

## Display activities with biological agents

If you take up targeted activities with biosubstances in risk group 2 or activities not requiring a permit with biosubstances in risk group 3 for the first time, you must report this. You can find out more here.

### Competent Department

- [Gewerbeaufsicht des Landes Bremen, Dienstort Bremen](#)

### Basic information

The Biological Agents Ordinance (BioStoffV) summarizes biological agents under the term "biological agents". Biological agents are essentially microorganisms, such as bacteria, fungi or viruses, which can endanger humans through infections, toxic, sensitizing or other health-damaging effects.

Many employees are exposed to biological agents in the course of their work. Some examples are activities in the areas of healthcare, waste treatment, wastewater technology, animal husbandry and food production.

Here, the legislator distinguishes 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 facilities, archives or work in forestry. The organisms are classified into risk groups 1-4 according to the risk of infection they pose based on the latest scientific findings, with risk group 1 representing the lowest risk.

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 first admission
  - a specific activity with biosubstances of risk group 2
  - an activity with biosubstances of risk group 3, insofar as the activities are not subject to a permit requirement
  - 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 commencement of activities involving other risk group 3 or 4 biosubstances

- the admission of an infected patient to a patient ward of protection level 4
- the cessation of an activity requiring a permit in accordance with the German Ordinance on Biological Agents (BioStoffV).

## Requirements

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 a permit must be justified in accordance with Section 45 IfSG or Section 3 TierSEV.

## What documents do I need?

- 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
  - Assignment of tasks in accordance with the Occupational Health and Safety Act
  - Location sketch, floor plan sketch showing the safety equipment (such as autoclave, MSW, centrifuge and others), the facilities for decontamination, cleaning and disinfection (including hand wash basin, disinfectant, hand wash and disposable towel dispenser, eye wash), viewing window and direction of opening of the doors, storage location of personal protective equipment and street clothes
  - List of biological agents in accordance with the Biological Agents Ordinance
  - Result of the risk assessment in accordance with the Biological Agents Ordinance in conjunction with the Occupational Health and Safety Act
  - Deviations from protective measures
  - Test report of the installation test of the devices whose safety depends on the installation conditions
  - Disinfection / hygiene plan

The obligation to notify can also be fulfilled by sending the competent authority a copy of a notification, approval or permit in accordance with another legal provision within the deadline if this contains equivalent information.

## Procedure

- The notification must be submitted in writing to the competent authority in accordance with state law.
- The competent authority will check the documents.
- As a rule, no confirmation of notification is issued.

## Legal bases

- [§ 16 Biostoffverordnung \(BioStoffV\)](#)

## **What deadlines must be paid attention to?**

The notification must be made no later than 30 days

- before the commencement of notifiable activities,
- before changing the permitted or notified activities or
- before discontinuation of an activity requiring a permit.

Notification of the admission of infected patients to a patient ward of protection level 4 must be made immediately.

## **How long does it take to process**

The obligation to notify is deemed to have been fulfilled if the notification is received by the competent authority within the deadline. As a rule, there is no confirmation of notification, but further documents can be requested or, if the requirements are not met (Annexes BioStoffV, TRBA 100 and others), the rectification of the defects can be demanded.

## **What are the costs?**

Based on the health cost directory of the state of Bremen.