

99006051261000

Notification of commencement of activities involving biological agents Acceptance

Heruntergeladen am 12.06.2025

<https://fimportal.de/services/99006051261000>

Modul	Sachverhalt
Leistungsschlüssel	99006051261000
Leistungsbezeichnung I	Notification of commencement of activities involving biological agents Acceptance
Leistungsbezeichnung II	Report activities involving biological agents
Typisierung	3 - Bundesaufsichtsverwaltung: Regelung
Quellredaktion	Baustein Leistungen
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	fachlich freigegeben (gold)
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Occupational safety and health (individuell, 006)
Verrichtungskennung	Entgegennahme (261)
SDG-Informationsbereich	Erlangung von Lizenzen, Genehmigungen oder Zulassungen im Hinblick auf die Gründung und

Modul	Sachverhalt
	Führung eines Unternehmens
Lagen Portalverbund	Erlaubnisse und Genehmigungen (2010400), Arbeitssicherheit (2030500)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	10.12.2024
Fachlich freigegeben durch	Federal Ministry of Labor and Social Affairs (BMAS)
Handlungsgrundlage	https://www.gesetze-im-internet.de/biostoffv_2013/_16.html
Teaser	Before you work with biological substances, for example in laboratories or in the health service, you must notify the competent authority. A permit is required for work in protection levels 3 and 4, which is not covered here.
Volltext	<p>Biological agents are essentially microorganisms, such as bacteria, fungi or viruses, which can endanger humans through infections, toxic, sensitizing or other health-damaging effects. People who work in certain areas are more exposed to biological agents than the general population.</p> <p>Some examples are activities in the following areas</p> <ul style="list-style-type: none"> • Healthcare, • waste treatment, • waste water technology, • animal husbandry • food production. <p>The legislator differentiates between targeted and non-targeted activities. A targeted activity is, for example, the planned cultivation of a known bacterium, such as a tuberculosis pathogen. However, non-targeted activities are predominantly carried out where the biological agents occur as accompanying substances or contaminants and are not the objective of the work. Examples of this are waste sorting</p>

Modul

Sachverhalt

facilities, archives or work in forestry. The organisms are classified in risk groups 1-4. This depends on the risk of infection according to the latest scientific findings. Risk group 1 means the lowest risk.

As an employer, you must report the following activities to the competent authority:

- In laboratories, in laboratory animal husbandry and in biotechnology, if
 - Your employees are working for the first time on a specific activity involving biosubstances in risk group 2 or risk group 3(**).
 - your employees are working for the first time on a non-targeted activity of protection level 2 with biosubstances of risk group 3, provided that the activities are aimed at these biosubstances, are carried out regularly and are not subject to a permit requirement.
 - If the permitted or notified activities are changed and this is significant for safety and health protection. This includes, for example
 - activities aimed at increasing the virulence of the biological agent or
 - the commencement of activities involving other biosubstances of risk group 3 or 4.
- In hospitals, if an infected patient has been admitted to a patient ward of protection level 4.

when an activity requiring a permit is terminated.

Erforderliche Unterlagen

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 where these activities are to be carried out.
- the measures planned to protect the health and safety of employees.
- the result of the risk assessment in connection with the Occupational Health and Safety Act.
- The risk assessment must be carried out by an

Modul

Sachverhalt

expert.

- If the employer does not have the relevant knowledge himself, he must seek expert advice.
- the type of biological substance.

You can also comply with the obligation to notify by sending the competent authority a copy of a notification, authorization or permit under another legal provision within the deadline if this contains equivalent information.

Voraussetzungen

If necessary, you must apply for a permit for activities involving pathogens (Section 44 of the Infection Protection Act, IfSG for short) or a permit for activities involving animal pathogens (Section 2 of the Animal Pathogens Ordinance, TierSEV for short). If you have already received a permit or are exempt from a permit for activities involving pathogens (Section 45 IfSG) or animal pathogens (Section 3 TierSEV), you must justify this.

Kosten

Verfahrensablauf

Bearbeitungsdauer

Frist

You must submit the notification at least 30 days • before commencing notifiable activities, • before changing the permitted or notified activities • or before terminating an activity requiring a permit carry out. You must report the admission of an infected patient to a patient ward at protection level 4 immediately.

weiterführende Informationen

https://www.baua.de/DE/Themen/Arbeitsgestaltung-im-Betrieb/Biostoffe/_functions/BereichsPublikationssuche_Formular.html?nn=8701972
<https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRBA/TRBA.html>

Hinweise

You are committing an administrative offense if you

- not,
- not correctly,

Modul

Sachverhalt

- not completely
- or not in time.

If you act intentionally and endanger the life or health of an employee, you are liable to prosecution.

Rechtsbehelf

Appeal (depending on state law, the appeal may be excluded)

Action before the administrative court

Kurztext

- Biological agents are essentially microorganisms that can endanger people
 - Many employees are exposed to biological substances at work, for example in areas such as
 - healthcare
 - waste treatment
 - wastewater technology
 - animal husbandry
 - Food production
 - Organisms are classified in risk groups 1-4, depending on the risk of infection according to the current state of science
 - Risk group 1 means lowest risk
 - Employers are obliged to report the following activities to the competent authority:
 - In laboratories, in laboratory animal husbandry and in biotechnology:
 - First-time non-targeted activities of protection level 2 with biosubstances of risk group 3, including those marked with (**), provided that the activities are targeted at these biosubstances and are to be carried out regularly
 - First-time targeted activities with biosubstances of risk group 2 and risk group 3(**)
 - activities with biosubstances of risk group 3 that are not subject to authorization
 - 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
 - commencement of activities with other

Modul	Sachverhalt
	<p>biosubstances of risk group 3 or 4</p> <ul style="list-style-type: none"> • the admission of an infected patient to a patient ward of the protection level • Activity requiring a permit is discontinued
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	