



**Germany's national System for prevention
of risks from biological agents –
the role of the committee on biological agents
and its cooperation with other bodies**

**Gabriela Förster MD
Vice President of the Committee on Biological Agents (ABAS)
Specialist for Occupational medicine**



German Law System concerning Biosafety and Biosecurity



Law	Law on Occupational Safety and Health	Genetic Engineering Act	Law for the Prevention of Infection
Ordinance	Ordinance on Biological Agents	Ordinance on Safety of Genetic Engineering	
Aim	<ul style="list-style-type: none">➤ Occupational safety and health	<ul style="list-style-type: none">➤ Occupational safety and health➤ Protection of the environment➤ Protection of material goods	<ul style="list-style-type: none">➤ Public health:<ul style="list-style-type: none">– Preventing infectious diseases– Early recognition of infections– Avoid transmission of infections
Jurisdiction	Federal Ministry of Labour and Social Affairs (BMAS)	Federal Ministry of Food and Agriculture (BMEL)	Federal Ministry of Health (BMG)
Federal Institute	Federal Institute for Occupational Safety and Health (BAuA)	Federal Office of Consumer Protection and Food Safety (BVL)	Robert Koch-Institute (RKI)



Regulations

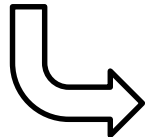


Directive 2000/54/EC

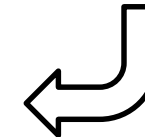
Protection of workers from risks related to exposure to biological agents at work

Directive 2010/32/EU

Prevention from sharp injuries in the hospital and healthcare sector



Ordinance on Biological Agents
(BioStoffV)



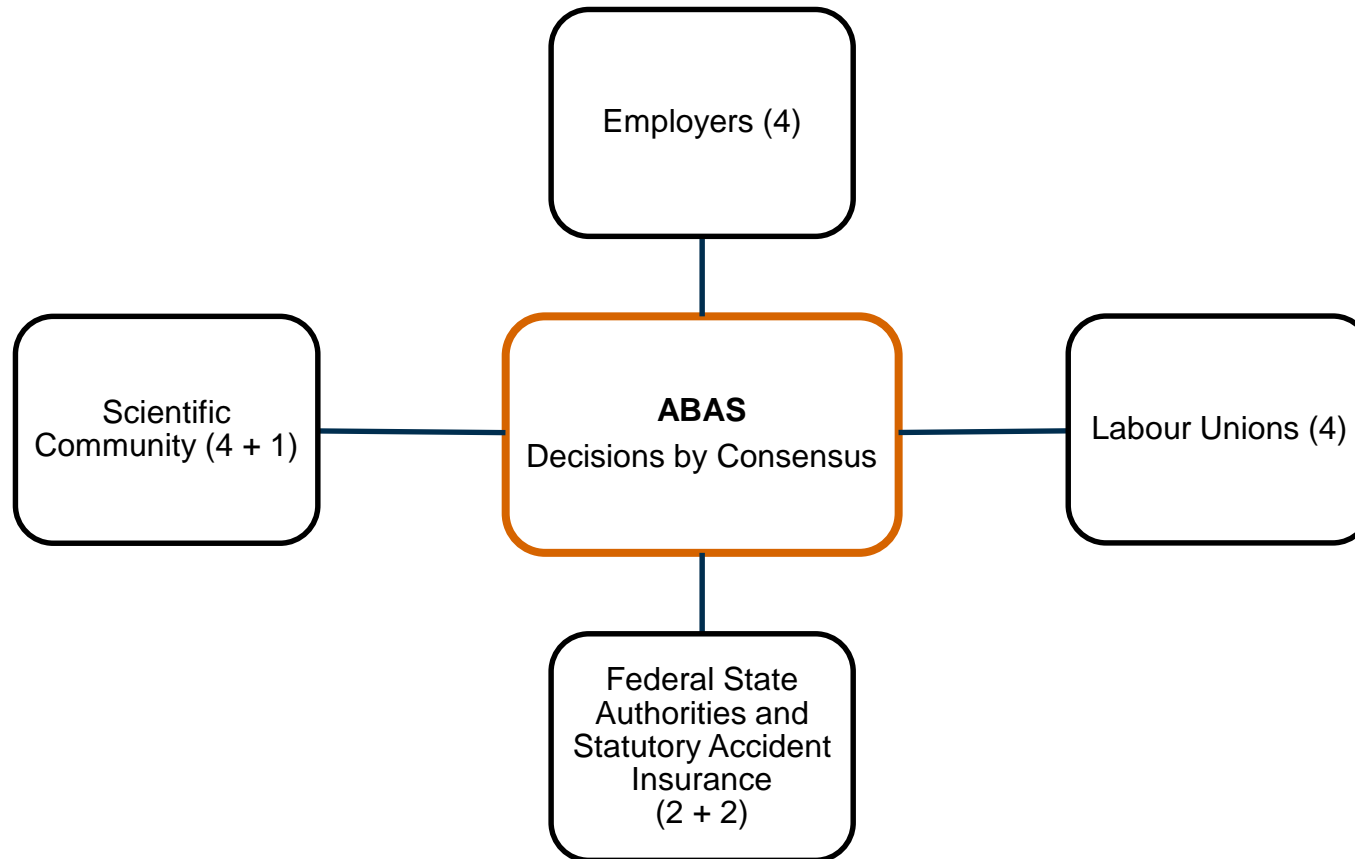
Committee on
Biological Agents
(ABAS)



