Position Paper of the Committee for Biological Agents on the Laboratory Biorisk Management Standard (CWA 15793:2008)

I. Summary

The Committee for Biological Agents (ABAS) reaches the conclusion that the requirements of the Laboratory Biorisk Management Standard CWA 15793:2008 are largely met in Germany through compliance with existing national legislation. The CWA document does not quote any laws or specify assignments to risk groups. The document is deliberately generic in nature in order to accommodate national differences.

The binding character of German legislation eliminates the need for certification to CWA 15793:2008 in Germany. However, this does not rule out the voluntary application of the CWA 15793:2008 standard when defining and implementing biosafety and biosecurity measures.

II. Objective of the Laboratory Biorisk Management Standard (CWA 15793:2008)

The CEN Workshop Agreement (CWA) 15793:2008 entitled “Laboratory Biorisk Management Standard” was published in 2008 following an initiative of the American Biological Safety Association (ABSA), the European Biosafety Association (EBSA) and Det Norske Veritas (DNV). This document outlines biosafety and biosecurity requirements e.g. for the effective management of associated risks. With the implementation of quality management structures in laboratories, it aims to help users avert risks associated with the handling, storage and disposal of infectious biological materials and toxins.

The CWA document has its own categorization system and is primarily geared towards the “user/operator/business developer” of biological facilities. By implementing the CWA standard, organizations should be able to participate in the international exchange of goods, services, human resources and information, regardless of individual state legislation, its degree of enforcement and level of implementation. Organizations in countries which do not have an equivalent legal framework, and cannot refer to existing national laws to prove the compliance of their facilities, should also be given the opportunity to meet the requirements. In this respect, the CWA is a compendium of all biosafety requirements irrespective of whether they are actual laws or administrative provisions. Instead of focussing on the scope of application of individual pieces of legislation, the CWA defines key requirements that should encompass all relevant laws.

III. Integration of the CWA 15793:2008 into the CBRN Action Plan of the European Union

The *Laboratory Biorisk Management* CEN Workshop was largely financed with funds from the European Programme for the Protection of Critical Infrastructure by the Directorate-General for Justice, Freedom and Security (DG JLS) of the European Commission, and funding or contributions in kind by ABSA, the Public Health Agency of Canada, AstraZeneca UK Ltd and DNV. The Public Health Agency of Canada has made the document available online for free download: (ftp://ftp.cenorm.be/PUBLIC/CWAs/wokrshop31/CWA15793.pdf).

In a special-purpose CBRN Task Force (chemical, biological, radiological, nuclear) set up in 2008, the DG JLS put recommendations forward for discussion which were aimed to reduce the threat or use of chemical, biological, radiological or nuclear materials by terrorist organisations. In light of the different levels of availability, compliance and surveillance of biosafety and biosecurity standards/measures in laboratories in the 27 EU Member States, the DG JLS recommended that facilities in the Member States working with specific microorganisms and

toxins establish the CWA standard 15793:2008, while making reference to equivalent national and international standards, as well as national approval and accreditation procedures.

In the course of the planned implementation of the CBRN Action Plan in Member States in 2010 and beyond, it must be ensured that the implementation of the CWA in facilities, or CWA certification of facilities by a third party, is not a precondition for activities such as the provision of research grants, or the transfer of certain microorganisms and toxins between facilities for research purposes. CWA certification by a third party must be regarded as one of many ways to prove compliance and must take place on a voluntary basis.

IV. Comparison with current laws, ordinances and regulations in Germany

The Subcommittee 1 "New Developments" of the Committee for Biological Agents (ABAS) has examined the biosafety and biosecurity requirements outlined in the CWA 15793 standard, and compared them to laws, ordinances, regulations and provisions which apply in Germany.

The table in the Annex quotes individual laws and ordinances and assigns them to the various CWA requirements.

To gain a better understanding of the German legal system, the following should be noted: depending on their specific objective, biosafety issues are within the jurisdiction of laws addressing occupational safety and health, infection prevention, animal disease control, and crop protection. In addition, legislation on genetic engineering and pertinent regulations to combat terrorism and protect critical infrastructures can also apply. This leads to considerable overlap, particularly in the case of laboratories. Core worker protection regulations are enshrined in the Act on Safety and Health at Work (*Arbeitsschutzgesetz*) and in subordinate regulations and Technical Rules if the special requirements of genetic engineering law do not apply. Occupational safety and health regulations also cover the protection of the general public to the extent that in-house measures have such scope. Pure "security" measures to protect against criminal or terrorist activities are not included, however.

The legislation provides a clear definition of responsibilities for implementing the regulations. Management systems are not specified. However, the Act on Safety and Health at Work requires the employer to ensure the continuous improvement of occupational safety and health by creating a suitable organisation and establishing appropriate corporate management structures where applicable. Employers are granted the flexibility to adapt the form these structures take to their specific business situations.

Notes: The following concepts and requirements outlined in CWA 15793:2008 are not defined in the same level of detail in German legislation:

1. Biosecurity

"Biosecurity" is a term which does not appear as an actual German term in current German legislation. There is a need to clarify responsibility for "biosecurity" and "information security" and to define how these areas interact with occupational safety and health.

2. Toxins

The CWA 15793 also refers to toxins in addition to biological agents. In Germany individual toxins are regulated by legislation on hazardous substances (Chemicals Act (ChemG), Hazardous Substances Ordinance (GefahrStoffV), and Technical Regulations for Hazardous Substances 526 "Laboratories" (TRGS 526 "Laboratorien")). This primarily regulates occupational safety and health in the same way as the legal framework described here for biological agents. Risk assessment plays a central role and forms the basis for defining the

necessary protection measures and precautions. Employer obligations as formulated in the Act on Safety and Health at Work apply as standard.
Because inclusion of legislation on hazardous substances would be beyond the scope of this paper, this paper generally does not make reference to such sources of law or notes on toxins.

3. “Biorisk Advisor”
Only German genetic engineering law requires the appointment of a biosafety officer. The Biological Agents Regulation (Biostoffverordnung, (Section 10, paragraph 5)) stipulates that specific activities with group 3 or 4 biological agents may only be assigned to workers if those workers have sufficient expertise and knowledge. Section 44 of the Protection against Infection Act stipulates that a permit is required to handle pathogens. To receive this permit the applicant must have two years’ full-time experience working with pathogens.

4. Continued Training and Qualification
BioStoffV and GenTSV require adequate competency levels and expertise. Up to now, no explicit provisions have been made for continued training and education, which is essential given the rapid development of “biosafety” and “biosecurity” in recent years. However, policy-makers demand that further training and up skilling measures – which are required to perform tasks – be made possible, while paying due attention to the needs of the business operation (ASiG §§2, 5 and GentSV §19).

