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Ordinance on Safety and Health Protection at Workplaces Involving Biological Agents (Biological Agents Ordinance - BioStoffV)

Ordinance on Safety and Health Protection at Workplaces Involving Biological Agents (Biological Agents Ordinance - BioStoffV) of 15 July 2013 (Federal Law Gazette [BGBl.] Part I p. 2514), last amended by Article 146 of the Law of 29 March 2017 (Federal Law Gazette I p. 626)

Part 1

Scope, definitions and classification into risk groups

Section 1

Scope

(1) This Ordinance shall apply to activities involving biological agents. It sets out measures for the protection of the safety and health of employees against hazards arising from such activities. It also sets out measures for the protection of other persons insofar as they may be at risk due to the use of biological agents by employees or business owners without employees.

(2) This Ordinance also applies to activities subject to legislation governing genetic engineering to the extent that such legislation does not provide for equivalent or more stringent rules for the protection of employees.

Section 2

Definitions

(1) Biological agents shall mean

1. micro-organisms, cell cultures and endoparasites including their genetically modified forms,

2. agents associated with transmissible spongiform encephalopathy (TSE), that may constitute a hazard to humans as a result of infections, communicable diseases, toxin formation, sensitisation or other effects which are harmful to human health.

(2) The following agents shall be considered as equivalent to biological agents:

1. ectoparasites which may cause autonomous diseases in humans or create sensitising or toxic effects,

2. technologically produced biological entities with new properties that may pose a threat to humans in the same way as biological agents.

(3) Micro-organisms shall mean all cellular or non-cellular microscopically or sub-microscopically small biological entities which are capable of replicating or transferring material, in particular bacteria, viruses, protozoa and fungi.

(4) Cell cultures shall mean cells isolated from multicellular organisms and grown in vitro.

(5) Toxins pursuant to para. 1 shall mean metabolic products or cell components of biological agents which may have a toxic effect in humans when they are inhaled, ingested or absorbed through the skin, and may therefore result in acute or chronic damage to health or death.

(6) Biological agents classified into risk group 3 and marked as (**) shall mean biological agents for which the infection risk for employees is limited as there will normally be no airborne transmission. Such biological agents are listed in Annex III of Directive 2000/54/EC of the European Parliament and the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (Official Journal L 262 of 17 October 2000, p. 21) and in the publications pursuant to section 19 para. 4 no. 1.

(7) Activities shall mean

1. the use of biological agents, particularly their isolation, production and replication, disintegration, use and consumption, treatment and processing, filling and refilling, mixing and separation, and their transport on company premises, their stocking and storage, inactivation and disposal, as well as

2. occupational activities involving humans, animals, plants, products, objects or materials, if biological agents may be generated or released as a result of these activities and employees may be in contact with them.

(8) Activities shall be considered as specific when

1. such activities are directly focused on one or several biological agents,

2. at least the species of the biological agent or agents is/are known, and

3. the exposure of employees under normal operating conditions is sufficiently known or predictable.

Activities shall be considered as non-specific when at least one pre-requisite pursuant to clause 1 is not fulfilled. This particularly applies to activities pursuant to para.7 no. 2.

(9) Employees shall mean persons who have been designated as such pursuant to section 2 para 2 of the Act on Health and Safety at Work (Arbeitsschutzgesetz). The following persons shall be considered to be equivalent to employees when they perform activities involving biological agents:

1. schoolchildren,

2. students,

3. other persons, especially those working in scientific institutions or healthcare facilities,

4. home workers pursuant to section 1 para.1 of the Home Work Act (Heimarbeitsgesetz).

The rules on the participation of employee representation bodies shall not apply to schoolchildren, students and other persons pursuant to no. 3.

(10) Employers shall mean persons who have been designated as such pursuant to section 2 para.3 of the Act on Health and Safety at Work. The following persons shall be considered to be equivalent to employers:

1. business owners without employees,

2. the client or intermediary as defined by the Home Work Act.
- (11) For the purpose of this Ordinance, persons with professional expertise shall mean persons who have the expertise to perform a task defined in this Ordinance. The requirements regarding their professional expertise shall depend on the respective type of activity and the level of risk. The knowledge required for such professional expertise shall be proven by a suitable vocational training and recent professional activity in this field. Depending on the activity and the level of risk, participation in specific further education courses may be required.
- (12) Technological state of the art shall mean the level of development of advanced processes, facilities or operating practices that suggests evidence of the practical suitability of an action for the protection of the safety and health of employees. The determination of the technological state of the art shall in particular take account of comparable processes, facilities and operating practice that have been successfully tested in practice.
- (13) Protection levels shall be oriented to the risk group of the biological agent in question and shall be a yardstick for the level of the infection hazard associated with an activity. Four different protection levels shall be laid down corresponding to the risk groups pursuant to section 3. The protection levels shall comprise the additional protective measures specified or recommended in Annexes II and III.
- (14) For the purpose of this Ordinance, healthcare facilities shall mean workplaces where persons are medically examined, treated or nursed as inpatients, or medically examined or treated as outpatients.
- (15) For the purpose of this Ordinance, biotechnology shall include biotechnological production and biotechnological research involving the specific use of defined biological agents.