Technical Rules for Biological Agents
(TRBA)



Committee on Biological Agents (ABAS) (§ 19 Biological Agents Ordinance (BioStoffV))



The German Federal Ministry of Labour and Social Affairs consults the Committee on Biological Agents on all aspects of occupational health and safety.



Structure of the Committee on Biological Agents



Subcommittee 1 – General issues and new developments

- International Occupational safety and health
- Risk and Workplace assessment
- Evidence-based regulation
- “BioStoffTage” – every year, expert talk and discussion about special subjects open to the public

- TRBA 130 Occupational safety measures in acute **biohazard** situations (DE, EN)
- TRBA 200 Requirements for **professional expertise** in accordance with the Biological Agents Ordinance (DE, EN)
- TRBA 400 **Guideline for risk assessment** and for the instruction of Employees in relation to activities with biological agents (DE, EN)



Structure of the Committee on Biological Agents



Subcommittee 2 - Protective measures

- TRBA 100 Protective measures for activities involving biological agents in **laboratories** (DE, EN)
- TRBA 120 **Animal facilities**
- TRBA 212 – 214 Protective measures for activities involving biological agents in **waste industries**.
- TRBA 220 Safety and health for activities involving biological agents in **sewage plants** (DE, EN)
- TRBA 230 Protective measures for activities involving biological agents in **agriculture**, forestry and comparable activities (DE, EN)
- TRBA 240 Protective measures for activities involving microbially contaminated **archival materials** (DE, EN)
- TRBA 250 Biological agents in **health care** and welfare facilities (DE, EN)
- TRBA 260 Protective measures for activities involving biological agents in **veterinary medicine** and comparable activities
- TRBA 500 **Basic measures** to be taken for activities involving biological agents (DE, EN)



Structure of the Committee on Biological Agents



Expert Group on Classification

- Evaluation and Classification of microorganisms (MOs)
- Updating Classification -TRBA (new developments in taxonomy, review of classification: new findings e.g. Infection potential; classification of new MOs: SARS, MERS, ...)
- Adapting Criteria of Classification of MOs to science and technology (TRBAs 450 – 468)

Expert Group on Laboratory Technology

- Analysis and evaluation of existing safety technology, e.g. mobile S3 lab units
- Reports on technical safety measures, e.g. gloveboxes
- Recommendations for users/operators (Techn. Reports)



Example of contents – Safety and Health for Activities involving Biological Agents in Sewage Plants (TRBA 220)



Scope

- non specific activities involving biological agents in sewage plants and describe protective measures to reduce the health hazard to workers

Definitions

- e.g. allergy, infection

Risk assessment – describes risks due to biological agents and activities, e.g.