5. Continuous Improvement of Biorisk Management
Currently the BioStoffV and GenTSV do not require continuous auditing and improvement of the results achieved. In accordance with the ArbSchG and BioStoffV, however, the employer is required to update the risk assessment at regular intervals.

6. Emergency Exercises and Drills
The action to be taken by affected parties in emergency situations, as specified in the legislation examined, is considered to be adequate.

7. Certification by a Third Party
The German Consensus Statement (GDS) of 1993 is not in favour of the certification of occupational safety and health measures by a third party.

Compared to CWA 15793:2008, German legislation lacks requirements with regard to the appointment of a biorisk advisor for activities that involve non-genetically modified organisms which are pathogenic for humans, and with regard to the handling of toxins of biological origin. These requirements are the subject of debate within the context of amendments to the Biological Agents Regulation.

Annex "Correlation of current laws, ordinances and regulations of the CWA requirements" (edition Dec. 02 2010)

CWA No.	CWA title	CWA requirement	Corresponding legislation[1]	Comments and explanations
4.1.	**General requirements**			
4.1.1	Biorisk management system	The organization shall establish, document, implement and maintain a biorisk management system in accordance with the requirements of this Laboratory biorisk management standard.	ArbSchG, §§ 3, 5, 6	**No specific management systems are defined in German occupational health and safety (OHS) law.** The **employer** is responsible for establishing a suitable organization and, where applicable, appropriate corporate management structures for OHS measures, and for the improvement and documentation of same. The employer is responsible for organising risk assessment and implementing identified protection measures.
4.1.2	Continual improvement	The organization shall continually improve the effectiveness of the biorisk management system through the use of the policy, objectives, self-audit programme, audit results, analysis of data, risk assessment, corrective and preventive actions and the management review.	ASiG, §§ 2, 5 GenTG, § 6 GenTSV, § 16	According to German law, the occupational safety expert and the company physician, in their role to provide assistance, advice and guidance, are an integral part of the in-house occupational health and safety organization. In the case of genetic engineering operations, the operator is required to appoint a biosafety officer for expert advice and guidance. The biosafety officer also has specific supervisory duties.
4.2	**Policy**			
4.2.1	Biorisk management policy	The organization's top management shall develop, authorize and sign a policy concerning the management of laboratory biorisk (laboratory biosafety and laboratory biosecurity). It shall clearly state the overall biorisk management objectives and a commitment to improving biorisk management performance. The policy shall be appropriate to the nature and scale of the risk associated with the facility and associated activities and commit to: a) protecting staff, contractors, visitors, community and environment from	ArbSchG / BioStoffV GenTG / GenTSV	The biorisk management objectives which the CWA assigns to management are laid down in laws in Germany. German legislation does not require the development of specific models and corporate strategies or a concrete corporate policy.

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		biological agents and toxins that are stored or handled within the facility; b) reducing the risk of unintentional release of, or exposure to biological agents and toxins; c) reducing the risk to an acceptable level of unauthorized intentional release of hazardous biological materials, including the need to conduct risk assessments and implement the required control measures; d) complying with all legal requirements applicable to the biological agents and toxins that will be handled or possessed, and with the requirements of this standard; e) ensuring that the need for effective biorisk management shall take precedence over all non "health and safety" operational requirements; f) effectively informing all employees and relevant third parties and communicating individual obligations with regard to biorisk to those groups; g) continually improving biorisk management performance.		
4.3	**Planning**			
4.3.1	**Planning for hazard identification, risk assessment and risk control**			
4.3.1.1	Planning and resources	The organization shall ensure that a risk assessment system is established, implemented and maintained in accordance with this standard and that	ArbSchG, §§ 3, 5 BioStoffV, §§ 5 -8, 12	For protection objectives and employer obligations, see 4.1.1 These parts of legislation provide a more detailed definition of the risk assessment

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		the performance of the risk management system is reported to senior management for review and as a basis for improvement.	TRBA 400, No. 4 TRBA 100, No. 4	process for biorisks, and gives details on when to review and update a risk assessment. TRBA 100 refers specifically to activities in laboratories.
		The organization shall identify resource requirements and provide adequate resources, including the assignment of trained personnel for management, performance of work, and verification activities, including internal review.	GenTG, § 6	The operator is responsible for risk prevention in genetic engineering operations. The operator has responsibility for ensuring risk assessments are performed and for regular reviews of, and improvements to, safety measures in place.
			GenTSV, §§ 4, 5, 7 §§ 8, 12, 14, 18	The criteria for assessing the risk and classifying the safety levels of genetic engineering operations are defined in the GenTSV, as are the general protection duties of the operator and the operator's responsibility to perform risk assessment. This legislation also defines the specific duties of the project leader and the biosafety officer within the context of implementing the regulations.
			ASiG, §§ 2, 3, 5, 6	The occupational safety expert and the company physician have key advisory and support duties. ***Note:*** *The duties of the employer or operator also define the resource planning schedules to an extent.*
4.3.1.2	Risk assessment - timing and scope	The organization shall ensure the approach to risk assessment is defined with respect to its scope, nature and timing so that it is proactive rather than reactive.		The ArbSchG takes a broad, integrated approach: it requires the assessment of all the risks associated with the activity in the context of risk assessment, the central instrument of a systematic occupational health and safety policy. Risk assessment is a method which primarily involves the following steps: - Identifying existing hazards - Assessing such hazards - Deciding what protection measures are necessary - Implementing the protection measures - Examining the effectiveness of the measures taken It is updated regularly and for specific purposes.
4.3.1.3	Hazard identification	The hazards associated with proposed work shall be identified and documented.		
4.3.1.4	Risk assessment	The organization shall ensure that suitable methodologies for assessing and recording risks are identified, implemented and maintained.		

