Measures Relevant to the Security and Oversight of Biological Materials

Prepared by the Federal Republic of Germany

1. In brief, this paper will present a general outline of the current legal framework in the Federal Republic of Germany which ensures the safe handling of microorganisms, as well as how to prevent the misuse of such organisms.


3. These Directives and national legislation based on these Directives form the legal basis for extensive control of the handling of microorganisms by state authorities, together with additional special laws which regulate the handling of human and zoonotic pathogens (Infection Protection Act), animal pathogens (Animal Infectious Disease Act) and plant pathogens (Plant Protection Act). These special laws also regulate the import or export of such organisms and provide the legal framework for ordinances which in addition regulate domestic transfers.

4. All regulations are based on the internationally used system which classifies microorganisms according to four risk groups ranging from 1 = no harm to 4 = maximum risk. According to international standards, the risk groups correspond to four safety levels which describe in detail the technical safety requirements for each level.

5. Within the context of the BTWC, the following key issues are of special importance, although this is not an exhaustive list:

   - beginning with safety level 2, access control is required for areas in which microorganisms are handled, with access control involving code systems and special access locks with interlocked doors for safety level 4,
   - beginning with safety level 2, disinfection and inactivation of effluents contaminated with microorganisms is required for any material leaving a facility,
• beginning with safety level 2, all microorganisms have to be stored in containers to which only authorized persons have access.

Generally, all activities require risk assessment and all activities involving the handling of microorganisms must be documented in detail. The handling of microorganisms at safety level 2 or higher needs to be documented by listing all persons by name engaged in the activities.

6. Classified by safety levels, facilities where work is done involving microorganisms have to be notified or require a licence. The most stringent notification and licensing regime is laid down in the genetic engineering legislation.

7. The licensing procedure by competent state authorities requires that the facility asking for authorization submit:

• a detailed description of the organism,
• a detailed description of the planned activity,
• a risk assessment of the planned activity,
• a list of the persons engaged in the activity.

Work cannot start before a licence has been issued or a facility has been notified and the facility has been audited by the competent authority.

8. Notified and licensed facilities undergo routine controls at least once a year which ensure that all regulations are complied with and that the relevant documentation of work is correct. The scope of the facility or activity for higher safety levels can only be changed with an amended licence from the competent authority. Activities at a low safety level need thorough documentation.

9. The handling of human pathogens requires a personalized authorization of the person responsible, as well as the licensing of the facility by the competent state authority. Personalized authorization is issued once the professional competence and the person's reliability have been scrutinized in detail. Authorization is restricted to the microorganisms named and to activities described in detail in the authorization. The authorization can be withdrawn at any time.

10. The import of human and animal pathogens is controlled by state authorities. Each procurement must be authorized by the competent authority. Without a permit, customs will not hand over the material to the importer.

11. With all these regulations and other laws, Germany is striving to prevent unauthorized access to pathogenic microorganisms. The existing acts, ordinances and regulations also ensure that unauthorized activities will not be carried out in future.