- routes for the intake and transmission of MO
- exposure to sensitizing biological agents like activities involving sewage sludge
- where cleaning work is performed on channel structures, ODTs must be expected
- during high pressure flushing, inhalation intake of aerosols

Protective measures

- technical e.g. avoidance of aerosol formation describes mode of action blowing device
- organisational e.g. vehicle cabins must be cleaned every working day
- hygienic e.g. washing facilities, facilities for cleaning soiled footwear, single use towels
- personal protective equipment, e.g. protective clothing, foot protection, eye protection, respiratory protection equipment

Preventive occupational health care

- Mandatory health care – activities involving regular contact with faeces-containing sewage or faeces-contaminated objects in respect of the hepatitis A virus (HAV)



Sensitizing substances – Cooperation with Committee on Hazardous Substances



TRBA/TRGS 406 Substances causing airway sensitization

- Moulds (e.g. *Aspergillus* spp), bacteria (e.g. *Thermo actinomyces vulgaris*), mites, also components of bacteria
- Materials from plants, e.g. grain, feeding stuff
- Materials from animals, e.g. animal hair
- Chemical substances, e.g. disinfectants

Examples for sectors like agriculture and forestry, animal facilities, waste management ...

Protection measures: technical, organisational, personal

Technical Control Value of 5×10^4 CFU/m³ to review the effectiveness of preventive technical measures in certain subsectors of waste management.





Guideline for risk assessment and for the instruction of workers in relation to activities with biological agents (TRBA 400)



Toxic effects

- exotoxin produced by bacteria,
- mycotoxin produced by moulds (e.g. aflatoxins, ergotamine)
- ectoparasites
- endotoxins, they are found in the outer membrane of gramnegative bacteria, β -Glukane found in funghi). Can cause fever, rhinitis, pneumonitis, bronchitis.

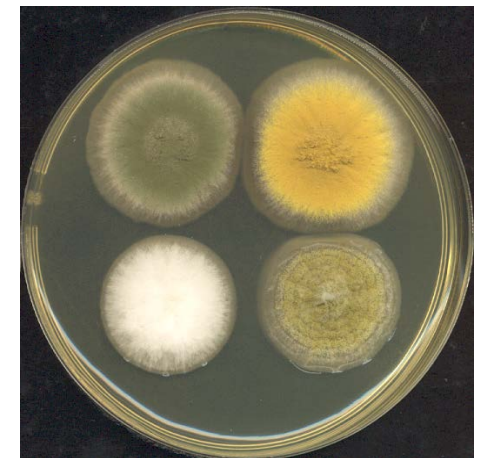


Sensitizing and toxic effects

- no health-based limit values on a scientifically solid base
- no specific technical rules for all activities with biological agents



Convention - exposure matrix with respect to degree and duration of the exposure and the level of exposure.



Adrian J. Hunter, Wikimedia Commons,



Convention on sensitizing and toxic hazards – Exposure matrix



Removal wallpaper and plaster with concrete grinder with direct extraction, additional exhaust ventilation of the working area.



Plaster milling machine with direct extraction.



Chipping off without extraction.

Duration/ frequency	Exposure level	Increased	High	Very high
		$10^4 - 10^5 \text{ CFU/m}^3$ $10^2 - 10^3 \text{ EU/m}^3$	$10^5 - 10^6 \text{ CFU/m}^3$ $10^3 - 10^4 \text{ EU/m}^3$	$> 10^6 \text{ CFU/m}^3$ $> 10^4 \text{ EU/m}^3$
Short		Increased risk	Increased risk	High risk
Medium		Increased risk	High risk	High risk
Long		Increased risk	High risk	Very high risk



Guideline for risk assessment and for the instruction of workers in relation to activities with biological agents (TRBA 400)