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4.3.1.5	Risk management	The organization shall ensure suitable methodologies for the allocation of actions resulting from risk assessments, including time lines, responsible persons and associated reporting and approval mechanisms are identified, implemented and maintained.	ArbSchG, §§ 5, 6	The ArbSchG does **not** describe the specific procedure or the individual steps taken to perform risk assessment. Numerous guidelines issued by accident insurance funds, OHS authorities and external OHS service providers are based on the steps above. They also stipulate the need to define responsibilities and track time lines.
			BioStoffV, §§ 5 - 8 TRBA 400 No. 4 TRBA 100 No. 4, 5	The risk assessment must incorporate all risks present in all work areas, depending on individual tasks to be performed. The documentation must contain information on the result of the assessment, specified action and the result of subsequent reviews. To assess biorisks, it is essential to gather work-related information on the possible occurrence, identity and classification of the biological agent; the operational processes and work procedures followed; as well as possible exposure, in order to define the biosafety level and appropriate protection measures. Risk assessment must be proactive in that it is performed before work commences, and should be subsequently updated on a regular basis.
			GenTG, § 6 GenTSV, §§ 4-8 in conjunction with Annexes III - V	The Technical Rules provide guidance on the specific code of practice, the assessment of activities in a laboratory, the definition of the biosafety level and the protection measures required in laboratories. In the case of genetic engineering operations, the risks are also assessed before the operations commence (supported by the formal reporting, notification, and approval processes set down by law). This results in a safety classification which is associated with the implementation of specific measures. The basic framework, criteria and procedures to be followed for safety classification are defined, as are the specific measures.
			ASiG, §§ 2, 3, 5, 6	***Note:*** *Legislation on genetic engineering specifies the responsibilities of the project leader and the biosafety officer (GenTSV, § 14, 18). Genetic engineering operations involve a legal obligation to keep records. The biosafety officer is obliged to submit reports to the operator on how he has fulfilled his duties.* The occupational safety expert and the company physician have advisory and support roles during the risk assessment process.

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4.3.2	**Conformity and Compliance**	The organization shall ensure that all relevant requirements are identified and fulfilled within the biorisk management system. Legal requirements include national / federal, regional / state, provincial, city and local regulatory requirements with which the organization shall comply.		The requirement is a matter of course and is common practice.
4.3.3	**Objectives, targets and program**			
4.3.3.1	Biorisk control objectives and targets	The organization shall establish, implement and maintain documented biorisk control objectives and targets for an effective control of biorisk at relevant functions and levels in the organization.	BioStoffV, §§ 5-8, 11 ASiG, §§ 3, 6 GenTSV, § 18	The risk assessment must examine how effective the measures taken are in terms of meeting protection objectives (see 4.3.1.2.ff.). As part of their role to provide advice and guidance on safety matters and worker health, the occupational safety experts and company physicians also have inspection duties (e.g. regular inspections of workplaces, identification of the cause of occupational accidents etc.). Genetic engineering law describes specific supervisory duties of the biosafety officer.
4.3.3.2	Monitoring controls	Management shall establish the controls and put in place documented procedures for monitoring the effectiveness of the controls being applied to reduce or eliminate the hazards identified in the risk assessment process.		

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4.4	**Implementation and operation**			
4.4.1	**Roles, responsibilities and authorities**			
4.4.1.1	Top management	Top management shall take ultimate responsibility for the organization's biorisk management system. Top management shall ensure that roles, responsibilities and authorities related to biorisk management are defined, documented and communicated to those who manage, perform and verify work associated with the control of biological agents and toxins. Top management shall demonstrate its commitment by ensuring the availability of resources to establish, implement, maintain and improve the biorisk management system.	ArbSchG, § 13	The responsibilities of the employer or operator are described in 4.1.1 and 4.3.1.1. Legislation on genetic engineering or occupational health and safety does not break down the responsibilities and assign them to a specific management level. Depending on the size and type of the plant, some or all of the obligations incumbent on the employer can be delegated in writing. If this is the case, it must be ensured that the designated individual has the competence and authority to perform the task. Genetic engineering law also permits the operator to delegate his tasks.

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4.4.1.2	Senior manager	A senior manager shall be designated with operational responsibility for overseeing the system for management of biorisk. Functions of the system for the management of biorisk shall include: a) providing appropriate resources to ensure adequate provision of personnel, facilities and other resources deemed necessary for the safe and secure operation of the facility; b) reporting to top management on the performance of the biorisk management system and any need for improvement; c) ensuring promotion of the biorisk management system throughout the organization; d) instituting review, audit and reporting measures to provide assurance that the requirements of this standard are being implemented and maintained effectively.		

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4.4.1.3	Biorisk management committee	A biorisk management committee shall be constituted to act as an independent review group for biorisk issues. Reporting to senior management, the committee shall: a) have documented terms of reference; b) include a representative cross-§ of expertise, appropriate to the nature and scale of the activities undertaken; c) ensure issues addressed are formally recorded, actions allocated, tracked and closed out effectively; d) be chaired by a senior individual; e) meet at a defined and appropriate frequency, and when otherwise required.	GenTSV, § 16 (ASiG, § 11) BioStoffV, § 13	German legislation does not provide for a `biorisk management committee´ as defined here. In the case of genetic engineering operations, at least one biosafety officer or several biosafety officers (= committee for biological safety (ABS)) must be appointed depending on the nature and scale of the work. The biosafety officer does not have authority to issue instructions but does have a specific control and advisory role. It makes sense for the biosafety officer/committee for biological safety to work in tandem with the occupational health and safety (OHS) committee stipulated in the ASiG. The BioStoffV currently does not require a biosafety officer or similar. However, notification to the competent authority in accordance with § 13 of the BioStoffV must include the name and qualification of the person responsible for health and safety at the workplace. This person can be the laboratory manager, team leader or similar.
4.4.1.4.	Biorisk management advisor	A competent individual(s) shall be designated to provide advice and guidance on biorisk management issues. This individual shall report directly to the responsible senior manager and have delegated authority to stop work in the event that it is considered necessary to do so. This role shall be independent of those responsible for implementing the programme of work.		
4.4.1.5	Scientific management	An individual(s) with responsibility for the scientific programme within the facility shall be designated with responsibilities relevant to biorisk management. Functions shall include: a) ensuring that all work is conducted in accordance with established policies	BioStoffV, § 13 GenTSV, § 14	The tasks described here are generally performed by the laboratory manager (see 4.4.1.3 and 4.4.1.4) or the project leader. **Note:** *Re f.) see 4.4.1.6*

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		and guidelines described in this standard; b) supervising workers, including ensuring only competent and authorized personnel can enter and work in the facility; c) planning and conducting work activities, and ensuring adequate staffing levels, time, space and equipment are available; d) ensuring required authorizations for work are in place; e) ensuring laboratory biosafety and laboratory biosecurity risk assessments have been performed, reviewed and approved, and that the required control measures are in place; f) ensuring that all at-risk employees have been informed of risk assessments and/or provisions for any recommended precautionary medical practices (e.g. vaccinations or serum collection		
4.4.1.6	Occupational health	The organization shall have access to appropriate occupational health expertise and establish an occupational health programme commensurate with the activities and risks of the facility.	BioStoffV, §§ 12, 15 GenTSV, § 14, Annex VI ArbMedVV, §§ 3 ff.	Based on the results of the risk assessment, the employer must ensure that appropriate occupational health services are available. In addition to a general medical consultation as regards occupational health, this also comprises mandatory or optional physical examinations. In the case of genetic engineering operations, the operator must also ensure appropriate preventive measures are taken within the workplace. The project leader is responsible for organizing the necessary medical check-ups.
4.4.1.7	Facility management	Facilities manager(s) shall be appointed with responsibilities relevant to facilities and equipment determined in accordance with requirements set out in this standard.	ArbSchG, § 8	A full set of provisions is not provided for this in legislation governing occupational health and safety/genetic engineering. If staff of more than one employer work in one place (e.g. contractors from other companies), the employers must work together to perform the risk assessment. In particular, this implies the mutual communication of the risks associated with