Section 3

Classification of biological agents into risk groups

- (1) According to the scientific and technological state of the art, biological agents shall be classified into one of the following risk groups corresponding to the infection risk they cause:
1. Risk Group 1: Biological agents that are unlikely to cause human disease,
 2. Risk Group 2: Biological agents that can cause human disease and might be a hazard to employees; they are unlikely to spread to the community; there is usually effective prophylaxis or treatment available,
 3. Risk Group 3: Biological agents that can cause severe human disease and present a serious hazard to employees; they may present a risk of spreading to the community, but there is usually effective prophylaxis or treatment available,
 4. Risk Group 4: Biological agents that cause severe human disease and are a serious hazard to employees; they may present a high risk of spreading to the community; there is usually no effective prophylaxis or treatment available.
- (2) For biological agents classified into risk groups 2 to 4, Annex III of Directive 2000/54/EC of the European Parliament and the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (Official Journal L 262 of 17 October 2000, p. 21) shall apply. When this Annex is adjusted to reflect technical progress in a procedure pursuant to Art. 19 of the Directive, the amended version may already be applied from its entry into force. It must be applied after expiry of the specified implementation deadline.
- (3) Where a biological agent is not classified according to para. 2, the Federal Ministry of Labour and Social Affairs may classify it into a risk group pursuant to para. 1 after having consulted the Committee pursuant to section 19. The classifications shall be published in the Joint Ministerial Gazette. The employer shall observe such classifications.

(4) Where a biological agent has been classified neither under para. 2 nor under para. 3, the employer intending to engage in a specific activity involving this biological agent shall classify it into one of the risk groups pursuant to para. 1. In this context, the employer shall respect the following:

1. Where several risk groups are to be considered for the classification, the biological agent shall be classified into the highest potential risk group;
2. Viruses which have already been isolated in humans shall be classified no lower than into risk group 2 unless such viruses are unlikely to cause human disease;
3. Strains which have been attenuated or lost known virulence genes may be classified into a lower risk group than the parental strain provided they were adequately investigated and assessed. Where the parental strain was classified into risk groups 3 or 4, a downgrading may only take place on the basis of a scientific assessment that may be undertaken by the Committee according to section 19.

Part 2

Risk assessment, assignment to protection levels, documentation and record-keeping obligations

Section 4

Risk assessment

(1) In the context of the risk assessment according to section 5 of the Act on Health and Safety at Work (Arbeitsschutzgesetz), the employer shall evaluate the risk for his/her employees resulting from the activities involving biological agents prior to the start of such activities. The risk assessment shall be performed professionally. If the employer does not have the appropriate expertise, he/she shall seek expert advice.

(2) The employer shall immediately update the risk assessment when

1. this is required because of substantial changes in working conditions or new information such as accident reports or findings from occupational medical examinations, or
2. the verification of the functioning and effectiveness of protective measures has shown that the established protective measures are not effective.

In all other cases, the employer shall check the risk assessment at least every two years and update it, if necessary. When the verification shows that an update of the risk assessment is not required, the employer shall duly record this in the documentation pursuant to section 7 together with the date of the verification.

(3) For the purposes of risk assessment, the employer shall investigate the following issues in particular:

1. the identity, the risk group classification and the infection pathways of the biological agents, their potential sensitising or toxic effects and uptake pathways to the extent that this information is accessible to the employer; in this context, the employer shall also collect information on other adverse health effects that can be caused by the biological agents,
2. the type of activity taking into account the operating procedures, processes and materials used including the facilities and equipment,
3. the type, duration and frequency of exposure of employees to the extent that this information is accessible to the employer,
4. the possibility of using biological agents, processes or materials that would result in no or a lower risk for the employees (substitution checks),

5. activity-related findings
 - a) on stress or exposure situations including psychological stress,
 - b) on known diseases and the countermeasures to be implemented,
 - c) from preventive occupational health care.

(4) On the basis of the information collected pursuant to para. 3, the employer shall independently assess the infection risk and the risks due to sensitising, toxic and other adverse health effects. These individual assessments shall be collated in an overall assessment that provides the basis for the definition and implementation of protective measures. This shall also apply when several biological agents are present or used simultaneously in one activity.

(5) Where it is impossible to obtain the necessary information for the risk assessment such as the risk group classification for activities involving products containing biological agents, the employer shall procure such information from the manufacturer, the importer or the person responsible for marketing. Clause 1 does not apply to foodstuffs in the form of finished products intended for final consumption.

Section 5

Activities with an assigned protection level

(1) For activities in laboratories, the husbandry of laboratory animals, biotechnology and healthcare facilities, the employer shall, in addition to section 4 para. 3, determine whether the activities performed are specific or non-specific. The employer shall assign such activities to a protection level corresponding to their infection risk.

(2) The assignment to a protection level shall depend on

1. the risk group of the identified biological agent in the case of specific activities; when activities involving several biological agents are performed, the assignment to a protection level shall be governed by the biological agent with the highest risk group,
2. in the case of non-specific activities, the risk group of the biological agent which, based on the
 - a) probability of its occurrence,
 - b) type of activity,
 - c) type, duration, concentration and frequency of the identified exposure determines the level of the infection risk for the employees.

