

99006050001000

Apply for authorisation to take up work with biological agents

Heruntergeladen am 27.06.2025

<https://fimportal.de/xzufi-services/6022553/L100022>

| Modul | Sachverhalt |
|---------------------------|--|
| Leistungsschlüssel | 99006050001000 |
| Leistungsbezeichnung I | Apply for authorisation to take up work with biological agents |
| Leistungsbezeichnung II | Apply for authorisation to take up work with 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 | |

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| Einheitlicher Ansprechpartner | |
| Fachlich freigegeben am | |
| Fachlich freigegeben durch | |
| Handlungsgrundlage | <p>Biostoffverordnung (BioStoffV):</p> <ul style="list-style-type: none"> • § 15 Erlaubnispflicht |
| Teaser | <p>If you wish to start working with biosubstances of protection level 3 or 4 in laboratories, in laboratory animal husbandry or in biotechnology for the first time, you must apply for a permit. The same applies to health service facilities that are intended for activities at protection level 4.</p> |
| Volltext | <p>If you wish to start working with biosubstances of protection level 3 or 4 in laboratories, in laboratory animal husbandry or in biotechnology for the first time, you must apply for a permit. The same applies to health service facilities that are intended for activities at protection level 4.</p> <p>The Biological Agents Ordinance (BioStoffV) summarises biological agents under the term "biological agents". Biological agents are essentially microorganisms, such as bacteria, viruses or fungi, which can endanger humans through infections, toxic or sensitising effects.</p> <p>Biological agents are categorised into risk groups 1 to 4 according to the risk of infection they pose, with risk group 1 representing the lowest risk. Biological agents in risk groups 3 and 4 can cause serious illnesses in humans and pose a serious risk to employees. For this reason, the German Ordinance on Biological Substances (BioStoffV) provides for an authorisation procedure before certain activities can begin. This means that certain activities involving biological substances may only be carried out once the competent authority has issued a permit.</p> <p>The authorisation requirement applies to the four</p> |

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areas of healthcare, biotechnology, laboratories and laboratory animal husbandry. Activities involving organisms in risk group 3 (**) do not require a licence. For the following activities:

- in laboratories, in laboratory animal husbandry and in biotechnology, the first commencement of activities of protection level 3 or 4, i.e. with biosubstances of risk group 3 or 4
- in health service facilities, activities of protection level 4, i.e. activities involving biosubstances of risk group 4

Erforderliche Unterlagen

The application must be accompanied by the following documents in accordance with the Biological Agents Ordinance:

- Name and address of the employer,
- Address of the business premises (if different from the employer's address),
- Name and contact details of the licence holder in accordance with the Infection Protection Act,
- Copy of the licence in accordance with 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 details of the planned maintenance and servicing of the 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 authorised 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 type O) of the named persons,

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- Site plan of the workplace and floor plan (including colour coding of escape and rescue routes),
- List of biological agents in accordance with the German Ordinance on Biological Agents (Biostoffverordnung) Description of activities 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 the status of implementation of the measures and designation of the person responsible for this (the 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"),
- 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 approval notice,

If necessary, the competent authority may request further documents.

Voraussetzungen

Fulfilment of the structural, technical, organisational and requirements of the BioStoffV to protect employees and other persons from the hazards of the activities.

Kosten

Fees are charged in accordance with Section 16 of the State Fees Act in conjunction with No. 0.1 of the Ministry of the Environment's Schedule of Fees (GebVerZ UM) (up to EUR 10,000).

Verfahrensablauf

After you have applied for authorisation to start working with biological agents, the competent authority will check the application and request additional documents if necessary. This is followed by an on-site inspection of the facilities used for the work.

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| Bearbeitungsdauer | |
| Frist | The licence must be applied for before the activity is taken up for the first time. The activity may only be commenced after the licence has been granted. |
| weiterführende Informationen | |
| Hinweise | <p>This regulation of the BioStoffV represents a preventive ban with a reservation of authorisation. This takes into account the hazard potential of the corresponding activities and enables the necessary state control. The permit covers the structural, technical and organisational requirements in accordance with the BioStoffV and therefore all operational requirements. The authority must grant the licence 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 licence by means of ancillary provisions such as conditions and requirements (formative administrative act). A permit provides legal certainty for both parties (authorising 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 offence. If it is a deliberate act that endangers the life or health of an employee, this is a criminal offence under Section 26(2) of the Occupational Health and Safety Act.</p> |
| Rechtsbehelf | • Action before the administrative court |
| Kurztext | |
| Ansprechpunkt | |
| Zuständige Stelle | |
| Formulare | |
| Ursprungsportal | |