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				individual tasks, and agreeing and coordinating the protection measures needed.
			BGV A1, § 6	To avert risks, the organizations can appoint a person who coordinates the scheduled tasks and has the authority to issue orders.
			BetrSichV, § 4	The safe operation and correct handling of equipment must be ensured.
4.4.1.8	Security management	A security manager shall be designated with responsibilities determined in accordance with requirements set out in this standard.		No provisions for this kind of role are made in legislation on occupational health and safety/genetic engineering.
4.4.1.9	Animal handling	In laboratories where animals are maintained, an animal care manager shall be designated with responsibilities determined in accordance with requirements set out in this standard.	*TierSchG, § 8b* *TRBA 120* *TierSeuchErV, § 2*	No provisions for this kind of role are made in legislation on occupational health and safety/genetic engineering. **Note:** • *Facilities housing laboratory animals have an animal welfare officer. However, the role and duties of the animal welfare officer are different to those described in the CWA standard.* • *TRBA 120 describes the protection measures for housing laboratory animals. Similarly Annex V of the GenTSV describes the protection measures for animal rooms in the four containment levels. The project leaders are responsible for genetic engineering operations in animal rooms.* • *According to the TierSeuchErV, a permit must be obtained to work with animal disease agents.*
4.4.2	**Personal Training, awareness and competence**	The organization shall ensure that personnel that have responsibilities and/or perform tasks that may impact biorisk management in the workplace are competent to do so. Competence levels shall be judged on appropriate education, training and experience. The organization shall define required competency levels and shall maintain	ArbSchG, §§ 7, 12	Suitable staff competency levels with regard to compliance with required security and OHS measures when performing tasks is a basic requirement of occupational health and safety policies, as is regular instruction and training. (See also 4.4.2.1 – 4.4.2.4)

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		records verifying that staff members have attained and demonstrated those levels of competency.		
4.4.2.1	Recruitment	The organization shall ensure that qualifications, experience and aptitudes relating to biorisk are considered as part of the recruitment process.	BioStoffV, §§ 10, 12	Training must be provided before commencement of tasks and at least once annually thereafter. Tasks involving group 3 and 4 biological agents may only be assigned to appropriately qualified and knowledgeable staff. Special working instructions must be provided where necessary.
4.4.2.2	Competence	The organization shall ensure that personnel conduct activities within the facility under close supervision until competency has been demonstrated.	GenTSV § 14	Only appropriately qualified personnel may be entrusted with genetic engineering operations (responsibility of the project leader). The project leader is also responsible for annual training and instruction measures.
4.4.2.3	Continuity and succession planning	The organization shall ensure that adequate back-up and contingency measures are in place to address the need for continuity and succession planning.	IfSG, §§ 44, 47 TierSeuchErV, §§ 2, 4 SÜG, § 1, 2 SÜFG, §§ 8, 9, 11 Appropriate Länder-specific legislation	Work involving human or animal pathogens requires a special permit. Work with such pathogens may only be performed under the supervision of a permit holder. To obtain this permit, the applicant must have a high level of education, training and experience. (Lack of suitability or reliability are reasons for exclusion). Persons working with certain biological materials are subject to security screening in accordance with § 1(5) of the SÜG.
4.4.2.4	Training	The organization shall ensure that requirements and procedures for biorisk-related training of personnel are identified, established and maintained.		**Note**: • *No provisions for a continuous training concept are made in legislation governing occupational health and safety/genetic engineering.* • *The requirements that define the term "expertise" are currently not specified in the BiostoffV.*
4.4.3	**Consultation and Com-munication**	The organization shall ensure that relevant biorisk information relating to its activities is communicated to and from employees and other relevant parties. Employee involvement and consultation arrangements shall be	ArbSchG, § 12 BioStoffV, § 12 GenTSV, §§ 12, 12a BioStoffV, § 13 IfSG, §§ 49, 50 TierSeuchErV, §§ 5, 6	The instruction and training of staff (standard operating procedures, physical instruction, briefing sessions and working instructions) are central to occupational health and safety. Training must be provided before commencement of the work and at least once a year thereafter, and must be documented accordingly. Obligatory notification is articulated in the Biological Agents Regulation, the Protection against Infection Act and the Animal Disease Agent Ordinance.

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		documented. Personnel shall have access to adequate and up-to-date information pertaining to the biorisks of the organization.	GenTG, §§ 8-12, 21	Legislation on genetic engineering defines notification, application and authorization processes that apply depending on the facility, safety level classification and the type of genetic engineering operation. Furthermore, the law also provides for the compulsory notification of the competent authority responsible for supervision.
4.4.4	**Operational control**	The organization shall identify those operations and activities that are associated with possible biological risk and where control measures shall be applied. The organization shall plan these activities, including maintenance, and ensure that they are carried out under specified conditions.		See 4.3.1.2 - 4.3.1.5: Appropriate checking and control procedures to ensure occupational health and safety must be defined during the risk assessment.
4.4.4.1	General safety	The organization shall ensure that a formal process is in place to identify and manage risk associated with general safety.	*GenTNotfV, § 3*	The regulations of the BiostoffV and GenTG only permit operations to be performed in facilities that comply with the biosafety/safety level defined as a result of the hazard or risk assessment process. The performance of genetic engineering operations in facilities with appropriate biocontainment not only protects workers but also ensures general safety, such as the protection of the environment, humans and animals. ***Note:*** *Provisions are made in the GenTNotFallV for external emergency plans which must be drawn up in conjunction with the specific authorities prior to commencing safety level 3 and 4 genetic engineering operations.*
4.4.4.2	Biological agents and toxin inventory and information	The organization shall ensure that an accurate and up-to-date biological agents and toxin inventory is established and maintained. It shall ensure that records relating to the inventory of biological agents and toxins are current, complete and stored securely with adequate backup provision. It shall ensure that transfers of	BioStoffV, § 8 GenTG, §§ 8-10 GenTAufzV, §§ 1, 2	In the context of performing risk assessment in accordance with the BiostoffV, a catalogue of biological agents must be kept and maintained for specific activities (and only to a certain extent for non-specific activities). An inventory in the sense of the CWA is not required. In the course of reporting, notification, and approval procedures as defined by genetic engineering law, the planned operations, and the organisms envisaged for such operations, must be declared. All records on ongoing or completed genetic engineering operations must also contain information on the donor and recipient organisms, and genetically modified organisms.

