99006051261000

Display inclusion of activities involving biological agents

Modul	Sachverhalt
Leistungsschlüssel	99006051261000
Leistungsbezeichnung I	Display inclusion of activities involving biological agents
Leistungsbezeichnung II	Display inclusion of activities involving biological agents
Typisierung	3 - Bundesaufsichtsverwaltung: Regelung
Quellredaktion	Baden-Württemberg
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher Ansprechpartner	

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Fachlich freigegeben am	
Fachlich freigegen durch	
Handlungsgrundlage	[Verordnung über Sicherheit und Gesundheitsschutz bei Tätigkeiten mit Biologischen Arbeitsstoffen (Biostoffverordnung – BioStoffV):](https://www.gesetze-im-internet.de/biostoffv_2013/) • § 16 Anzeigepflicht
Teaser	If you take up targeted activities with biosubstances of risk group 2 or risk group 3 (**) for the first time in laboratories, in laboratory animal husbandry or in biotechnology, you must report this. Notification is also required in these areas for the first-time commencement of non-targeted activities of protection level 2 with biosubstances of risk group 3 or 3 (**), provided that the activities are targeted at these biosubstances and are to be carried out regularly.
Volltext	If you take up targeted activities with biosubstances of risk group 2 or risk group 3 (**) for the first time in laboratories, in laboratory animal husbandry or in biotechnology, you must report this. Notification is also required in these areas for the first-time commencement of non-targeted activities of protection level 2 with biosubstances of risk group 3 or 3 (**), provided that the activities are targeted at these biosubstances and are to be carried out regularly. The Biological Agents Ordinance (BioStoffV) summarises biological agents under the term "biological agents". Biological agents are essentially microorganisms such as bacteria, viruses or fungi that can endanger humans through infections, toxic or sensitising effects. Many employees are exposed to biological agents in the course of their work. This is particularly the case in activities in the healthcare sector, laboratories, animal husbandry and biotechnology. The legislator differentiates between targeted and

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	non-targeted activities. A targeted activity is, for example, the planned cultivation of a known bacterium, such as _Escherichia coli_ or _S. aureus_. 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 initial admission: • targeted activities with biosubstances of risk group 2 as well as with biosubstances of risk group 3, and risk group 3 (**), • non-targeted activities of protection level 2 with biosubstances of risk group 3, including those labelled with (**), provided that the activities are targeted at these biosubstances and are to be carried out regularly, • any change to the activities authorised under § 15 BioStoffV or notified under § 16 BioStoffV if these are significant for safety and health protection, for example activities aimed at increasing the virulence of the biological agent or the inclusion of activities with other biological agents of risk group 3 or 4, • the commissioning of a patient ward of protection level 4 upon admission of an infected patient and the subsequent decommissioning, • the cessation of an activity requiring a biosubstance licence in accordance with 15.
Erforderliche Unterlagen	The following information is required for the notification: • Name and address of the employer, • Address of the business premises (if different from the employer's address), • Name and contact details of the holder of the licence under the Infection Protection Act, • Copy of the licence under the Infection Protection Act (not required for health service facilities), • Result of the risk assessment, stating • the biological agents used or occurring and the protection level of the activity, • the structural, technical, organisational and personal protective measures, including information on the planned maintenance and servicing of the

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	structural and technical measures, • Name of the person responsible in accordance with Section 13 (2) of the Occupational Health and Safety Act and the written assignment of tasks to this person • Name, contact details 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 number 6 paragraph 3, • Proof of professional experience in accordance with TRBA 200 number 6 paragraph 3, • Proof of occupational health and safety competences in accordance with TRBA 200 number 6 paragraph 3, • Copy of the written appointment and definition of tasks, • Certificate of good conduct (document typeOB) of the named persons, • Information on the number of persons expected to be employed who will carry out work requiring a permit Site plan of the workplace and floor plan (including colour coding of escape and rescue routes), • List of biological agents in accordance with the Biological Agents Ordinance Activity description with allocation to the workrooms, • Documentation of protective measures, • Concept for planned maintenance and servicing of the structural and technical protective measures, • Result of the risk assessment in accordance with the Biological Agents Ordinance in conjunction with the Occupational Health and Safety Act, including status of implementation of the measures and designation of the person responsible for this (procedure for carrying out and documenting the risk assessment is set out in TBRA 400 "Instructions for risk assessment 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 transport and equipment used, • Authorisation under genetic engineering law: copy of the authorisation notice.

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	If necessary, the competent authority may request further documents.
Voraussetzungen	If necessary, a licence in accordance with Section 44 of the Infection Protection Act (IfSG) or Section 2 of the Animal Pathogens Ordinance (TierSEV) must be applied for or an exemption from authorisation in accordance with Section 45 IfSG or Section 3 TierSEV must be established. In addition, in the case of genetically modified biological substances, authorisation is required in accordance with genetic engineering law.
Kosten	none
Verfahrensablauf	After you have reported the commencement of activities involving biological agents, the competent authority will check the report and request additional documents if necessary.
Bearbeitungsdauer	
Frist	The notification must be made no later than 30 days • before the commencement of notifiable activities, • before changing the authorised or notified activities or • before discontinuation of an activity subject to authorisation. Notification of the admission of an infected patient to a patient ward of protection level 4 must be made immediately.
weiterführende Informationen	
Hinweise	If the information required for the notification can be taken from equivalent notifications under other legal provisions, the notification obligation can also be fulfilled by sending copies of these notifications to the competent authority.
Rechtsbehelf	none
Kurztext	
Ansprechpunkt	

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Zuständige Stelle	
Formulare	
Ursprungsportal	