Exposure matrix for moulds and endotoxins in different sectors

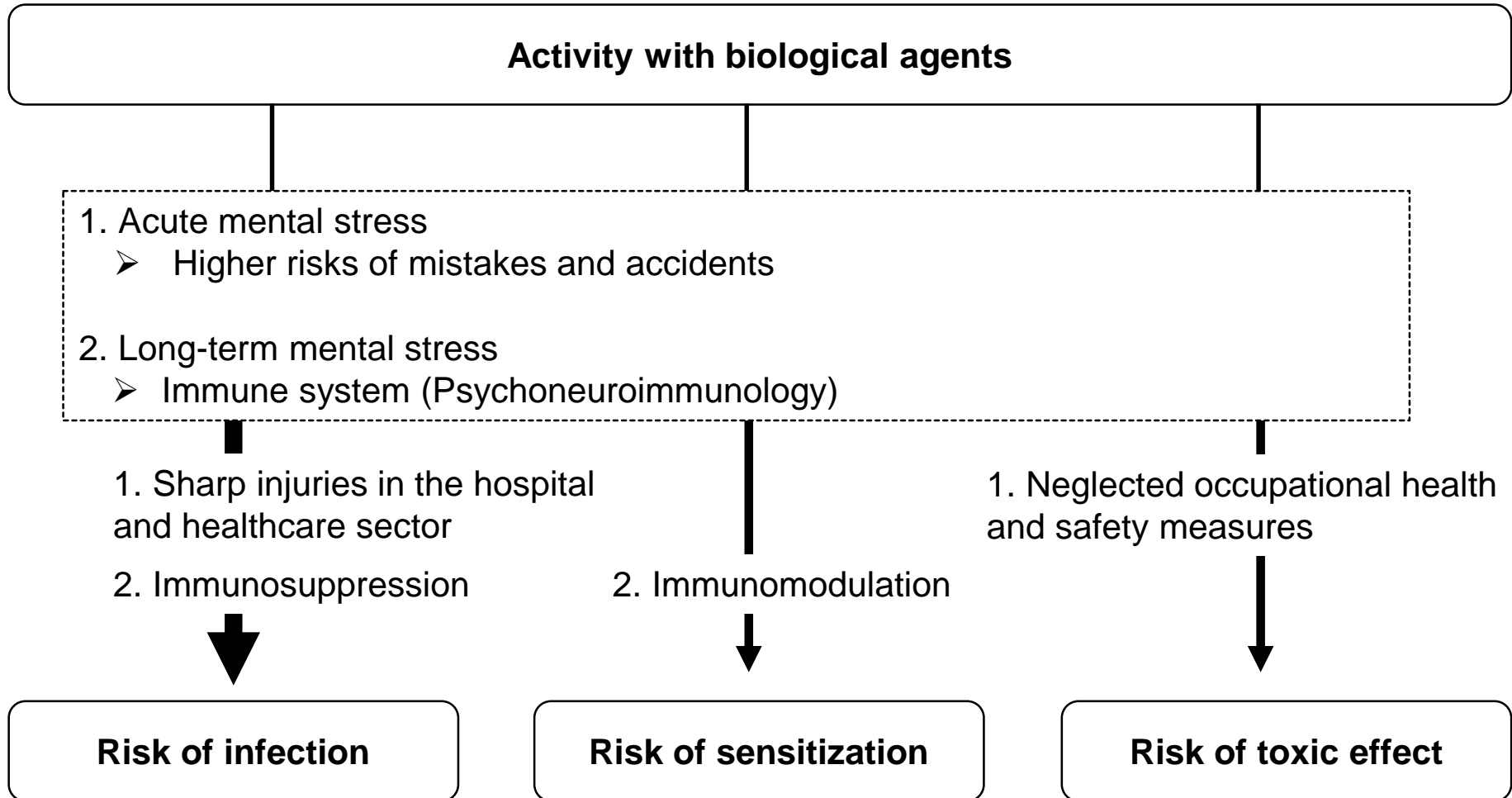
SCHIMMELPILZE in Branchen und Arbeitsbereich	Anzahl der Analysen	ES "Sehr hoch"	ES "Hoch"	ES "Erhöht"	<ES "Erhöht"
	[n]	[%]	[%]	[%]	[%]
Gebäudesanierung	11	100	0	0	0
Sägen, trocken	11	100	0	0	0
Abfallverbrennung	12	17	83	0	0
Kranbahnhof im Müllbunker, allgemein	17	10	97	0	0