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		biological agents and toxins between laboratories at the facility or into and out of the facility are recorded and controlled in line with the level of the risk.	IfSG, § 44 TierSeuchErV, §§ 2, § 9 TRBA 100, No. 5 GenTSV Annex III	Etiologic agents which are pathogenic for humans and/or animals may only be released or accepted by holders of a permit as defined by the IfSG or TierSeuchErV. Obligatory documentation requirements also apply for animal pathogens. Safe in-house transportation must be ensured. Suitable measures commensurate with the associated risk must be taken. ***Note:*** *Transportation outside the plant is fully regulated by national (GGVSE), European (ADR) and international legislation (e.g. IATA).*
4.4.4.3	Work programme, planning and capacity	The organization shall ensure that the programme of work for the facility is defined, documented and reviewed. The organization shall establish criteria for work that requires prior approval. It shall ensure there is sufficient resource capacity and capability to manage workflow, whether planned or unplanned	ArbSchG, §§ 3-5	The risk assessment also examines the issue of workflow, as well as resources and staffing if necessary. If processes or operational procedures change, the risks must be reassessed before activities can commence. Responsibility for defining work programmes and ensuring their correct execution rests within the organisation.
4.4.4.4	Change management	The organization shall ensure that all changes associated with the design, operation and maintenance of the facility are subject to a defined and documented change management process.	BioStoffV, § 10 GenTG, § 6 GenTSV, § 12	The risk assessment must play a key role in internal decision-making processes (see 4.3.1.2 – 4.3.1.5). Adaptation to technical progress, new findings and advances in science is one of the basic requirements of occupational health and safety.
4.4.4.5	Work practices, decontamination and personal protection			
4.4.4.5.1	Good microbiological technique	The organization shall ensure that all personnel handling biological agents and toxins are competent in good microbiological techniques and that	TRBA 100, Annex 1 GenTSV Annex III	**G**ood **M**icrobiological **P**ractices are established and stipulated.

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		appropriate resources (including time and equipment) are available to ensure such practices can be adhered to effectively.		
4.4.4.5.2	Inactivation of biological agents and toxins	The organization shall establish and maintain procedures to ensure that appropriate methods for disinfection and decontamination are chosen and implemented effectively. The organization shall ensure that all contaminated or potentially contaminated waste items have been identified and documented (including those that may result from an emergency), and that effective procedures are put in place to devise effective decontamination and other appropriate treatments.	BioStoffV, § 11 TRBA 100 No. 5 GenTSV, §§ 11, 13 Annex III	The BioStoffV and the sub-legislative framework define clear regulations for the management and inactivation of contaminated waste. The appropriate measures must be specified as part of the risk assessment. Hygiene procedures are required for biosafety level 2 and above. Similar regulations are found in genetic engineering law. The requirements for treating waste and wastewater are described in detail.
4.4.4.5.3	Waste management	The organization shall establish and maintain an appropriate waste management policy for biological agents and toxins.		
4.4.4.5.4	Clothing and Personal protective Equipment (PPE)	The organization shall ensure that PPE needs are identified and suitable equipment is specified, made available, used and maintained appropriately within the facility.	ArbSchG, §§ 3, 4, 15 PSA-BV, § 2 BioStoffV, § 11 TRBA 100 No. 5 GenTSV, § 9, Annex III	Suitable personal protective equipment (PPE) must be made available in line with the results of the risk assessment. Attention must be paid to the priority of the protective measures. Collective measures have priority over individual measures. Otherwise the TOP principle applies, which stipulates that technical measures come before organizational measures, and PPE only if it is absolutely necessary for added protection. Workers are required to use the PPE provided to them as intended. The employer must bear the cost of the PPE. The protection measures enshrined in legislation on genetic engineering have a similar priority.
4.4.4.6	Worker health programme	The organization shall ensure that risk to worker health, and that of other personnel whose health could be	ArbSchG, § 11 BiostoffV, §§ 12, 15 ArbMedVV Annex	Prevention measures that form part of worker health protection require a general medical consultation as regards occupational health and safety, as well as mandatory and optional check-ups, where applicable, and optional vaccination.

CWA No.	CWA title	CWA requirement	Corresponding legislation[1]	Comments and explanations
		directly impacted by exposure to biological agents and toxins, is managed effectively including prevention and protection measures. The requirements of the health surveillance programme shall be determined by a defined health hazard identification and risk assessment process involving all relevant personnel.	Part II GenTSV Annex VI ASiG, § 3 BioStoffV, § 1 GenTG, § 1 GenTSV, § 1	They are defined in the context of the risk assessment process, which generally involves the company physician who provides expert advice and guidance. Identical regulations apply in the area of genetic engineering. The BioStoffV applies for activities involving biological agents including activities within the hazardous area. Legislation governing genetic engineering generally involves the protection of third parties: the protection of life and health is one of the specific protection objectives.
4.4.4.6.1	Vaccination of personnel	Based on risk, the need for vaccination shall be identified and shall cover groups identified as being potentially exposed to biological agents or toxins. The organization shall ensure that a vaccination policy be defined and implemented, and that access to laboratories or work is controlled for individuals until they comply with the policy.	ArbMedVV Annex Part II GenTSV Annex VI	Provisions are made for mandatory check-ups for workers involved in specific activities with listed biological agents, and for certain non-specific activities in defined task areas. In the context of mandatory check-ups on workers who handle biological agents for which a vaccine is available, these workers must be offered the vaccine. Vaccination is not compulsory in Germany. For this reason, if workers refuse the vaccine this is not a valid reason to consider them unfit for work**.**
4.4.4.7	Behavioural factors and control of workers	The organization shall establish and maintain a programme to address risk associated with human behaviour, including the management of how workers interact with the facility and its equipment.	ArbSchG, §§ 3, 4, 15	For information on employee briefing and instruction see 4.4.3. Employers and workers are responsible for ensuring compliance with all the necessary precautions and protection measures.
4.4.4.7.1	Personnel reliability	The organization shall ensure that a personnel reliability policy is defined and implemented, and that access to facilities or work is controlled for individuals according to the policy.	 TRBA 100 No. 5 GenTSV Annex III, V	Occupational health and safety law does not contain specific rules governing personnel reliability. The competent authority must check the reliability of the applicant before granting the applicant a permit to work with pathogens as defined by the IfSG and TseuchErrV, or before granting authorization to set up/operate a genetic engineering facility. For staff security clearance, see 4.4.2.4. Provisions are made for restricted access to high-risk areas.