Section 6

Activities not assigned to a protection level

(1) Activities not covered by section 5 para. 1 do not have to be assigned to a protection level. These are activities as defined in section 2 para. 7 no. 2. Such activities include cleaning and refurbishing, activities in the fields of veterinary medicine, agriculture, forestry, waste water and waste management industries, biogas installations and slaughterhouses.

(2) Where specific information mentioned in section 4 para. 3 nos. 1 and 3 cannot be collected for such activities because the range of biological agents occurring is subject to fluctuation or because the type, duration, concentration or frequency of exposure may change, the employer shall collate the information required for the risk assessment and the definition of protective measures in particular on the basis of

1. announcements pursuant to section 19 para. 4,
2. experience with comparable activities, or
3. other established ergonomic findings.

Section 7

Documentation of the risk assessment and record-keeping obligations

(1) Irrespective of the number of employees, the employer shall initially document the risk assessment performed prior to the start of such activities and subsequently each update assessment pursuant to clause 2. The documentation of the risk assessment shall in particular include the following information:

1. the type of activity including the conditions of exposure,
2. the outcome of the substitution check pursuant to section 4 para. 3 no. 4,
3. the protection levels determined pursuant to section 5 para. 2,
4. the protective measures to be implemented,
5. the reasons for non-compliance with the rules and findings announced pursuant to section 19 para. 4 no. 1.

(2) As one element of the documentation, the employer shall draw up a list of the biological agents used or present (list of biological agents) insofar as they are known and relevant for the risk assessment pursuant to section 4. The list shall include information on the classification of the biological agents into a risk group as defined in section 3 and on their sensitising, toxic and other adverse health effects. The information must be accessible to all employees concerned and their representative bodies.

(3) In the case of activities of protection levels 3 or 4, the employer shall in addition maintain a list of the employees performing such activities. This list shall include the type of activity and the biological agents present and any accidents and incidents. It shall be archived on an individual basis for a period of not less than 10 years after the end of that person's activity. The employer shall

1. make the information in the list relating to them accessible to the employees; the protection of personal data shall be ensured,
2. give an employee whose employment ends an excerpt of the list containing the information relating to him/her; evidence of the information being handed over shall be archived by the employer in the same way as personnel records.

The list of employees may be kept together with the list of biological agents pursuant to para. 2.

(4) The documentation of information pursuant to para. 1 clause 2 nos. 2 and 5 and the list pursuant to para. 2 may be waived if the activities in question exclusively involve biological agents of risk group 1 without sensitising or toxic effects.

Part 3

Basic obligations and protective measures

Section 8

Basic obligations

(1) The employer shall integrate occupational health and safety concerns regarding activities involving biological agents into his/her business organisation and shall provide the necessary human, financial and organisational resources. In this process, he/she shall involve employee representation bodies in an appropriate form. He/she shall ensure in particular that

1. all factors related to the safety and health of employees including psychological factors are sufficiently taken into account in the design of the work organisation, the work processes and workplaces and in the selection and provision of equipment for work,
2. employees or their representative bodies are involved as far as operationally possible when new equipment for work that affects the occupational health and safety of employees is introduced.

(2) The employer shall take suitable measures to create safety awareness among his/her employees and to further develop in-plant occupational health and safety action in case of activities involving biological agents.

(3) The employer may authorise the start of an activity involving biological agents only after the risk assessment pursuant to section 4 has been performed and the necessary measures have been taken.

(4) Prior to starting the activity, the employer shall

1. substitute hazardous biological agents primarily by agents that are not hazardous or less hazardous insofar as this is possible given the type of activity or the technological state of the art,
2. select or design work processes and equipment so that biological agents are not released at the workplace if a risk for employees cannot be excluded by a measure pursuant to no. 1,
3. reduce to a minimum the exposure of employees by suitable physical, technical and organisational measures if the risk for employees cannot be excluded through measures pursuant to nos. 1 or 2 or if the biological agents are released as part of their intended use,
4. additionally provide personal protective equipment if the measures pursuant to nos. 1 to 3 are not sufficient to exclude or adequately reduce the risk; the employer shall restrict the use of stressful personal protective equipment to an absolutely necessary level and must not introduce it as a permanent measure.

(5) The employer shall define and take protective measures on the basis of the risk assessment and according to the technological state of the art and established scientific findings. For this purpose, he/she shall comply with the provisions of this Ordinance including its Annexes and shall take into account the rules and findings published pursuant to section 19 para. 4 no. 1. In case of compliance with these rules and findings, it may be assumed that the stipulated requirements are fulfilled (presumption of conformity). Deviations from these rules and findings are possible if other measures guarantee the protection of the occupational health and safety of employees at least in a comparable manner. When the technological state of the art or established scientific findings have advanced and occupational health and safety has improved as a result of this development, the protective measures shall be adapted within a reasonable period of time.