Examples for infectious biological agents for unintentional exposures activities in different sectors

- Tätigkeiten mit Kontakt zu Erde (Freiland)	<i>Clostridium tetani</i>	2	Wundstarrkrampf	Perkutan (Kontakt zu verletzter Haut, auch bei Mikroläsionen)	► Infektionsgefährdung vorhanden
- staubende Erdarbeiten	<i>Borrelia burgdorferi</i>	2	Borreliose	Parenteral (Stich der Schildzecke)	► Infektionsgefährdung vorhanden
- Kontakt zu Wildtieren und ggf. zu deren Ausscheidungen (letzteres insbesondere bei Kontakten zu Erde gegeben)					
- Tätigkeiten in niedriger Vegetation (Gefahr von Zeckenbissen)	<i>Erdmiejegabe:</i> <i>Tollwutvirus (RABV)</i>	3 (**)	Tollwut	Parenteral (Biss), perkutan (Kontakt verletzter Haut/Schleimhaut zum Speichel infizierter Tiere)	► Infektionsgefährdung vorhanden
	<i>Eurosp. Fledermaus-Tollwutvirus (EBLV)</i>	3 (**)	Tollwut		
	<i>Hantaviren</i> (je nach Verbreitung)	2/3	Verschiedene Krankheitsformen	Aerogen (Inhalation von Stäuben, ggf. parenteral/Riesel)	Siehe TRBA 230



Risk assessment with activities involving biological agents in relation to mental stress





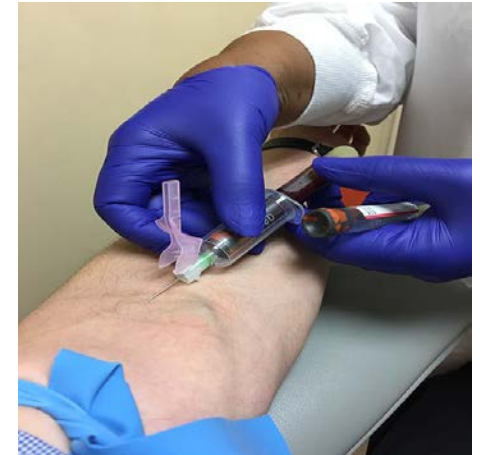
Evidence based safety and health



Prevention measures should have a sufficient evidence base.
A collection of state of the art information is good evidence.

For example:

- Classification of prokaryotes (bacteria and archaea) into risk groups (TRBA 466).
- GESTIS Biological Agents Database (Hazardous substance information system of the German Social Accident Insurance).
- „Technical Control Value“ (TKW) to review the effectiveness of technical protective measures. TKW is based on best available technology.
- Use of working equipment that has a safety mechanism to prevent needlestick injuries in the health sector.
- Strict methods of evaluation will not always work for prevention.



Matthew Lammers, Wikimedia Commons,



Parachutes reduce the risk of injury after gravitational challenge, but their effectiveness has not been proved with randomised controlled trials



Committee on Occupational Medicine advises the Federal Ministry of Labour and Social Affairs on all issues of medical occupational safety and health



Mandatory health care

- with a biological agent classified as Risk Group 4, or specific biological agents (in a defined list)

or with of tasks involving unintentional contact with biological agents, e.g.

- in research facilities or laboratories
- looking after pre-school children,
- conducting medical examinations; medical investigation, treatment or care,
- in sewage treatment plants,
- outdoors, in forests, parks, gardens and zoos; in facilities rearing and keeping birds.

Optional health care

- is preventive occupational health care which must be offered as an option when certain dangerous activities are performed.

Project group “Vaccination Management and Chemoprophylaxis within the scope of the Ordinance on Occupational Health Care”, wrote the Technical Rule AMR 6.5. about Vaccination.



Enforcement



- The 16 German Federal States are responsible for the enforcement of the regulations
- They act autonomously
- In some states different authorities are responsible for biosafety, biosecurity and public health
- More staff is needed for enforcement





Any questions?