

# Applying for permission to work with biological agents

If you want to start working with biosubstances of protection level 3 or 4 in laboratories, laboratory animal facilities or in biotechnology for the first time, you must apply for a permit. You can find out more here.

## Competent Department

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

## Basic information

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

The organisms are classified into risk groups 1 to 4 according to the risk of infection they pose based on the latest scientific findings, with risk group 1 representing the lowest risk.

Biological agents in risk groups 3 and 4 are highly pathogenic pathogens. For this reason, the BioStoffV provides for a licensing procedure before certain activities can begin. This means that certain activities involving biological substances are prohibited unless a permit has been issued by the trade supervisory authority of the state of Bremen. Only the existence of a permit legalizes these activities.

Permits are required for the four areas of healthcare, biotechnology, laboratories and laboratory animal husbandry if certain criteria are met in accordance with the Biological Substances Ordinance.

A permit is required for the following activities

- in laboratories, in laboratory animal husbandry and in biotechnology, the first-time commencement of activities at protection level 3 or 4
- in health service facilities, work at protection level 4, i.e. activities involving highly pathogenic biological substances.

## Requirements

Compliance with the structural, technical and organizational requirements of the BioStoffV to protect employees and other persons from the hazards of the activities.

### What documents do I need?

- The application must be accompanied by the following documents in accordance with the Biological Agents Ordinance
  - Name and address of the employer,
  - Name of the permit holder in accordance with the Infection Protection Act,
  - Result of the risk assessment stating
    - the biological agents used or occurring and the protection level of the activity,
    - the structural, technical, organizational and personal protective measures, including information on the planned maintenance and servicing of the structural and technical measures,
  - If necessary, the competent authority may request further documents.
  - Written assignment of tasks by the responsible person in accordance with Section 13 (2) of the Occupational Health and Safety Act
  - Name 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 No. 6 Para. 3
    - Proof of professional experience in accordance with TRBA 200 No. 6 Para. 3
    - Proof of occupational health and safety competencies in accordance with TRBA 200 No. 6. para. 3
    - Copy of the written appointment
  - Certificate of good conduct (document type O) of the named persons
  - Copy of the permit in accordance with Section 44 of the Infection Protection Act (not required for health service facilities)
  - Site plan of the building and floor plan (including color coding of escape and rescue routes)
  - List of biological agents in accordance with the Biological Agents Ordinance
  - Description of activities
  - Documentation of protective measures
  - Maintenance concept
  - Result of the risk assessment in accordance with the Biological Agents Ordinance in conjunction with Section 5 of 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 transportation and equipment used
  - If applicable, approval according to genetic engineering law: copy of the approval notice

## Procedure

- The application for a permit must be submitted in writing or electronically to the competent authority.
- The competent authority checks the documents.
- If the examination is positive, the authority will issue a permit for activities involving biological agents.
- The permit must be granted if the requirements of the BioStoffV are met, which are necessary to ensure the protection of employees and other persons from the risks posed by biological agents.

## Legal bases

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

## What deadlines must be paid attention to?

The permit must be applied for before the activity is taken up for the first time. The activity may only be commenced after the permit has been issued (reservation of permit with prohibition of activity).

## How long does it take to process

Not specified.

## What are the costs?

The costs are variable and range between EUR 155.50 and EUR 1000.  
It is based on the health cost directory of the state of Bremen.