

99006050001000, 99006050001000

Applying for permission to work with biological agents

Heruntergeladen am 15.06.2025

<https://fimportal.de/xzufi-services/208198578/L100038>

Modul	Sachverhalt
Leistungsschlüssel	99006050001000, 99006050001000
Leistungsbezeichnung I	Applying for permission to work with biological agents
Leistungsbezeichnung II	Applying for permission to work 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	Erteilung (001)
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
Handlungsgrundlage	§ 15 Ordinance on Biological Substances (BioStoffV) https://www.gesetze-im-internet.de/biostoffv_2013/_15.html
Teaser	If you want to start working with biosubstances of protection level 3 or 4 in laboratories, laboratory animal facilities or in biotechnology for the first time, you must apply for a permit. 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 that can endanger humans through infections, toxic, sensitizing or other health-damaging effects.</p> <p>The organisms are classified into risk groups 1 to 4 according to the risk of infection they pose based on the latest scientific findings, with risk group 1 representing the lowest risk.</p> <p>Biological agents in risk groups 3 and 4 are highly pathogenic pathogens. For this reason, the BioStoffV provides for a licensing procedure before certain activities can begin. This means that certain activities involving biological substances are prohibited unless the responsible district government has issued a permit. Only the existence of a permit legalizes these activities.</p> <p>Permits are required for the four areas of healthcare, biotechnology, laboratories and laboratory animal husbandry if certain criteria are met in accordance with the Biological Substances Ordinance.</p> <p>A permit is required for the following activities</p>

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- in laboratories, in laboratory animal husbandry and in biotechnology, the first-time commencement of activities at protection level 3 or 4
- in health service facilities, work at protection level 4, i.e. activities involving highly pathogenic biological substances.

Erforderliche Unterlagen

The application must be accompanied by Biological Agents Ordinance, the following documents must be enclosed with the application:

- Name and address of the employer,
- Name of the permit holder in accordance with the Infection Protection Act,
- Result of the risk assessment stating

a) the biological agents used or occurring and the protection level of the activity,

b) the structural, technical, organizational and personal protective measures, including information on the planned maintenance and servicing of the structural and technical measures,

- If necessary, the competent authority may request further documents.
 - Written assignment of tasks by the responsible person in accordance with Section 13 (2) of the Occupational Health and Safety Act
 - Name and certificates of competence for the competent persons appointed in accordance with the Biological Agents Ordinance
 - Proof of professional qualification in accordance with TRBA 200 No. 6 Para. 3
 - Proof of professional experience in accordance with TRBA 200 No. 6 Para. 3
 - Proof of occupational health and safety competencies in accordance with TRBA 200 No. 6. para. 3
 - Copy of the written appointment
 - Certificate of good conduct (document type O) of the named persons
 - Copy of the permit in accordance with the Infection

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Protection Act (not required for health service facilities)

- Site plan of the building and floor plan (incl. color coding of escape and rescue routes)
- List of biological agents in accordance with the Ordinance on Biological Substances
- Description of activities
- Documentation of protective measures
- Maintenance concept
- Result of the risk assessment in accordance with the Ordinance on Biological Agents in conjunction with the Occupational Health and Safety Act, including the status of implementation of the measures and the name of the person responsible for this (procedure for carrying out and documenting the risk assessment is described in TBRA 400 "Instructions for risk assessment and for informing employees about activities involving biological agents"). and for informing employees about activities involving biological agents")
- In-house hazard prevention plan: description of how to avert hazards that may occur if a containment measure fails due to a release of biological agents
- Information on waste and waste water disposal: Information on inactivation procedures, in-house transportation and equipment used
- If applicable, approval according to genetic engineering law: copy of the approval notice

Voraussetzungen

Compliance with the structural, technical, organizational and requirements of the BioStoffV to protect employees and other persons from the hazards of the activities.

Kosten

Amount of costs (variable): from EUR 500 to EUR 1,500

Depends 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 application for a permit must be submitted in writing or electronically to the competent authority.
- The competent authority checks the documents.
- If the examination is positive, the authority will issue a permit for activities involving biological agents.
- The permit must be granted if the requirements of

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	the BioStoffV are met, which are necessary to ensure the protection of employees and other persons from the risks posed by biological agents.
Bearbeitungsdauer	
Frist	The permit must be applied for before the activity is taken up for the first time. The activity may only be commenced after the permit has been issued (reservation of permit with prohibition of activity).
weiterführende Informationen	
Hinweise	<p>The following information is available:</p> <p>This regulation of the BioStoffV represents a preventive ban with a reservation of permission. This takes into account the hazard potential of the corresponding activities and enables the necessary state control. The permit covers the structural, technical and organizational requirements in accordance with BioStoffV and therefore all operational requirements.</p> <p>The authority must issue the permit if all requirements of the BioStoffV are met that must be complied with in order to ensure the protection of employees and other persons from the risks posed by biological substances. It can determine the scope of the permit through ancillary provisions such as conditions and requirements (formative administrative act). A permit provides legal certainty for both parties (approving authority and employer).</p> <p>If an activity specified in Section 15 (1) sentence 1 BiostoffV is commenced without a permit, this constitutes an administrative offense. If it is a deliberate act that endangers the life or health of an employee, this is punishable under Section 26 (2) of the Occupational Health and Safety Act.</p>
Rechtsbehelf	<p>Administrative court action</p> <p>Appeal (depending on state law, the appeal may be excluded)</p>

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Kurztext	
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	Erlaubnis von Tätigkeiten mit biologischen Arbeitsstoffen beantragen, Applying for permission to work with biological agents