(6) The employer shall verify the functioning of technical protective measures regularly and test their effectiveness at least every second year. The outcome and the date of the effectiveness test shall be recorded in the documentation pursuant to section 7. Where a value has been defined in an announcement pursuant to section 19 para. 4 for a working area, work process or type of equipment, and where this value describes the achievable concentration of biological agents in the workplace air according to the technological state of the art (technical control value), this value shall be used as reference for the effectiveness test of the respective protective measures.

(7) For work to be performed at home the employer may authorise only activities involving biological agents of risk group 1 without any sensitising or toxic effect.

Section 9

General protective measures

(1) All activities involving biological agents shall at least respect the general standards of hygiene. The employer shall ensure in particular that

1. workplaces and equipment are kept at a level of cleanliness adequate to the work process and cleaned regularly,
2. floors and surfaces of equipment and work spaces are easy to clean,

3. washing facilities are available,
4. changing rooms separated from the workplace are available if working clothes are required; such working clothes shall be changed and cleaned regularly and as needed.

(2) As regards protection level 1, the employer shall observe special hygiene measures over and beyond the measures stipulated in para.1 in line with the rules and findings published pursuant to section 19 para. 4 no. 1 for activities in laboratories, the husbandry of laboratory animals, biotechnology and activities in healthcare facilities.

(3) Unless only activities involving biological agents of risk group 1 without sensitising and toxic effects are performed, the employer shall take more extensive protective measures in relation to the risk assessment. In so doing, he/she shall in particular

1. design or select work processes and equipment so that the exposure of employees to biological agents and the risk of being injured by punctures or cuts is prevented or minimised, where technically feasible,
2. substitute activities and work processes involving dust or aerosol formation including cleaning processes by such activities without or with a lower level of dust or aerosol formation where feasible in the light of the technological state of the art; if it is not feasible, the employer shall take suitable measures to minimise exposure,
3. limit the number of exposed employees to the level needed to perform the activity,
4. take the necessary measures to disinfect, inactivate or decontaminate and to properly and safely dispose of biological agents, contaminated objects, materials and equipment,
5. clean, maintain, repair and properly dispose of personal protective equipment including protective clothing; employees shall use the personal protective equipment provided as long as there is a risk,
6. take the necessary steps to ensure that personal protective equipment including protective clothing can be taken off safely and stored separately from other pieces of clothing when employees leave the workplace,
7. ensure that employees do not consume any food or beverages in working areas where biological agents may be present; prior to taking up activities the employer shall therefore create separate areas which may not be entered with personal protective equipment including protective clothing.

(4) The employer shall store biological agents safely, transport them safely on the company premises and take precautions to prevent their misuse or incorrect use. In this process, he/she shall ensure that only containers are used which

1. are of a suitable quality to safely enclose their content,
2. are labelled in such a manner that the associated risks are adequately and clearly visible,
3. are designed in a form and with a labelling so that their content cannot be confused with foodstuffs.

(5) For the medical examination, treatment and care of patients outside healthcare facilities, section 11 paras. 2 to 5 shall apply. For such activities, the employer shall provide work instructions stipulating the use of personal protective equipment and working clothes as well as the required hygiene and disinfection measures.

Section 10

Additional protective measures and requirements for activities of protection levels 2, 3 or 4 in laboratories, the husbandry of laboratory animals and biotechnology

(1) Prior to starting activities of protection levels 2, 3 or 4 in laboratories, the husbandry of laboratory animals and biotechnology the employer shall, in addition to the protective measures pursuant to section 9 and

1. in line with the assigned protection levels,
 - a) define suitable areas with an assigned protection level and label them with their assigned protection level and the biohazard sign pursuant to Annex I,
 - b) take the protective measures pursuant to Annexes II or III; the protective measures designated as 'recommended' shall be taken when the risk for employees can be reduced as a result,
2. safely dispose of used pointed or sharp equipment in conformity with the requirement pursuant to section 11 para. 4,
3. limit access to biological agents of risk groups 3 or 4 to authorised, competent and reliable employees; activities of protection levels 3 or 4 may only be entrusted to these employees after they have been briefed and trained on the basis of work instructions.

(2) Prior to starting activities of protection levels 3 or 4, the employer shall appoint a person who is reliable and has professional expertise corresponding to the high level of risk. He/she shall entrust this person with the following tasks:

1. Giving advice on
 - a) the risk assessment pursuant to section 4,
 - b) other issues of relevance for safety,
2. Providing support in
 - a) controlling the effectiveness of protective measures,
 - b) carrying out the training pursuant to section 14 para. 2,
3. Verification of compliance with protective measures.

The employer shall lay down the duties and powers of this person in writing. He/she may not suffer disadvantages as a result of performing the duties entrusted to him/her. He/she must be given sufficient time to perform his/her duties. Clause 1 does not apply to activities involving biological agents of risk group 3 marked as (**).

Section 11

Additional protective measures and requirements for activities of protection levels 2, 3 or 4 in healthcare facilities

(1) Prior to starting activities of protection levels 2, 3 or 4 in healthcare facilities the employer shall, in addition to the protective measures pursuant to section 9 and in line with the risk assessment, shall

1. define effective disinfection and inactivation processes,
2. design surfaces to be disinfected in such a way that they are easy to clean and resistant to the disinfectants used; for activities of protection level 4, the requirements of Annex II relating to surfaces shall also apply, too.