CWA No.	CWA title	CWA requirement	Corresponding legislation[1]	Comments and explanations
4.4.4.7.2	Contractors, visitors and suppliers	The organization shall ensure that suppliers, contractors, visitors and sub-contractors adhere to the requirements of established management systems and do not compromise biorisk management of the facility.	ArbSchG, § 8 TRBA 100 No. 5 GenTSV Annex III	If staff of more than one employer work in one place, the employers are obliged to work together to define security and OHS policy. (See also 4.4.1.7). The protection of third parties is ensured by access regulations, as well as specifications governing the release of potentially contaminated equipment and facilities prior to repair and modification work.
4.4.4.7.3	Exclusion	The organization shall ensure that measures are set in place for the removal and exclusion of personnel (both temporary and, if appropriate, permanent) from the facility where deemed necessary through risk assessment.	BGV A1 § 7	No specific provisions are made for this in legislation on occupational health and safety and genetic engineering. The employer/operator is responsible for taking appropriate measures to ensure the welfare of the workers. The business operator may not assign work to employees who are evidently not able to perform this work without posing a hazard to themselves or others.
4.4.4.8	Infrastructure and operational management	The organization shall ensure that facilities, equipment and processes are designed and run in a safe and secure way with respect to biorisk management.	BioStoffV §§ 10, 11 TRBA 100 GenTSV, § 8, Annex III IfSG, § 49 TierSeuchErV, §§ 4, 7	Regulations governing repair, maintenance and facility management are generally derived from occupational health and safety policy. Specific technical and structural requirements are described in TRBA 100 and in Annex III of the GenTSV. Appropriate maintenance and repair measures are required to maintain the specific safety level. Legislation governing protection against infection stipulates the use of suitable rooms and facilities to perform the individual operations.
4.4.4.8.1	Planning, design and verification	The organization shall ensure that a formal planning, design and redesign process is adopted for the facility, based upon an assessment of risk associated with the materials to be used and activities undertaken. The design process shall identify and incorporate all relevant legislative requirements, together with information from recognized standards, guidelines, industry good practices and facility-specific risk assessments. The design process shall identify and	ASiG, §§ 3, 6 ArbSchG, § 5 BioStoffV, §§ 5-8, 10 BioStoffV, § 13 GenTG, §§ 5, 7-9 GenTSV, §§ 14, 18	The occupational safety expert, company physician and other experts should be involved in the process of planning and designing work areas and workplaces at an early stage. Planning must be on the basis of the risk assessment and incorporate all legal regulations. In the context of reporting, notification, and approval procedures, the competent surveillance authorities are generally responsible for verification, at least for higher safety or biosafety levels.

CWA No.	CWA title	CWA requirement	Corresponding legislation[1]	Comments and explanations
		consult all relevant parties associated with the facility and its operation. All design features, construction techniques, materials and equipment selected shall be documented in line with the need to provide sufficiently specific and detailed instruction and information on the design specification. The organization shall ensure that new construction and physical facility modifications are carried out according to an approved plan.		
4.4.4.8.2	Commissioning and decommissioning	The organization shall ensure that there is a formal process for initial commissioning of new facilities and the final decommissioning of existing ones.	ASiG, § 6 BetrSichV, § 10 GenTG, §§ 8, 21	It is the responsibility of the occupational safety expert to check and inspect the safety of the operating facilities and the technical equipment particularly before initial commissioning, and to examine work processes from a safety aspect, particularly before they are introduced. During the risk assessment process, it is essential to define what technical inspections are required for particular equipment and systems after installation and prior to initial commissioning. Genetic engineering facilities and initial genetic engineering operations are subject to reporting, notification, and approval requirements (see also notification requirements prior to commencing operations as defined in § 13 of the BioStoffV). The competent surveillance authority must be notified immediately if a genetic engineering facility is decommissioned.
4.4.4.8.3	Maintenance, control, calibration, certification and validation	The organization shall establish and maintain documented procedures to ensure equipment and elements of the physical plant that may impact on biorisk be identified, purchased, maintained, calibrated, certified or validated in a manner consistent with the intent and requirements of the	BioStoffV, §§ 5-8, 11 GenTSV, §§ 18, 19, Annex III BetrSichV, §§ 3, 10, 11	During the risk assessment, control and validation measures for the contamination of workplaces must be defined, where appropriate. The decontamination measures that are required before the maintenance and repair of potentially contaminated equipment and facilities must be specified. Technical inspections may only be carried out by appropriately qualified and authorized persons. Safety-related equipment and facilities must be checked and validated at regular intervals. The intervals must be defined as part of the risk

CWA No.	CWA title	CWA requirement	Corresponding legislation[1]	Comments and explanations
		biorisk management programme.		assessment process. Inspections and inspection results must be documented.
4.4.4.8.4	Physical security	The organization shall ensure that the controls for the physical security of cultures, specimens, samples and potentially contaminated materials or waste determined as part of the risk assessment process are implemented and maintained.	BioStoffV, § 10 TRBA 100 No. 5 GenTSV, § 9, Annex III	Points 4.4.4.8.4 and 4.4.4.8.5. refer to access control and the control of sensitive information. No provisions are made for such control mechanisms in organisational health and safety and genetic engineering law. The containment requirements of higher biosafety or safety levels, including access regulations, involve physical isolation and separation measures.
4.4.4.8.5	Information security	The organization shall have a policy and procedure in place to identify sensitive information; a review and approval process shall be used to control access to such information.		

CWA No.	CWA title	CWA requirement	Corresponding legislation[1]	Comments and explanations
4.4.4.8.6	Control of supplies	The organization shall ensure that purchases (including services) conform to specific requirements. Controls shall be applied depending on potential impact on the biorisk involved. The organization shall ensure suppliers are evaluated and selected based on their ability to provide products / services that meet the requirements of this standard. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.		No provisions for the compulsory certification of suppliers or service providers are made in either occupational health and safety legislation or genetic engineering legislation.
4.4.4.9	Transport of biological agents and toxins	The organization shall ensure that procedures for the safe and secure transport of cultures, specimens, samples and contaminated and potentially contaminated materials are established and maintained in accordance with legal requirements for the transport of dangerous goods.	GGVSE (in conjunction with ADR, IATA)	Legislation on occupational health and safety and genetic engineering only regulates transportation within a plant. Comprehensive regulations on transportation outside the plant are provided in national, European (ADR) and international legislation (e.g. IATA). A hazardous substances officer must be appointed, where appropriate.
4.4.4.10	Personal security	The organization shall have a policy in place to provide personal security support services to staff members that include, where appropriate, personal security awareness training.		Personal security training is not covered by the provisions of occupational health and safety and genetic engineering law.

