

99006051261000

Heruntergeladen am 12.06.2025

<https://fimportal.de/xzufi-services/53662/L100042>

Modul	Sachverhalt
Leistungsschlüssel	99006051261000
Leistungsbezeichnung I	
Leistungsbezeichnung II	Biological agents; notification of activities involving biological agents
Typisierung	3 - Bundesaufsichtsverwaltung: Regelung
Quellredaktion	Bayern
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher Ansprechpartner	
Fachlich freigegeben am	07.04.2025

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Fachlich freigegeben durch	Bayerisches Staatsministerium für Umwelt und Verbraucherschutz (Bavarian State Ministry of the Environment and Consumer Protection)
Handlungsgrundlage	https://www.gesetze-im-internet.de/biostoffv_2013/_16.html https://www.gesetze-im-internet.de/biostoffv_2013/_16.html
Teaser	Employers must notify the responsible trade supervisory office at the government of, among other things, the first-time commencement of a specific activity with biosubstances of risk group 2 and risk group 3(**).
Volltext	Activities involving biological agents (bio-substances) can be hazardous to health. Employees who carry out such activities must therefore be given special protection. Biological agents are microorganisms, cell cultures and endoparasites (parasites that live in humans) - including their genetically modified forms. The term also includes agents associated with TSEs (prions). Biological agents can endanger humans through infections, infection-related acute or chronic diseases, toxin formation or sensitizing effects. The employer must notify the competent authority: 1. in laboratories, in laboratory animal husbandry and in biotechnology, the first commencement of • targeted activities with biosubstances of risk group 2 and with biosubstances of risk group 3 that are marked with (**), • 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, 2. any change to the permitted or notified activities if these are significant for safety and health protection, for example activities aimed at increasing the virulence of the biosubstance or the inclusion of activities with other risk group 3 or 4 biosubstances,

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3. the commissioning of a patient ward of protection level 4 upon admission of an infected patient and the subsequent decommissioning,
4. the cessation of an activity requiring a permit in accordance with Section 15 of the German Ordinance on Biological Substances (BioStoffV).

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 in which these activities are to be carried out
- the result of the risk assessment in accordance with § 4 BioStoffV,
- the type of biosubstance,
- the measures planned to protect the health and safety of employees.

Erforderliche Unterlagen

- Certified copy of the permit according to § 44 IfSG or § 2 TierSEV or statement/justification for exemption from permit according to § 45 IfSG or § 3 TierSEV

(not necessarily to be attached if permission from the competent government has already been obtained)

- Location sketch, floor plan of the rooms
- List of bio-substances used or occurring in accordance with § 7 Para. 2 BioStoffV (list of bio-substances)

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.

Kosten
Verfahrensablauf

The notification must be submitted in writing to the responsible trade supervisory office.

Bearbeitungsdauer

The obligation to notify is deemed to have been

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	fulfilled if the notification is received by the responsible trade supervisory office within the deadline. As a rule, there is no confirmation of notification, but the office may request further documents or, if the requirements are not met (Annexes BioStoffV, TRBA 100, etc.), it may demand that the deficiencies be rectified.
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. The notification • the admission of an infected patient to a patient ward of protection level 4 • the decommissioning of the patient ward must be made immediately.
weiterführende Informationen	https://www.gewerbeaufsicht.bayern.de/gefahrenschutz/gefahrstoffe_biologische_arbeitsstoffe.htm https://www.gewerbeaufsicht.bayern.de/gefahrenschutz/gefahrstoffe_biologische_arbeitsstoffe.htm https://www.baua.de/DE/Themen/Arbeitsgestaltung-im-Betrieb/Biostoffe/_functions/BereichsPublikationssuche_Formular.html?nn=8580646 https://www.baua.de/DE/Themen/Arbeitsgestaltung-im-Betrieb/Biostoffe/_functions/BereichsPublikationssuche_Formular.html?nn=8580646 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 https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRBA/pdf/TRBA-100.pdf?__blob=publicationFile&v=4 https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRBA/pdf/TRBA-100.pdf?__blob=publicationFile&v=4 https://www.gewerbeaufsicht.bayern.de/ueber_uns/standorte/index.htm https://www.gewerbeaufsicht.bayern.de/ueber_uns/standorte/index.htm
Hinweise	The obligation to notify may also be fulfilled by submitting a copy of a notification, authorization or permit under another legal provision to the competent trade supervisory office within the period specified in

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	the next section if this contains equivalent information.
Rechtsbehelf	
Kurztext	
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	BayernPortal, BayernPortal