Position paper of the Committee for Biological Agents (ABAS) concerning "Biosecurity from an occupational safety and health perspective – Assessment of the interfaces"

Abstract

With the definition and objectives of biosafety and biosecurity in mind it becomes evident that biosecurity is not an inherent occupational safety and health topic. When studying and defining the term as opposed to "biosafety" it becomes clear, however, that many measures which are primarily requested to protect employees, e.g. restricting access to authorised persons, are equally biosecurity measures. On the other hand further reaching measures of only minor relevance for the protection of employees are often required to prevent the abuse of biological agents and/or toxins. Biosecurity measures can thus be considered as an extension of a biosafety programme in the framework of a general security management concept, which may be necessary only in the context of targeted activities in the framework of protection levels 3 and 4 and when working with toxins.

Biosecurity questions are regulated according to their exactly defined objectives in the legal areas of occupational safety and health and infection protection as well as in the legal areas of genetic engineering legislation, and in the framework of the elimination of epizootic diseases and plant protection. Moreover, the dangerous goods legislation and the relevant rules applicable in the fight against terrorism and in the protection of critical infrastructures may be applicable. In particular in the laboratory area this often leads to regulation overlaps. It has to be mentioned that the basic requirements for the protection of employees are defined in the Act on Occupational Safety and Health as well as the ordinances and technical rules issued on the basis of the law unless the special requirements of genetic engineering law apply. "Security" measures alone are not included in these rules.

Distinction between the terms "Biosafety" and "Biosecurity"

The terms "biosafety"[1] and "biosecurity"[2] each describe their own concept and goals, including some communalities. The difficulty of finding distinct definitions for these terms starts with the fact that these English terms cannot be adequately translated into German − or into the other European languages. Both terms would be translated as "Biosicherheit" and/or "Biologische Sicherheit"; *biosafety* focuses on the protection of people and the environment, whereas *biosecurity* aims at securing biological material and information against misuse and criminal acts.

Biosafety programmes reduce the probability that persons and the environment are exposed to pathogenic or − as the case may be − genetically engineered biological agents and toxins. This is achieved by technical (including constructive), organisational and personal requirements to be complied with by the establishment and the operation of laboratories and other institutions of the different safety and protection levels.

[1] **Laboratory biosafety** describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to biological agents and toxins, or their accidental release.

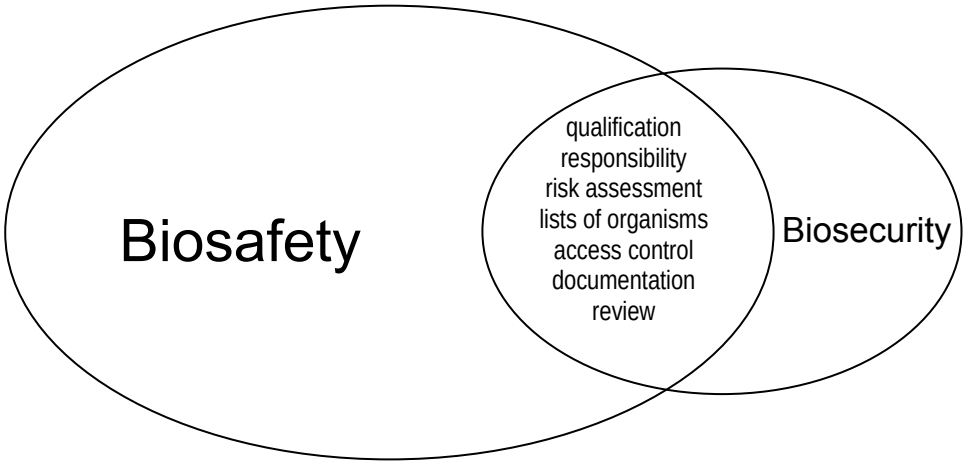
[2] **Laboratory biosecurity** describes the protection, control and accountability for biological agents and toxins within laboratories, in order to prevent their loss, theft, misuse, diversion of, unauthorized access or intentional unauthorized release. (World Health Organization, CDS/EPR/2006.6)

This includes e.g. enclosure measures (locks, vacuum system…), the use of closed devices and equipment, access restrictions as well as the qualification and further training of employees.

On the other hand biosecurity is also meant to prevent any loss, theft or misuse of microorganisms, biological agents or scientific information. On the basis of assessing misuse risks this can be achieved e.g. by controlling persons and their activities, by controlling the use and whereabouts of biological agents and by intentionally restricting access to information.