CWA No.	CWA title	CWA requirement	Corresponding legislation[1]	Comments and explanations
4.4.5	Emergency response and contingency plans	The organization shall establish and maintain plans and procedures to identify the potential for incidents and emergency situations involving biological agents, toxins and materials, to prevent their occurrence, to respond to emergency situations and to limit the likely illness or other damage that may be associated with them. Emergency planning shall cover all aspects of biorisk and include general safety, security and medical issues.	ArbSchG, §§ 9, 10 BioStoffV, §§ 5-8, 10-12 TRBA 100 No. 5 GenTSV, § 8, Annex III BGV A1 § 22, 26 GenTNotFallV, § 3	Legislation on occupational health and safety and genetic engineering includes provisions for emergency response and first aid measures. Emergency plans must be created for safety/biosafety level 3 and higher. A sufficient number of insured parties must be familiar with the use of a fire extinguisher. One or more first aiders must be available, depending on the number of insured parties. Genetic engineering law requires external emergency plans for safety level 3 and higher.
4.4.5.1	Emergency scenarios	The organization shall ensure that all credible and foreseeable emergency scenarios that may impact the organization's biorisks have been identified.		***Note:*** *No mandatory provisions are made for emergency exercises and drills*.

CWA No.	CWA title	CWA requirement	Corresponding legislation[1]	Comments and explanations
4.4.5.2	Emergency plans	The organization shall ensure that biorisks are taken into account when preparing and implementing emergency plans. The organization shall ensure a system is established to effectively manage medical and/or environmental emergencies, including, but not limited to, the identification of potentially infected workers and provision of immediate medical care to exposed, ill or injured workers. The organization shall also ensure that control measures in place can be demonstrated as being reasonable and proportionate to the scale and nature of the emergency. Emergency plans shall be effectively communicated to all employees and relevant third parties, and tested, with the intention that everyone is aware of their obligations.		
4.4.5.3	Emergency exercises and simulations	The organization shall ensure that structured and realistic emergency exercises and simulations, including security drills are conducted at regular intervals, based on risk, to test the plans, prepare personnel, and learn from any good practices or deficiencies identified.		
4.4.5.4	Contingency plans	The organization shall ensure that in the event of an emergency, adequate contingency measures shall be in place to ensure the safety and security of continued operations.		

CWA No.	CWA title	CWA requirement	Corresponding legislation[1]	Comments and explanations
4.5	**Checking and corrective action**			
4.5.1	Performance measurement and analysis of data	The organization shall ensure that appropriate data are determined, collected and analysed to assess the suitability and effectiveness of the biorisk management system and to evaluate where continual improvement of the system can be made.		See 4.3.1.2 – 4.3.1.5 The effectiveness of the measures taken must be examined and checked within the context of the risk assessment process.
4.5.2	Records, document and data control	The organization shall ensure that records, documents and data are established, controlled and maintained to provide evidence of conformity to the requirements of this standard and that they remain legible, readily identifiable and retrievable.	ArbSchG, § 6 BioStoffV, § 8 GenTAufZV, §§ 3, 4 TierSeuchErV, § 9	The risk assessment must be documented. Records must be kept of the genetic engineering operations. Activities with animal pathogens (including procurement and release) must be documented.
4.5.3	Inventory monitoring and control	The organization shall ensure that a review of the inventory is conducted at predetermined intervals based on risk and at a level and frequency whereby materials can be accounted for in an appropriate manner. The organization shall ensure that the measures are put in place to minimize the quantities of biological agents and toxins that make up the inventory.		An inventory as defined by the CWA is not required by legislation governing occupational health and safety, prevention of infection, and genetic engineering (see also 4.4.4.2).
4.5.4	**Accident and incident investigation, non-conformity, corrective and preventive actions**			
4.5.4.1	Accident / incident investigation	The organization shall establish and maintain documented procedures to define, record, analyse and learn from accidents and incidents involving biological agents and toxins.	BioStoffV, §§ 10, 12, 13, ASiG, §§ 3, 6	The cause of any accidents or incidents must be identified. The risk assessment process has to be repeated, where necessary, and measures must be taken to prevent any recurrence. The occupational safety expert must be included in this process and assume a key role. The company physician is responsible for examining work-related illnesses.

CWA No.	CWA title	CWA requirement	Corresponding legislation[1]	Comments and explanations
4.5.4.2	Control of nonconfor-mities	The organization shall ensure that situations that do not conform to the requirements of this standard are identified and controlled to prevent undesirable consequences. Records of the nature of the non-conformity and any subsequent action taken shall be maintained.	GenTSV, §§ 8, 12, 14, Annex III	Workers in hazardous areas and the works council or employee committee must be notified immediately of accidents, and of incidents that can put the health and safety of the workers at risk. Any injuries suffered during genetic engineering operations or in genetic engineering facilities must be reported immediately to the project leader. The project leader must notify the operator of every incident which does not follow the expected course of events in genetic engineering operations.
4.5.4.3	Corrective action	The organization shall ensure action is taken to eliminate the causes of non-conformities with the requirements of this standard in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.	BioStoffV, § 16 GenTG, § 21	Accidents and incidents must be reported to the competent authority.
4.5.4.4	Preventive action	The organization shall ensure action is taken to identify and eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential nonconformities		

CWA No.	CWA title	CWA requirement	Corresponding legislation[1]	Comments and explanations
4.5.5	Inspection and audit	The organization shall ensure that a programme of inspection and audit is conducted which is appropriate to the risk associated with the facility. Inspections and audits shall be conducted at planned intervals to determine if the biorisk management system conforms to the documented plans and to the requirements of this standard, and that it is effectively implemented and maintained. Management responsible for the area being inspected / audited shall ensure that any actions are taken without undue delay to eliminate detected non-conformities and their causes. Follow-up activities arising shall include the verification of the actions taken and the reporting of verification results.		As no provisions are made for a special management system within the meaning of CWA 15793 in legislation governing either occupational health and safety or genetic engineering, there are also no regulations for auditing, corrective measures or mandatory reporting. (See 4.1 and 4.2) As illustrated in this paper, according to German law the operation of microbiological and genetic engineering laboratories is subject to extensive legal regulations which contain detailed instructions, in addition to reporting, notification, and approval processes that apply when working with biological agents or genetically modified organisms. The employer is obliged to perform continuous risk assessment and constantly adapt the system accordingly. Furthermore, German legislation also contains provisions for mandatory reporting to surveillance authorities. In addition to the responsibility of the employer to ensure in-house compliance with mandatory precautions and protection measures, state supervisory authorities (labour inspectorate, public health officer, veterinary authorities, etc.) are responsible for the mandatory inspection and supervision of laboratories and operating facilities.
4.6	**Review**			
4.6.1	Biorisk management review	Top management shall review the organization's biorisk management system at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. The review shall include assessing opportunities for improvement and the need for changes to the system, procedures, policies and objectives. Records from the management review shall be maintained.		

