

99006050001000

Permission to take up work with biological agents Granted

Heruntergeladen am 27.06.2025

<https://fimportal.de/xzufi-services/S1000020010000012168/S100002>

Modul	Sachverhalt
Leistungsschlüssel	99006050001000
Leistungsbezeichnung I	Permission to take up work with biological agents Granted
Leistungsbezeichnung II	Apply for permission to work with biological agents
Typisierung	3 - Bundesaufsichtsverwaltung: Regelung
Quellredaktion	Hamburg
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	<div lang="en-x-mtfrom-de">Biological agents</div> , <div lang="en-x-mtfrom-de">biomaterials</div> , <div lang="en-x-mtfrom-de">Working with highly dangerous biological agents</div> , <div lang="en-x-mtfrom-de">Permission to handle dangerous biological substances</div> , <div lang="en-x-mtfrom-de">Permission for highly pathogenic biological agents</div> , <div lang="en-x-mtfrom-de">Permission for biological substances with protection level</div>
Leistungstyp	

Modul	Sachverhalt
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	17.10.2022
Fachlich freigegeben durch	
Handlungsgrundlage	Section 15 Biological Substances Ordinance (BioStoffV)
Teaser	You need a permit if you want to start working with biological substances in laboratories, animal testing facilities or in biotechnology for the first time.
Volltext	As an employer, you need permission from the relevant authority if you: Start activities involving biological agents of protection level 3 or 4 in laboratories, in laboratory animal husbandry or in biotechnology for the first time or Carry out activities involving highly pathogenic biological agents of protection level 4 in healthcare facilities.
Erforderliche Unterlagen	Transfer of tasks according to Section 13 (2) of the Occupational Safety and Health Act (ArbSchG) Approval under genetic engineering law (copy of the approval notice) Copy of the written order of the competent person Proof of the professional qualification of the qualified person Proof of professional experience of the qualified person Proof of the occupational safety competences of the qualified person Copy of the permit according to Section 44 of the Infection Protection Act (InfSchG) List of biological agents according to Section 7 (2) of the Biological Agents Ordinance (BioStoffV) Job description Documentation of protective measures Maintenance concept Internal hazard prevention plan Information on waste and wastewater disposal
Voraussetzungen	Your facility has the necessary structural, technical and organizational measures and qualified personnel to

Modul	Sachverhalt
	ensure the safety of employees and other persons from dangers arising from the activities carried out.
Kosten	Fees apply. The amount of the fee is determined according to the fee schedule for the areas of occupational health and safety as well as plant and product safety (ArbSchGebO HA).
Verfahrensablauf	Submit the application form in writing or electronically with the required documents to the responsible authority. The responsible authority will examine your application and documents. If necessary, it will request further documents from you. The responsible authority will check the requirements and decide on your application. You will receive the notification. You will usually receive the fee notice separately. You pay the fees.
Bearbeitungsdauer	Processing takes approximately 4 weeks.
Frist	Apply for permission in good time before you plan to start your activities. You need permission before you start your activities (permission subject to a ban on activities).
weiterführende Informationen	http://www.gesetze-im-internet.de/biostoffv_2013/_15.html http://www.gesetze-im-internet.de/biostoffv_2013/_15.html https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRBA/TRBA.html https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRBA/TRBA.html
Hinweise	This regulation of the BioStoffV represents a preventive ban subject to a permit. This takes into account the risk potential of the corresponding activities and enables the necessary state control. The permit covers the structural, technical and organizational requirements according to the BioStoffV and thus all operational requirements. The authority will grant permission if all requirements of the Biological Agents Ordinance to protect employees and other persons from the hazards posed by biological agents are met. The competent authority can determine the scope of the permit through ancillary provisions such as conditions

Modul	Sachverhalt
	and requirements (formative administrative act). If you start such an activity without permission, you are committing an administrative offence. If it is an intentional act that endangers the life or health of your employees, you are committing a criminal offence.
Rechtsbehelf	Contradiction
Kurztext	Permission from the competent authority is required for employers in the case of: Activities involving biological agents of protection level 3 or 4 in: Laboratories Laboratory animal husbandry biotechnology Activities involving highly pathogenic biological agents of protection level 4 in: Health care facilities
Ansprechpunkt	
Zuständige Stelle	Justice and Consumer Protection Authority
Formulare	
Ursprungsportal	Hamburg Service, Hamburg Service (Currently this link is only available in german)