob=publicationFile
https://www.gesetze-im-internet.de/biostoffv_2013/_4.html
https://www.gesetze-im-internet.de/biostoffv_2013/_5.html
https://www.gesetze-im-internet.de/biostoffv_2013/_6.html
https://www.gesetze-im-internet.de/biostoffv_2013/_7.html
https://www.gesetze-im-internet.de/biostoffv_2013/_12.html

Teaser

Do you have a permit to work with pathogens and now want to take up this activity for the first time? Then you must notify the competent authority of the activity. You can find more information here.

Volltext

The term "pathogens" refers to agents capable of reproduction (viruses, bacteria, fungi, parasites) or other biologically transmissible agents that can cause an infection or a transmissible disease in humans.

If you as the responsible person or permit holder intend to take up specific activities with pathogens (permit-free or subject to a permit), you must notify the competent authority.

The obligation to notify exists regardless of whether the activities have already been previously notified by another responsible person or permit holder, or whether they are new activities that have not yet been notified. The activity is taken up "for the first time" if the responsible person has never previously worked with the specific pathogen.

There is no obligation to notify employees who work under the supervision of a person who has the required permit for activities involving pathogens.

Activities involving pathogens include in particular

- Experiments with pathogens capable of reproduction,
- microbiological tests and methods for the detection of pathogens subject to mandatory reporting,
- targeted enrichment or multiplication of pathogens,

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- the storage of pathogens.

Important:

Even if you do not require a permit but carry out activities involving pathogens, you must report this.

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 the permit within the meaning of the Infection Protection Act
- Information on the nature and scope of the intended activities and disposal measures: Listing or naming of the pathogens in accordance with the Infection Protection Act and classification of the pathogens (biological agents) in risk groups in accordance with the Biological Agents Ordinance Presentation of the disposal routes and disposal procedures for infectious waste in accordance with "Protective measures for activities involving biological agents in laboratories" and "Guidelines for the treatment, inactivation and testing of waste".
- 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 demarcation to other areas in which no activities involving biological agents of the specified risk group are carried out. Risk assessment and assignment of the activities to a protection level in accordance with the Biological Agents Ordinance. Description of the room equipment and room layout. A detailed description of the work rooms is required, in particular a description of the surfaces, laboratory tables, installations, ventilation systems, windows, desks. Description of the supply and disposal areas, the ancillary rooms, any animal stalls and the technical equipment. Compilation 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

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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 in accordance with the "Technical Rules for Biological Agents". Presentation of the labeling of workplaces, in particular the installation of doors, collection containers and furnishings with the biohazard symbol in accordance with "Biological Agents Ordinance Annex I" or DIN standard "Medical-microbiological laboratories; safety labeling".
- Submission of the operating instructions in accordance with the Biological Agents Ordinance and DIN standard "Medical-microbiological laboratories; requirements for the organizational plan"
- Submission of the hygiene plan in accordance with the "Technical Rule for Biological Agents" and DIN standard "Medical-microbiological laboratories; requirements for the hygiene plan")
- Information on the presence of an animal house

Voraussetzungen

- Permit or exemption in accordance with the Infection Protection Act
- There is no risk to public health. In particular suitable rooms or facilities must be available for the type and scope of the activities and the conditions for safe disposal must be met.

Kosten

The fees are based on the time spent and any expenses incurred.

Verfahrensablauf

You must submit the notification to the competent authority at least 30 days before you intend to start work.

The authority will check your documents and carry out an on-site inspection if necessary.

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 not prohibited after examination of the documents and the premises.

Modul	Sachverhalt
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 commencing, regardless of whether they require a permit • Those responsible or permit holders are subject to notification; their employees are not subject to notification • Responsible: Thuringian State Office for Consumer Protection
Ansprechpunkt	
Zuständige Stelle	Thuringian State Office for Consumer Protection, Department 31
Formulare	
Ursprungsportal	Tätigkeiten mit Krankheitserregern anzeigen, Display activities with pathogens