

Legal requirements and the Biorisk Committee's recommendations for work with material that may constitute biological hazard at Uppsala University

1. Purpose and Scope

This document compiles the Biorisk Committee's recommendations for the safe handling of material that may constitute a biological hazard, e.g., infectious agents and genetically modified organisms, at Uppsala University. Together with the systematic work environment management which includes safety inspections, risk assessments, measures, and follow-up, these recommendations serve as a guide for safe laboratory operations at the university. The recommendations are directed at all those who work with or are responsible for activities involving biological hazards, and complement applicable legislation and the university's existing environmental and work environment efforts.

2. Background and Legislation

For reference, the legislation setting out the legal requirements for work with the majority of biological hazards encountered in research environments is listed here. Also listed are the roles and responsibilities at Uppsala University.

2.1 Legislation regarding the handling of biological hazards in research environments

- **AFS 2023:10, 11 kap.** – Infection risks (Regulations of the Swedish Work Environment Authority)
- **AFS 2023:13, 9 kap** – Contained use of genetically modified microorganisms. For other uses of genetically modified organisms, see <https://www.genteknik.se/>
- **SJVFS 2006:84** – Swedish Board of Agriculture's regulations on handling animal by-products and the import of other products, excluding foodstuffs, that may spread infectious diseases to animals
- **MSBFS 2024:10** – Regulations on the transport of dangerous goods by road and terrain (ADR-S)

2.2 Summary of legislation regarding the handling of biological hazards in research environments

Please note that the following is a summary and does not contain all of the legal requirements listed in each regulation above.

- All laboratory procedures **shall** be preceded by a written risk assessment covering all sub-procedures.

- Risk assessments **shall** be readily accessible and read by all relevant staff before work begins.
- Safety representatives (*skyddsombud*) **shall** be kept informed about operations and given the opportunity to comment on risk assessments.
- Staff **shall** have the training and competence commensurate with the risk class and protection level required by the work.
- Protective measures with regard to humans, animals, plants, and the environment at large shall be taken in accordance with legal requirements and risk assessment.
- Committees or subcommittees for biosafety shall be established as needed.

2.3 Roles and responsibilities in the handling of biological hazards in research environments

- **Head of Department / equivalent** – Responsible for the department's compliance with environmental and work environment legislation.
- **Safety representative** – represents employees in work environment matters. Shall, among other things, have access to information and be given the opportunity to participate in, e.g., risk assessments.
- **Biosafety representative** – Supports the head of department and staff by disseminating information on biosafety, and collaborates with the safety representative.
- **Biosafety coordinator** – Supports departmental researchers and biosafety representative (biosäkerhetsombud), and serves as the point of contact for Uppsala University's Biosafety Committee, managing its routine work.
- **The Biosafety Committee** – Advisory committee at Uppsala University established by the Vice-Chancellor's decision UFV 2018/2180, consisting of experts from relevant subject areas.
- **Employees** – All persons engaged at Uppsala University, regardless of whether they are permanently employed, project-employed, doctoral students, students, consultants, or otherwise, are obliged to participate in work environment efforts. They shall follow given instructions, use protective equipment, report risks, incidents, accidents, and ill health.

3. Recommendations

In addition to what is specified by the aforementioned legislation, the Biorisk Committee recommends the following for work with biological hazards.

3.1 Training

In addition to what is mandatory by law, the Biorisk Committee recommends that **all** who work with material constituting a biological hazard complete the university's biosafety course or equivalent adapted to the specific operations.

3.2 Advice and support on questions relating to biological hazards

The Biorisk Committee recommends and encourages researchers, research group leaders, biosafety representatives, and heads of department to contact the Biorisk Committee as needed for advice and support on questions relating to biological hazards, such as the handling of infectious agents, genetically modified organisms, invasive species, and boundary questions between different regulatory frameworks. Contact person: henrik.gradstedt@uu.se

3.3 Biological hazards with regard to animals, plants, and the environment at large

Legislation on work environment and infection risks is often focused on the impact of biological hazards on humans. The Biosafety Committee recommends that users, in their risk assessment, also include an analysis of potential risks for animals, plants, and the environment at large. This is particularly pressing with regard to waste management and genetically modified organisms.

3.4 Recommendations for biological hazards in risk class 3

In addition to the general recommendations above for all work involving biological hazards, the Biorisk Committee also recommends the following for work with biological hazards in risk class 3:

- Degree project students should not work with biological hazards in risk class 3
- The research group carries out the risk assessment jointly
- The research group leader forwards the risk assessment to the head of department and the Biorisk Committee for information.
- Before commencing a new type of work with certain biological hazards in risk class 3 where accidents and releases from the laboratory could lead to serious consequences for society, humans, animals, plants, or the environment at large, the Biorisk Committee recommends that:
 - The risk assessment is supplemented with a discussion on the risk versus benefit of the work
 - An opinion on the work and protective measures in the laboratory is obtained from appropriate members of the Biorisk Committee, as well as from an appropriate external expert invited by the Biorisk Committee.

3.5 Recommendations for biological hazards in risk class 4

Handling of biological hazards in risk class 4 requires extreme protective measures, and there is currently **no** work with concentrated or cultured infectious agents in risk class 4 at Uppsala University. Should such a need arise, researchers and the responsible head of department are recommended to first contact the Biorisk Committee.