(2) Pursuant to section 9 para. 3 clause 2 no. 1, the employer shall, prior to starting activities and insofar as technically feasible and required to avoid infection risks, replace pointed and

sharp medical instruments by instruments which entail no or a lower risk of punctures and cuts.

(3) The employer shall ensure that used cannulas are not recapped. When activities are performed which require the multiple use of a medical instrument according to the technological state of the art and when the cannula has to be recapped, this is permissible if a process is used that makes it possible to safely recap the cannula by using one hand only.

(4) Pointed or sharp medical instruments shall be safely disposed of after use. For this purpose and prior to starting activities, the employer shall provide waste containers which are resistant to puncture and breakage and safely enclose the waste. He/she shall ensure that these waste containers are clearly recognisable as such by their colour, form and labelling. Clauses 1 and 2 shall also apply to used medical instruments with protective devices against punctures and cuts.

(5) The employer shall provide timely information to employees and their representative bodies about injuries caused by used pointed or sharp medical instruments when such injuries are attributable to organisational or technical causes. He/she shall define the approach to be followed.

(6) Activities of protection levels 3 or 4 may only be entrusted to employees with professional expertise who have been briefed and trained on the basis of work instructions.

(7) Prior to starting activities of protection level 4, the employer shall

1. define appropriate areas with an assigned protection level and label them with their assigned protection level and the biohazard sign pursuant to Annex I,
2. select and take the actions of protection level 4 from Annex II which are required and appropriate to reduce the risk to employees and other persons,
3. appoint a person as defined in section 10 para. 2 clause 1 and entrust this person with the duties pursuant to section 10 para. 2 clause 2.

Section 12

Preventive occupational health care

The Ordinance on Occupational Health Care as amended shall also apply to the category of persons mentioned in section 2 para. 9 clause 2.

Section 13

Incidents, accidents

(1) Prior to starting activities of protection levels 2 to 4, the employer shall define the necessary measures that are required in case of incidents or accidents in order to minimise the impact on the safety and health of employees and other persons and to restore normal operations. Depending on the type of potential events and the biological agents used or present, the following measures shall be defined in particular:

1. first aid and additional support for employees in case of a transmission of biological agents as a result of an accident including an opportunity for post-exposure prophylaxis,
2. measures to prevent the spreading of biological agents,
3. disinfection, inactivation or decontamination measures,
4. tests to ascertain whether the biological agents used have been released to the

workplace environment during incidents or accidents, insofar as this is technically feasible and validated test procedures exist. Pursuant to section 14 para. 1 clause 4 no. 3, these measures are part of the operating instructions.

(2) The employer shall inform employees of the measures defined and their implementation. When an incident or accident specified in para. 1 clause 1 occurs, the employer shall immediately take the measures defined according to para.1 clause 2. During this

intervention, only persons who are needed to achieve the objectives specified in para. 1 may remain in the risk area.

(3) Prior to starting activities of protection levels 3 or 4 in laboratories, the husbandry of laboratory animals, biotechnology and prior to starting activities of protection level 4 in healthcare facilities, the employer shall, in addition to the provisions of para. 1, prepare an internal plan for addressing the against risks that can occur in case of a failure of a containment measure and as a result a release of biological agents. In this plan, he/she shall define the specific risks and set out the names of the persons in charge of the company's internal rescue activities. This definition shall be updated regularly. Clause 1 does not apply to activities involving biological agents of risk group 3 marked with (**).

(4) For activities of protection level 4, the plan pursuant to para. 3 shall contain statements on the scope of safety drills and the regular intervals of their organisation insofar as such safety drills are required as a result of the risk assessment. The measures pursuant to para.3 shall be coordinated with the competent rescue and security services. Furthermore, the employer shall set up warning systems and establish communication links which permit giving an immediate warning to all employees concerned and alerting the rescue and security services. The employer shall ensure that these systems are operational.

(5) Prior to starting the activities, the employer shall define a procedure for accident reports and investigations and the process to inform employees and their representative bodies. The procedure shall be designed so that in case of severe accidents and needle-puncture injuries the potential organisational and technical causes of the accidents can be detected and recriminations are avoided. The employees and their representative bodies shall be immediately informed about incidents and accidents involving biological agents that may threaten the safety and health of employees.

Section 14

Operating instructions and training of employees

(1) On the basis of the risk assessment pursuant to section 4 and prior to starting the activity, the employer shall prepare written operating instructions for the specific work areas and biological agents. Clause 1 shall not apply when the activities performed exclusively involve biological agents of risk group 1 without sensitising or toxic effects. The operating instructions shall be made available to employees. They must be drafted using a form and language which is comprehensible to employees and shall contain the following information in particular:

1. the risks for employees associated with the intended activities, in particular regarding
 - a) the type of activity,
 - b) the biological agents which are used or present at the workplace and relevant for the given activity including their risk group, transmission pathways and health effects,
2. Information on protective measures and rules of behaviour which the employees have to take or comply with at the workplace for their own protection and the protection of other employees; these include in particular
 - a) internal specifications for hygiene,
 - b) information on measures to be taken to prevent exposure, including the correct use of sharp or pointed medical instruments,
 - c) information on wearing, using and disposing of personal protective equipment including protective clothing,

3. instructions concerning the behaviour and the measures to be taken in case of injuries, accidents or incidents and their internal reporting and first aid,

4. information on the proper inactivation or disposal of biological agents and contaminated objects, materials and equipment.

