

99006050001000, 99006050001000

Applying for permission to work with biological agents

Heruntergeladen am 15.06.2025

<https://fimportal.de/xzufi-services/489306366/L100040>

Modul	Sachverhalt
Leistungsschlüssel	99006050001000, 99006050001000
Leistungsbezeichnung I	Applying for permission to work with biological agents
Leistungsbezeichnung II	
Typisierung	3 - Bundesaufsichtsverwaltung: Regelung
Quellredaktion	Niedersachsen
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
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	

Modul	Sachverhalt
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	10.03.2023
Fachlich freigegeben durch	Lower Saxony Ministry for Social Affairs, Labor, Health and Equality
Handlungsgrundlage	https://www.gesetze-im-internet.de/biostoffv_2013/_15.html https://www.gesetze-im-internet.de/biostoffv_2013/_15.html
Teaser	To work with biosubstances of protection levels 3 and 4, you require a permit from the competent authority.
Volltext	Biological agents in risk groups 3 and 4 are highly pathogenic agents. For this reason, the BioStoffV stipulates a permit procedure before starting activities at protection level 3 and 4 in laboratories, in laboratory animal husbandry and in biotechnology as well as protection level 4 in special isolation stations. The relevant activities may only be carried out once the competent authority has granted the employer this permit. Note: If activities requiring a permit under the old ordinance were notified before the BioStoffV of 15.03.2013 came into force and the structural, technical and organizational conditions on which the notification was based have not been significantly changed after 30 September 2021, no permit is required in accordance with Section 15 (1) BioStoffV.
Erforderliche Unterlagen	• Assignment of tasks § 13 para. 2 ArbSchG • Qualified person: Proof of professional qualification in accordance with TRBA 200 No. 6 Para. 3 • Qualified person: Proof of professional experience in accordance with TRBA 200 No. 6 Para. 3 • Qualified person: Proof of occupational health and safety competencies in accordance with TRBA 200 No. 6 Para. 3 • Qualified person: Copy of the written appointment • Copy of the permit according to § 44 Infection Protection Act • Location sketch, floor plan of the rooms

Modul	Sachverhalt
	• List of biological agents according to § 7 para. 2 BioStoffV (list of biological agents) • Description of activities • Documentation of the protective measures • Maintenance concept • In-house plan for hazard prevention according to § 13 para. 3 BioStoffV • Information on waste and wastewater disposal
Voraussetzungen	•
Kosten	The amount of fees is determined by the Ordinance on Fees and Expenses for Official Acts and Services (General Fee Schedule - AllGO). Tariff item 5.7.1 Permit according to § 15 para. 1 BioStoffV including the request for further documents according to § 15 para. 2 sentence 2 or para. 3 sentence 3 BioStoffV according to time spent, but at least € 770
Verfahrensablauf	
Bearbeitungsdauer	
Frist	Activities may only be commenced after permission has been granted (reservation of permission with prohibition of activity).
weiterführende Informationen	
Hinweise	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 the BioStoffV and therefore all operational requirements. 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

Modul

Sachverhalt

requirements (formative administrative act). A permit provides legal certainty for both parties (approving authority and employer).

Applications for permits must be submitted to the relevant regional inspectorates within the scope of their designated local responsibilities. They can assist you with any questions you may have regarding the application.

https://www.gewerbeaufsicht.niedersachsen.de/startseite/arbeitsschutz/gefahrstoffe_und_biologische_arbeitsstoffe/gefahrstoffe-und-biologische-arbeitsstoffe-52103.html

https://www.gewerbeaufsicht.niedersachsen.de/startseite/arbeitsschutz/gefahrstoffe_und_biologische_arbeitsstoffe/gefahrstoffe-und-biologische-arbeitsstoffe-52103.html

Rechtsbehelf

Kurztext

- • A permit is required for the first-time commencement of activities with biosubstances of protection level 3 or 4 in laboratories, in laboratory animal husbandry and in biotechnology
- Also subject to authorization: Work at protection level 4 in health service facilities
- Responsible authority: State Trade Inspectorate of Lower Saxony

Ansprechpunkt

State Trade Inspectorate of Lower Saxony

Zuständige Stelle

Formulare

Application for a permit in accordance with § 15 of the Biological Agents Ordinance

Ursprungsportal

Erlaubnis von Tätigkeiten mit biologischen Arbeitsstoffen beantragen, Applying for permission to work with biological agents