Even though the objectives of biosafety and biosecurity are not the same, there are joint measures to achieve these goals. Both are based on risk assessment, employee qualification and responsibility, inventory lists and on controlling the use of biological agents, access controls, the documentation of agent transfer and shipments, emergency concepts etc. Biosafety measures are frequently equally effective in the area of biosecurity. In addition there are specific biosecurity aspects which are not related to employee protection.

The term “biorisk” which includes both aspects describes the combination of the probability that damage occurs and the potential impacts of this damage caused by a biological agent.



Biorisk Management

The above components are often integrated into a management system. The task of a biorisk management is to explain the various requirements of biosafety and biosecurity, depending on the risk assessment and the objectives of the institution affected. In the following, essential aspects regarding biosecurity are shown:

Biosecurity programme elements

1. Assessment of misuse risks ("Threat assessment")
2. Securing and controlling biological material
3. Review of employee reliability
4. Access controls
5. Information security
6. Transfer and transportation security

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Biosecurity requirements

In the framework of risk assessment, the identification and priorisation of possible misuse and threat scenarios caused by biological material comprising pathogens or toxins, play an essential role.

Different international and national workshops keep and/or discuss lists which concretely identify “bio-(logical) arms” and/or “weapons-grade material”. By way of example these are: the list of the Australian Group, the list under Council Regulation (EC) No. 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items; the export list under the Foreign Trade and Payments Act of 28 April 1961 as amended on 17 December 2009 and/or under the Foreign Trade and Payments Ordinance, the war weapons list under the War Weapons Control Act (Act to control war weapons of 20 April 1961 − last amended on 6 June 2009) and the “EU list of high threat pathogens” in the Annex of the EU Generic Preparedness Planning Technical Guidance Documents (2005).

The partly identical lists comprise viruses, bacteria, fungi and toxins that can be used for the development of bioweapons. In this context it has to be observed that not all of the listed "bio weapons-grade material" must be classified into risk groups 3 and 4. Some of the listed biological agents must be classified into risk group 2 − e.g. *Staphylococcus aureus*, *Vibrio cholerae*, Vesicular stomatitis virus (VSV) and Newcastle Disease Virus (NDV). The dual-use toxins include *Staphylococcus aureus* enterotoxins, *Clostridium botulinum* toxins, *Clostridium perfringens* toxins, the Cholera toxin, Shiga toxins, verotoxins etc.
The lists of the Australian Group, under the EC Dual Use Regulation, the Foreign Trade and War Weapons Control Act do not only list pure toxins. This regulatory area also includes gene segments associated with the generation of toxins and/or toxin sub-segments of corresponding pathogens (see e.g. No. 1C353 b) of Annex I of the EC Dual Use Regulation).

The below non-exhaustive list of biosecurity requirements was compiled using the following documents:

- UN Security Council Resolution 1540 (2004),
- WHO Biorisk management – Laboratory Biosecurity Guidance, 2006,
- EU Commission: CBRN Action Plan of 30 November 2009,
- US legislation: Biopreparedness Act 2002, Agricultural Bioterrorism Protection Act 2002, Code of Federal Register: 42 CFR part 73, 7 CFR part 331, 9 CFR part 121,
- Recommendations of the US National Security Advisory Board for Biosecurity (NSABB),
- relevant German biosafety and biosecurity legislation.

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Existing German and European laws are commented and assessed in the third column of the following table.

Biosecurity requirement	German/EU legislation	Assessment
Lists of biological agents and toxins	a. Lists based on security concerns: – List under the War Weapons Control Act (KrWaffKontrG) (War Weapons List), – List under the Foreign Trade and Payments Ordinance (AWV) (Export List) – List under Council Regulation (EU) No 428/2009 (Dual use - Export, Transit, Trade) b. Lists based on security concerns: – Biological Agents Ordinance (BioStoffV) – Annex III of Directive 2000/54/EC of the European Parliament and the Council – Organism list of the Central Committee on Biological Safety (ZKBS) – Epizootic Pathogens Import Ordinance (TierSeuchErEinfV) – Technical Rules for Biological Agents (TRBA) 460, 462, 464, 466 – etc.	There are enough safety and risk assessment lists in German/EU legislation which could, if necessary, be linked with biosecurity measures. The EU Commission will draw up a list of biosecurity relevant pathogens and toxins together with the Member States.
Restriction of the handling of listed agents and toxins/ licensing requirements	– Infectious Diseases Control Act (IfSG) (licensing and notification requirements) – Genetic Engineering Act (GenTG) and ordinances (licensing, registration and notification requirements), – Epizootic Pathogens Ordinance (TierSeuchErV) (licensing and notification requirements), – Biological Agents Ordinance (BioStoffV) (notification requirements) – Ordinance under the Chemical Weapons Convention (CWÜV)	Licensing and notification requirements concerning the handling of biological agents are governed by law, the toxins ricin and saxitoxin are regulated by our chemical weapons legislation.
Personal reliability/ personal safety/security check	– Infectious Diseases Control Act (IfSG) – Epizootic Pathogens Ordinance (TierSeuchErV) – Genetic Engineering Act (GenTG) – Security Clearance Check Act (SÜG) and the Ordinance on the Determination of the Scope for Security Checks (SÜFV)	IfSG, TierSeuchErV and GenTG all require competence and reliability as a prerequisite for issuing an authorisation/ license; SÜG and SÜFV classify handling highly pathogenic and highly toxic agents as security-relevant and require a security clearance check for

