

99006051261000, 99006051261000

Display activities with biological agents

Heruntergeladen am 12.06.2025

<https://fimportal.de/xzufi-services/208198577/L100038>

Modul	Sachverhalt
Leistungsschlüssel	99006051261000, 99006051261000
Leistungsbezeichnung I	Display activities with biological agents
Leistungsbezeichnung II	Display activities with biological agents
Typisierung	3 - Bundesaufsichtsverwaltung: Regelung
Quellredaktion	Thüringen
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	fachlich freigegeben (silber)
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Arbeitsschutz (006)
Verrichtungskennung	Entgegennahme (261)
SDG-Informationsbereich	Erlangung von Lizenzen, Genehmigungen oder Zulassungen im Hinblick auf die Gründung und Führung eines Unternehmens
Lagen Portalverbund	Arbeitssicherheit (2030500), Erlaubnisse und Genehmigungen (2010400)

Modul	Sachverhalt
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	27.02.2024
Fachlich freigegeben durch	Ministry of Labor, Health and Social Affairs NRW Thuringian Ministry of Labor, Social Affairs, Health, Women and Family 11.09.2024
Handlungsgrundlage	https://www.gesetze-im-internet.de/biostoffv_2013/_16.html https://www.gesetze-im-internet.de/biostoffv_2013/_16.html http://www.gesetze-im-internet.de/biostoffv_2013/_16.html http://www.gesetze-im-internet.de/biostoffv_2013/_16.html
Teaser	If you take up targeted activities with biosubstances of risk group 2 for the first time, or activities with biosubstances of risk group 3 that do not require a permit, you must report this. You can find out more here.
Volltext	<p>The Biological Agents Ordinance (BioStoffV) summarizes biological agents under the term "biological agents". Biological agents are essentially microorganisms, such as bacteria, fungi or viruses, which can endanger humans through infections, toxic, sensitizing or other health-damaging effects.</p> <p>Many employees are exposed to biological agents in the course of their work. Some examples are activities in the areas of healthcare, waste treatment, wastewater technology, animal husbandry and food production.</p> <p>Here, the legislator differentiates between targeted and non-targeted activities. A targeted activity is, for example, the planned cultivation of a known bacterium, e.g. a tuberculosis pathogen. However, non-targeted activities are predominantly carried out in which the biological agents occur as accompanying substances or contaminants and are not the target of the work. Examples of this are waste sorting facilities,</p>

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archives or work in forestry. The organisms are classified into risk groups 1-4 according to the risk of infection they pose based on the latest scientific findings, with risk group 1 representing the lowest risk.

As an employer, you are obliged to notify the competent authority of the following activities

- in laboratories, in laboratory animal husbandry and in biotechnology the first commencement

- a specific activity with biosubstances of risk group 2
- an activity with biosubstances of risk group 3, insofar as the activities do not require a permit are not subject to authorization
- any change to the permitted or notified activities if these are significant for safety and health protection, for example activities aimed at aiming to increase the virulence of the biosubstance or the inclusion of activities involving other risk group 3 or 4 biosubstances
- the admission of an infected patient to a patient ward of protection level 4
- the cessation of an activity requiring a permit in accordance with the German Ordinance on Biological Agents (BioStoffV).

Erforderliche Unterlagen

The notification must include the following information:

- Name and address of the employer,
- a description of the planned activities, including the name of the premises where these activities are to be carried out,
- the planned measures to protect the health and safety of employees.
- Assignment of tasks in accordance with the Occupational Health and Safety Act
- Location sketch, floor plan sketch showing the safety equipment (such as autoclave, MSW, centrifuges, etc.); the facilities for decontamination, cleaning and disinfection (including hand wash basin, disinfectant, hand wash and disposable towel dispenser, eye wash); viewing window and direction of opening of the doors;

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storage location of personal protective equipment and street clothes.

- List of biological agents in accordance with the Biological Agents Ordinance
- Result of the risk assessment in accordance with the Biological Agents Ordinance in conjunction with the Occupational Health and Safety Act
- Deviations from protective measures
- Test report of the installation test of the devices whose safety depends on the installation conditions
- Disinfection/hygiene plan

The obligation to notify can also be fulfilled by sending the competent authority a copy of a notification, authorization or permit in accordance with another legal provision within the deadline if this contains equivalent information.

Voraussetzungen

If necessary, a permit must be applied for in accordance with Section 44 of the Infection Protection Act (IfSG) or Section 2 of the Animal Pathogens Ordinance (TierSEV) or exemption from the permit must be justified in accordance with Section 45 IfSG or Section 3 TierSEV.

Every company that wants to carry out such activities with biosubstances needs the required specialist knowledge of its personnel in order to be able to do so.

Kosten

Is based on the respective administrative fee schedule of the federal state or on the fee statutes of the authorities responsible under federal state law.

Verfahrensablauf

- The notification must be submitted in writing to the competent authority in accordance with state law.
- The competent authority checks the documents
- As a rule, there is no confirmation of notification

The written notification must be submitted by an authorized representative of the company. The required notification form can be downloaded [here](#).

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Bearbeitungsdauer	The obligation to notify is deemed to have been fulfilled if the notification is received by the competent authority within the deadline. As a rule, there is no confirmation of notification, but further documents can be requested or, if the requirements are not met (Annexes BioStoffV, TRBA 100 etc.), the rectification of the defects can be demanded.
Frist	The notification must be made at least 30 days • before the commencement of notifiable activities, • before changing the permitted or notified activities or • before discontinuation of an activity requiring a permit. Notification of the admission of an infected patient to a patient ward of protection level 4 must be made immediately.
weiterführende Informationen	
Hinweise	<p>If a report is not made, not made correctly, not made in full or not made in good time in accordance with Section 16 Paragraph BiostoffV, this constitutes an administrative offense. If it is an intentional act that endangers the life or health of an employee, this is punishable under § 26 number 2 of the Occupational Health and Safety Act.</p> <p>Activities in HIV, HBV or HCV diagnostics classified in risk group 3 (***) must be notified if the activities are aimed at these biological agents and are to be carried out regularly.</p> <p>Only contact with blood samples during processing is not notifiable if the activities are not aimed at these biological agents in diagnostics and are not to be carried out regularly</p>
Rechtsbehelf	<p>Appeal (depending on state law, the appeal may be excluded)</p> <p>Action before the administrative court</p>
Kurztext	<ul style="list-style-type: none"> • Notification of activities involving biological agents • The competent authority must be notified when work with certain biological agents is commenced for

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the first time.

- This applies to targeted activities with biological agents of risk group 2, protection level 2 and with biological agents of risk group 3 **, protection level 3 and non-targeted activities of protection level 2 with biosubstances of risk group 3, including those marked with (**), provided that the activities are aimed at these biosubstances and are to be carried out regularly, in laboratories, in laboratory animal husbandry and in biotechnology.

- Any company wishing to carry out such activities with biosubstances requires the specialist knowledge of the personnel required by TRBA 200 in order to be able to carry them out.

- Certain documents must be submitted.

- Notification must be made at least 30 days before the start of the activity.

- Responsible: locally competent regional inspectorate of Department 6 Occupational Health and Safety of the Thuringian State Office for Consumer Protection (TLV).

Ansprechpunkt

Please contact the Thuringian State Office for Consumer Protection, Occupational Health and Safety Department, Regional Inspection South Thuringia.

Zuständige Stelle
Formulare

Notification for activities involving biological agents (biological substances) in accordance with Section 16 of the Biological Agents Ordinance (BioStoffV)

Ursprungsportal

Display activities with biological agents, Tätigkeiten mit biologischen Arbeitsstoffen anzeigen