FLI	**Biosafety and biosecurity principles of the FLI "Biorisk Policy"**	**Doc-No.:** A.2.2 **Version:** 4 **Page:** 1/5 **Updated:** 30.05.2023

Work of the Friedrich-Loeffler-Institute, Federal Research Institute for Animal Health (FLI), mainly focusses on the **health and wellbeing of farm animals** and on the **protection of humans** against infections transmitted by animals.

The fundamental objectives of research at the FLI are to **provide protection against infectious diseases** through reliable and rapid diagnostics, to develop preventive measures and to lay the foundations for modern control strategies for animal diseases and zoonoses.

These tasks of the FLI are defined in Art. 27 of the **Animal Health Act**, Art. 14 of the **Animal Vaccination Ordinance** and Art. 16, sec. 4 of the **Genetic Engineering Act**.

In the laboratories and animal facilities of the FLI, work with pathogenic and genetically modified organisms of risk categories 1 through 4 is carried out.

In the frame of these activities, risks to human and animal health and for the environment can never be completely ruled out. The FLI takes all necessary precautions to protect humans, animals and the environment from possible negative effects. As an employer, the FLI assumes responsibility for the health and safety of its employees and takes all necessary measures and precautions.

For all FLI activities, compliance with the minimum requirements which ensure an adequate level of protection for **employees and guests** as well as for **the surroundings and environment of the FLI** from risks arising from activities involving **biological agents** is imperative and the guiding principle of **biorisk management at the FLI**. This safety objective surpasses all scientific and official tasks of the FLI.

Biological agents are micro-organisms, including genetically modified micro-organisms, cell cultures and endoparasites of various risk categories which may cause infection or have sensitizing or toxic effects in humans and animals. Biological agents also include agents associated with Transmissible Spongiform Encephalopathy (TSE) that may cause infection or transmissible disease.

Possession, **use** and **transport** of biological agents which may represent a risk to human and animal health and for the environment must comply with the legal

requirements, regulations and provisions set forth by EU, federal and state laws as well as the internal specifications of the FLI.

The FLI takes **preventive measures** to ensure protection of the health and safety of employees exposed to hazardous biological agents as well as to protect animals and the environment.

The **biorisk management principles** of the FLI along with the **biorisk management manual** based on these provide guidance to employees and guests with regard to the handling of risks that may arise from the use or control of biological agents. They support the top management of the FLI, the Biorisk Officer (BRO) and the Department of Experimental Animal Facilities and Biorisk Management (ATB), the Biorisk Committee, the Veterinary Hygiene Officers (VHB), the Work Health and Safety Board (ASA), the Biosafety Committee (ABS) and the responsible Biosafety Officers (BBS), the Hazardous Materials Officer (GefSTB), the International Transportation Officer (IATAB), Occupational Health Services as well as all other individuals involved in research, diagnostics and education in **developing and implementing appropriate protective measures**.

The **Biorisk Committee** is the central regulatory element of FLI's biorisk policy. It advises, reviews, assesses, approves, decides, and controls the development of institutional biosafety guidelines and procedures, as well as risk assessments, in particular for activities involving new and novel pathogens, recombinant or synthetic nucleic acid molecules, and other biological agents and toxins with biohazard potential and safety-related issues. The Biorisk Committee thus takes on the role of a **Committee for Ethics in Safety-Relevant Research (KEF)** at the FLI.

The **fundamental objective of** the FLI's **biorisk policy** is to establish principles to effectively minimize the risk of unintentional release of or exposure to biological agents. Furthermore, strict compliance with regulations and a control system based on hazard and risk analyses (HACCP) are enforced to effectively prevent any intentional and willful removal or release of potentially hazardous biological agents.

To achieve these goals and tasks, the FLI is in the process of establishing a **Biorisk Management System (BMS)** to ensure the implementation of legal requirements for safe handling of biological agents at the FLI and to develop and actively promote a

culture of biosafety through thoughtful planning, effective implementation and control along with steady improvement. The BMS helps to make measures taken with regard to veterinary hygiene and occupational health and safety transparent and comprehensible for all affected staff members, supervisors as well as non-scientific and administrative staff.

Responsibilities of the Friedrich-Loeffler-Institute

1. The FLI is committed to implementing a high level of occupational health and safety, environmental and animal protection in its scientific work.

2. The FLI creates safe and healthy work conditions, provides the necessary tools and equipment and offers the required education and training measures for its employees and guests.

3. Employees and guests of the FLI shall be obliged to support all objectives and tasks of Biorisk Management and to comply with all regulations concerning occupational health and safety.

4. Risk assessments are drawn up for each work place for all employees, guests and contractors of the FLI.

5. The FLI strives to improve its biorisk management continually through continuous monitoring of the implementation of legal requirements for occupational safety, handling of biological agents and genetic engineering.

6. Regular meetings of the "Biorisk Committee" will be held to discuss topics including "biosafety" and "biosecurity", occupational safety and health, and problems in the implementation of requirements and to exchange information on these issues between top management and employees.

7. **„Dual-Use Research of Concern"**
   Research and development have been instrumental to the progress and improvement of living conditions. At the same time, however, there is a general risk that knowledge might be misused to the detriment of society and the environment.

This double applicability of scientific findings is referred to as “dual-use problem”.

This problem is of particular relevance in the field of research on pathogenic microorganisms: On the one hand, knowledge of the pathogenesis, transmissibility and genomics of pathogenic biological agents is essential to prevent their spread and transmission and to enable or enhance the treatment of infections and intoxications. On the other hand, this knowledge can also be used under certain circumstances to harm humans, animals or plants.

For this reason, the Friedrich Loeffler Institute (FLI) has established a code of conduct **including a checklist "Dual-Use Research of Concern"** that preserves the freedom of research for the benefit of society, while preventing the dissemination of information and research results to the detriment of society and the environment. Therefore, scientists of the FLI are obliged to question each of their planned experiments regarding “dual-use research of concern”.

Planned experiments have the following **objectives:**

	1. Enhance the harmful effect (virulence) of a biological agent or toxin
	2. Disrupt immunity or effectiveness of immunization without clinical justification
	3. Confer resistances against prophylactic and therapeutic interventions to a biological agent
	4. Increase the stability (tenacity), transmissibility (infectivity) or the ability to disseminate a biological agent or toxin („weapons-grade quality“)
	5. Alter the host range or tropism of a biological agent or toxin
	6. Enhance the susceptibility of a host population
	7. Generate novel pathogenic agents or toxins or reconstitutes eradicated or extinct biological agents (synthetic genomes)
	8. Facilitate the ability to bypass detection methods