The operating instructions shall be updated following every substantial change in working conditions.

(2) The employer shall ensure that, pursuant to para. 1 clause 1, employees are given oral training about all existing hazards and necessary protective measures on the basis of the operating instructions as amended. The training shall be provided in a way that creates safety awareness among employees. The employees shall also be informed of the conditions under which they have a right to preventive occupational health care pursuant to the Ordinance on Occupational Health Care. In the context of such training, general occupational health counselling shall be provided with information on special hazards, for instance in case of a diminished immunological response. Where necessary a physician as defined in section 7 para. 1 of the Ordinance on Occupational Health Care shall be involved.

(3) The training shall take place prior to the start of employment and subsequently at least once a year for each specific workplace, and it shall be conducted in a form and language which is comprehensible to employees. The content and the date of the training shall be documented in writing by the employer and shall be confirmed by the signatures of the employees that received training.

(4) For activities of protection levels 3 and 4, work instructions shall be drawn up in addition to the operating instructions and these shall be available at the workplace. Work instructions are also required for the following activities involving a higher infection risk:

1. maintenance, cleaning, modification or demolition work in or at contaminated equipment,
2. activities which, in the light of past experience, present a higher accident risk,
3. activities for which serious infections are to be expected in case of an accident; this may be the case when taking samples of human or animal origin.

Part 4

Licensing and notification obligations

Section 15

Licensing obligation

(1) The employer shall require a licence issued by the competent authority before first starting activities of protection levels 3 or 4 in laboratories, the husbandry of laboratory animals or biotechnology. The licence shall cover the physical, technical and organisational requirements pursuant to this Ordinance for the protection of employees and other persons against the hazards caused by such activities. Clause 1 shall also apply to healthcare facilities where activities of protection level 4 are to be performed. A licence shall not be required for activities involving biological agents of risk group 3 marked with (**).

(2) When another administrative decision, in particular a concession or licence under public law includes the licence specified in para. 1, the requirement pursuant to para. 1 shall be fulfilled by sending a copy of this administrative decision to the competent authority. Where necessary, the competent authority may request further documentation.

(3) The application for the licence pursuant to para. 1 shall either be made in writing or electronically. The following documentation shall be provided with the application:

1. name and address of the employer,
2. name and qualification of the person appointed pursuant to section 10 para. 2 or section 11 para. 7 no. 3,

3. name of the licence holder pursuant to section 44 of the Protection against Infection Act (Infektionsschutzgesetz),
4. site map, floor plan and designation of the rooms including escape and emergency routes,
5. description of the intended activities,
6. outcome of the risk assessment including information on
 - a) the biological agents which are used or present and the protection level of the activity,
 - b) the physical, technical, organisational and personal protective measures including information on the planned maintenance and repair of physical and technical measures,
7. the plan pursuant to section 13 para. 3,
8. information on waste and wastewater disposal.

Where necessary, the competent authority may request further documentation. If the application is made electronically, the competent authority may also require the applicant to send multiple copies and the accompanying documentation in writing.

(4) The licence shall be granted when the requirements of this Ordinance needed to ensure the protection of employees and other persons against the hazards involving biological agents are fulfilled.

Section 16 Notification obligation

(1) As specified in the provisions of paras. 2 and 3, the employer shall notify the competent authority of:

1. the initial start of
 - a) a specific activity involving biological agents of risk group 2,
 - b) an activity involving biological agents of risk group 3 insofar as such activities are not subject to the licensing obligations pursuant to section 15,in laboratories, the husbandry of laboratory animals and biotechnology,
2. any modification of the licenced or notified activities when significant for the protection of the safety and health of employees, for instance activities aimed at enhancing the virulence of the biological agent or the start of activities involving additional biological agents of risk groups 3 or 4,
3. the admission of an infected patient to a patient ward assigned to protection level 4,
4. the discontinuation of an activity requiring a licence pursuant to section 15.

(2) The notification shall include the following information:

1. name and address of the employer,
2. description of the intended activities,
3. outcome of the risk assessment pursuant to section 4,
4. the type of biological agent,
5. the planned actions for the protection of the safety and health of employees.

(3) The notification pursuant to para. 1 nos. 1, 2 or no. 4 shall be made no later than 30 days prior to starting or discontinuing the activities, the notification pursuant to para. 1 no. 3 shall be made immediately.

(4) The notification obligation may also be fulfilled by transmitting to the competent authority, within the deadline set out in para. 3, a copy of a notification, concession or licence pursuant to other legislation that contains equivalent information.