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Biosecurity requirement	German/EU legislation	Assessment
		persons handling these agents.
Register of institutions handling listed biological agents and toxins	– Infectious Diseases Control Act (IfSG) – Epizootic Pathogens Ordinance (TierSeuchErV)Genetic Engineering Act (GenTG) – Biological Agents Ordinance (BioStoffV)	With the help of authorisations/licenses issued and/or the legally required notifications, institutions are registered with the responsible authorities; no central register.
Register of persons handling listed biological agents and toxins	– Biological Agents Ordinance (BioStoffV) – Infectious Diseases Control Act (IfSG) – Epizootic Pathogens Ordinance (TierSeuchErV)	Registration of employees whose work focus is on biological agents from risk groups 3 and 4 pursuant to BioStoffV, see below. Personalised general permit according to IfSG for all human pathogens, for certain groups of pathogens or limited to defined pathogens, if necessary; no central register.
Forwarding/transfer of listed agents and toxins	– Infectious Diseases Control Act (IfSG) – Epizootic Pathogens Ordinance (TierSeuchErV)	Delivery only to other authorisation/license holders. Documentation of acquisition and dispensing pursuant to TierSeuchErV.
Import/export control of listed agents and pathogens	– Foreign Trade and Payments Act (AWG), – Foreign Trade and Payments Ordinance (AWV) – List under Council Regulation (EU) No 428/2009 (Dual use − Export, Transit, Trade) – Infectious Diseases Control Act (IfSG) – Epizootic Pathogens Import Ordinance (TierSeuchErEinfV)	Import and export is adequately regulated at EU level.
Transportation safety of listed agents and toxins	– dangerous goods legislation – Security Clearance Check Act (SÜG)/ Ordinance on the Determination of the Scope for Security Checks (SÜFV)	The provisions in the German dangerous goods legislation and in international regulations (UN, ICAO, IATA, IMO, ADR) are regarded as adequate. SÜG/SÜFV provide for security checks in some areas for defined types of transport.

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Biosecurity requirement	German/EU legislation	Assessment
Access controls for plants where employees work with listed agents and toxins	– Biological Agents Ordinance (BioStoffV) – TRBA 100 – TRBA 120 – Genetic Engineering Safety Ordinance (GenTSV)	Access is generally restricted from protection level 2 and security clearance level 2, respectively, to authorised personnel only, (keeping of laboratory animals − access is restricted from protection level 1).
Internal obligation to keep records when handling listed agents and toxins	– Biological Agents Ordinance (BioStoffV) – Ordinance concerning the duty to keep records in genetic engineering (GenAufzV)	BioStoffV: Duty to keep records pursuant to §13 (3) in risk groups 3 and 4 (list of persons, activities, biological agents used, if necessary accidents, incidents). In the case of genetic engineering activities of safety levels S3 and S4, extended record keeping is mandatory (as compared to S1 and S2).
Safe storage of listed biological agents and toxins	– Biological Agents Ordinance (BioStoffV) – TRBA 100 – Genetic Engineering Safety Ordinance (GenTSV)	Compulsory pursuant to BioStoffV and TRBA.
Inventory list for listed biological agents and toxins	– Biological Agents Ordinance (BioStoffV) – Genetic Engineering Act (GenTG) – Ordinance concerning the duty to keep records in genetic engineering (GenAufzV) – Epizootic Pathogens Ordinance (TierSeuchErV)	Listing of biological agents, GMO and epizootic pathogens is required, a complete list containing quantities/ "utilisation", however, is not required.

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Summary

1. The majority of the above provisions regulates the handling of risk-related biological agents, but does not include toxins.

2. For plants where staff works with listed biological agents, access restrictions are in place, but detailed access controls are not compulsory.

3. The duty to keep records is regulated pursuant to the Biological Agents Ordinance (BioStoffV); however, an inventory is not described and/or required explicitly.

4. Central registers on institutions and persons handling listed risk-related biological agents and substances do not exist.