[1] **The comparison was based on the latest versions of the following laws and legal regulations. The German abbreviation of the law is indicated in the Annex:**

- **ArbSchG** - Act on the Implementation of Measures of Safety and Health at Work to Encourage Improvements in the Safety and Health of Workers at Work (Act on Safety and Health at Work), (*Gesetz über die Durchführung von Maßnahmen des Arbeitsschutzes zur Verbesserung der Sicherheit und des Gesundheitsschutzes der Beschäftigten bei der Arbeit (Arbeitsschutzgesetz)*), of 7 August 1996
- **ArbMedVV** – Regulation on Preventive Occupational Health Care, (*Verordnung zur arbeitsmedizinischen Vorsorge*), of 18 December 2008
- **ASiG** - Act Concerning Company Doctors, Safety Engineers and Other Occupational Safety Specialists, (*Gesetz über Betriebsärzte, Sicherheitsingenieure und andere Fachkräfte für Arbeitssicherheit*), of 12 December 1973
- **BGV A1** – Accident Prevention Rules and Principles, (*Unfallverhütungsvorschrift, Grundsätze der Prävention*), 2005
- **BioStoffV** – Regulation Governing Occupational Health and Safety in Relation to Activities Involving Biological Agents (Biological Agents Regulation), (*Verordnung über Sicherheit und Gesundheitsschutz bei Tätigkeiten mit biologischen Arbeitsstoffen (Biostoffverordnung)*), of 27 January 1999
- **BetrSichV** – Regulation on Safety and the Protection of Health in the Provision of Equipment and Its Application in the Workplace, on Safety during the Operation of Facilities Requiring Surveillance, and on the Organisation of Occupational Safety and Health (Work Equipment Regulations), (*Verordnung über Sicherheit und Gesundheitsschutz bei der Bereitstellung von Arbeitsmitteln und deren Benutzung bei der Arbeit, über Sicherheit beim Betrieb überwachungsbedürftiger Anlagen und über die Organisation des betrieblichen Arbeitsschutzes (Betriebssicherheitsverordnung)*), of 27 September 2002
- **GenTG** – Act to Regulate Genetic Engineering (Genetic Engineering Act), (*Gesetz zur Regelung der Gentechnik (Gentechnikgesetz)*), of 20 June 1990
- **GenTSV –** Ordinance on Safety Levels and Safety Measures when Performing Genetic Engineering Operations in Genetic Engineering Facilities (Genetic Engineering Safety Ordinance), (*Verordnung über die Sicherheitsstufen und Sicherheitsmaßnahmen bei gentechnischen Arbeiten in gentechnischen Anlagen, (Gentechnik-Sicherheitsverordnung)*), of 24 October 1990
- **GenTAufzV –** Regulation on Mandatory Documentation when Conducting Genetic Engineering and for the Release of Genetically Modified Organisms (Regulation on Documentation in Genetic Engineering), (*Verordnung über Aufzeichnungen bei gentechnischen Arbeiten und bei Freisetzungen (Gentechik-Aufzeichnungsverordnung)*), 24 October 1990

- **GenTNotfV** – Regulation on the Creation of External Emergency Plans, and Information, Notification and Instruction Obligations, (Genetic Engineering Emergency Regulation), (*Verordnung über die Erstellung von außerbetrieblichen Notfallplänen und über Informations-, Melde- und Unterrichtungspflichten (Gentechnik-Notfallverordnung*)), of 10 December 1997
- **GGVSE** – Regulation on the Transport of Hazardous Goods by Road and Rail, (*Gefahrgutverordnung Straße und Eisenbahn*), of November 2006
- **IfSG** - Act on the Prevention and Control of Infectious Diseases in Man (Protection against Infection Act), (*Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz)*), of 20 July 2000
- **TierSchG** – Animal Welfare Act, (*Tierschutzgesetz*), of July 1972
- **TierSeuchErV** - Ordinance on the Handling of Animal Disease Agents (Animal Disease Agent Ordinance), (*Verordnung über das Arbeiten mit Tierseuchenerregern (Tierseuchenerreger-Verordnung)*), of 25 November 1985
- **TRBA 100** - Technical Rules for Biological Agents 100: Protective Measures for Specific and Non-specific Activities Involving the Handling of Biological Agents in Laboratories, (*Technische Regel für Biologische Arbeitsstoffe 100, Schutzmaßnahmen für gezielte und nicht gezielte Tätigkeiten mit biologischen Arbeitsstoffen in Laboratorien*), of December 2006
- **TRBA 120** - Technical Rules for Biological Agents 120: Laboratory Animal Housing, (*Technische Regel für Biologische Arbeitsstoffe 120, Versuchstierhaltung*), of May 2000
- **TRBA 400** - Technical Rules for Biological Agents 400: Guidelines for Risk Assessment and for Briefing Workers when Performing Activities Involving Biological Agents, (*Technische Regel für Biologische Arbeitsstoffe 400, Handlungsanleitung zur Gefährdungsbeurteilung und für die Unterrichtung der Beschäftigten bei Tätigkeiten mit biologischen Arbeitsstoffen*), of April 2006
- **SÜG** - Law on Prerequisites and Procedures for Security Clearance Checks Undertaken by the Federal Government (Security Clearance Check Act), (*Gesetz über die Voraussetzungen und das Verfahren von Sicherheitsüberprüfungen des Bundes (Sicherheitsüberprüfungsgesetz)*), of 20 April 1994
- **SÜFV** - Ordinance Establishing Government Authorities with Security-sensitive Duties Comparable to those of the Government Intelligence Services, and Establishing Public Offices of the Government and Non-public Offices with Vital or Defence Establishments (Ordinance Establishing Security Vetting Requirements for Vital and Defence Establishments), (*Verordnung zur Feststellung der Behörden des Bundes mit Aufgaben von vergleichbarer Sicherheitsempfindlichkeit wie die der Nachrichtendienste des Bundes und zur Feststellung der öffentlichen Stellen des Bundes und der nichtöffentlichen Stellen mit lebens- oder verteidigungswichtigen Einrichtungen (Sicherheitsüberprüfungs-feststellungsverordnung)*), of 30 July 2003