Part 5 Enforcement rules and Committee on Biological Agents

Section 17 Information of the authority

(1) The employer shall inform the competent authority immediately of

1. any accident or incident involving biological agents of risk groups 3 or 4 that may entail a health risk for employees,
2. diseases or fatalities among employees which are attributable to activities involving biological agents with a clear indication of the activity.

(2) Notwithstanding section 22 of the Act on Health and Safety at Work (Arbeitsschutzgesetz), the employer shall, upon request, transmit or communicate the following to the competent authority:

1. the documentation of the risk assessment,
2. the list pursuant to section 7 para. 3 clause 1 and the evidence pursuant to section 7 para. 3 clause 4 no. 2,
3. the activities during which employees have actually or potentially been exposed to biological agents and the number of these employees,
4. the protection and prevention measures taken including operating instructions and work instructions,
5. the measures defined or taken pursuant to section 13 paras. 1 and 2 and the plan prepared pursuant to section 13 para. 3.

Section 18 Exemptions granted by the authority

Upon written or electronic application by the employer, the competent authority may grant exemptions from the rules in sections 9, 10, 11 and 13 including Annexes II and III if the enforcement of the rule created a disproportionate hardship in special cases and if the exemption requested is compatible with the protection of the employees concerned.

Section 19 Committee on Biological Agents

(1) A Committee on Biological Agents (Ausschuss für Biologische Arbeitsstoffe (ABAS)) shall be established at the Federal Ministry of Labour and Social Affairs and shall be composed of competent experts representing employers, trade unions, Land authorities, the statutory accident insurance institutions and other competent experts, particularly those representing the scientific community. The total number of members shall not exceed 16 persons. A deputy member shall be appointed for each member. Membership in the Committee shall be an honorary function.

(2) The Federal Ministry of Labour and Social Affairs shall appoint the members of the Committee and their deputy members. The Committee shall adopt its own rules of procedure and shall elect a chairperson from its ranks. The rules of procedure and the election of the chairperson shall be subject to approval by the Federal Ministry of Labour and Social Affairs.

(3) The tasks of the Committee shall include

1. identifying the state of the art in science, technology, occupational medicine and occupational hygiene and other established findings regarding activities involving biological agents, issuing appropriate recommendations including inputs that may be used in public information systems on biological agents,
2. identifying how the requirements stipulated in this Ordinance can be met and determining the rules and findings corresponding to the technological and medical state of the art,
3. performing scientific assessments of biological agents and proposing their classification into risk groups,
4. advising the Federal Ministry of Labour and Social Affairs on issues of biological safety.

The work programme of the Committee shall be coordinated with the Federal Ministry of Labour and Social Affairs. The Committee shall cooperate closely with the other committees established at the Federal Ministry of Labour and Social Affairs.

(4) Following a review, the Federal Ministry of Labour and Social Affairs may

1. announce the rules and findings identified by the Committee pursuant to para. 3 clause 1 no 2 and the classifications pursuant to section 3 para. 3 in the Joint Ministerial Gazette,
2. publish the recommendations pursuant to para. 3 clause 1 no. 1 and the outcome of the consultations pursuant to para. 3 clause 1 no. 4 in a suitable manner.

(5) The Federal Ministries and the competent supreme Land authorities may send delegates to the meetings of the Committee. Upon request, they shall be given the floor in the meetings.

(6) The Federal Institute for Occupational Safety and Health (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin) shall conduct the business of the Committee.

Part 6

Administrative offences, criminal offences and transitional provisions

Section 20

Administrative offences

(1) For the purposes of section 25 para. 1 no. 1 of the Act on Health and Safety at Work, a person shall be deemed to have committed an administrative offence if he/she, intentionally or negligently,

1. in violation of section 4 para. 1 clause 1, fails to perform an assessment of the risk for employees or to do so properly, completely or in time,
2. in violation of section 4 para. 2 clause 1, fails to update a risk assessment or to do so in time,
3. in violation of section 4 para. 2 clause 2, fails to review a risk assessment or to do so in time,
4. in violation of section 7 para. 1 clause 1, fails to document a risk assessment or to do so properly, completely or in time,
5. in violation of section 7 para. 3 clause 1, fails to maintain a list mentioned therein or to do so properly or completely,
6. in violation of section 7 para. 3 clause 3, fails to archive a list mentioned therein or to archive it for at least 10 years,

7. in violation of section 8 para. 4 no. 4 sub-clause 1, fails to make available personal protective equipment or to do so in time,
 8. in violation of section 9 para. 1 clause 2 no. 3, fails to ensure that a washing facility is available,
 9. in violation of section 9 para. 1 clause 2 no. 4 sub-clause 1, fails to ensure that a changing room is available,
 10. in violation of section 9 para. 3 clause 2 no. 5 sub-clause 1, fails to maintain the personal protective equipment provided,
 11. in violation of section 9 para. 3 clause 2 no. 7 sub-clause 2, fails to establish the areas mentioned therein or to do so in time,
 12. in violation of section 9 para. 4 clause 2, fails to ensure that only the containers mentioned therein are used,
 13. in violation of section 10 para. 1 no. 1 letter a) or section 11 para. 7 no. 1, fails to define the areas with an assigned protection level or to do so in time or fails to label this area or to do so properly or in time,
 14. in violation of section 10 para. 2 clause 1 or section 11 para. 7 no. 3, fails to appoint a person or to do so in time,
 15. in violation of section 11 para. 1 no. 1, fails to define a procedure mentioned therein or to do so in time,
 16. in violation of section 11 para. 2, fails to replace an instrument mentioned therein or to do so in time,
 17. in violation of section 11 para. 3 clause 1, fails to ensure that a used cannula is not recapped,
 18. in violation of section 11 para. 4 clause 1, also in conjunction with clause 4, fails to dispose of an instrument mentioned therein or to do so in time,
 19. in violation of section 13 para. 1 clause 2 nos. 1, 2 or 3, fails to define a measure mentioned therein or to do so in time,
 20. in violation of section 13 para. 3 clause 1, fails to prepare an internal plan or fails to do so properly, completely or in time,
 21. in violation of section 13 para. 5 clause 1, fails to define a procedure for accident reports and investigations or to do so in time,
 22. in violation of section 14 para. 1 clause 1, fails to prepare written operating instructions or to do so properly, completely or in time,
 23. in violation of section 14 para. 2 clause 1, fails to ensure that an employee is briefed,
 24. starts an activity mentioned in section 15 para. 1 clause 1 without a licence,
 25. in violation of section 16 para. 1, fails to file a notification or to do so correctly, completely or in time, or
 26. in violation of section 17 para. 1, fails to inform the competent authority or to do so correctly, completely or in time.
- (2) For the purposes of section 32 para. 1 no. 1 of the Home Work Act (Heimarbeitsgesetz), a person shall be deemed to have committed an administrative offence if he/she intentionally

or negligently, in violation of section 8 para. 7, allows an activity mentioned therein to be performed.

**Section 21
Criminal offences**

(1) A person who puts the life or health of an employee at risk by a deliberate act specified in section 20 para. 1 shall be deemed to commit a criminal offence pursuant to section 26 no. 2 of the Act on Health and Safety at Work.

(2) Persons putting at risk the working capacity or health of persons engaged in home work shall be deemed to commit a criminal offence pursuant to section 32 para. 3 or para. 4 of the Home Work Act.

**Section 22
Transitional provisions**

For activities that have started prior to the entry into force of this Ordinance,

1. a professionally qualified person shall be appointed by 30 June 2014 in conformity with section 10 para. 2 or section 11 para. 7 no. 3,
2. there shall be no licensing obligation pursuant to section 15 para. 1 provided such activities were notified to the competent authority.

**Annex I
Biohazard sign**

(Source: Federal Law Gazette (BGBl.) I 2013, 2525)



**Annex II
Additional protective measures for activities in laboratories and comparable facilities
and in the husbandry of laboratory animals**

A Protective measures	B Protection levels		
	2	3	4

1. The area with an assigned protection level shall be separated from other areas with an assigned protection level or working areas in the same building.	recommended	mandatory	mandatory
2. The access to the area with an assigned protection level must be equipped with an airlock with interlocking doors.	no	mandatory where airborne transmission is possible	mandatory
3. The access to the area with an assigned protection level shall be limited to designated employees.	mandatory, with access control for listed biological agents* containing human pathogens	mandatory, with access control	mandatory, with access control
4. Permanent negative pressure shall be maintained in the area with an assigned protection level.	no	mandatory alarm monitoring where airborne transmission is possible	mandatory alarm monitoring
5. Supply air and exhaust air must be conducted through a high-efficiency particle filter or a similar installation.	no	mandatory for exhaust air where airborne transmission is possible	mandatory supply air and exhaust air
6. It must be possible to seal the area with an assigned protection level for fumigation.	no	mandatory where airborne transmission is possible	mandatory
7. A microbiological safety cabinet or a technical facility providing a similar level of protection shall be used.	mandatory for activities involving aerosol formation	mandatory	mandatory
8. Any area with an assigned protection level shall have dedicated equipment.	recommended	mandatory	mandatory
9. Any area with an assigned protection level shall be equipped with an autoclave or an equivalent sterilisation unit.	recommended	mandatory where airborne transmission is possible	mandatory
10. Contaminated process exhaust air must not be released into the working area.	mandatory	mandatory	mandatory
11. Effective disinfection and inactivation processes shall be defined.	mandatory	mandatory	mandatory
12. The surfaces in question shall be impervious to water and easy to clean.	bench	bench and floor	bench, walls, floor and ceilings

13. Surfaces shall be resistant to the chemicals and disinfectants used.	mandatory	mandatory	mandatory
14. Decontamination and washing facilities for employees shall be provided.	mandatory	mandatory	mandatory
15. Employees shall take a shower prior to leaving the area with an assigned protection level.	no	recommended	mandatory
16. Contaminated solid and liquid waste shall be inactivated prior to its final disposal using established physical or chemical methods.	mandatory when there is no professional disposal by subcontractors	mandatory where airborne transmission is possible; otherwise generally mandatory; professional disposal by subcontractors admissible only in sufficiently justified cases	mandatory
17. Waste water shall be inactivated prior to its final disposal using established physical or chemical methods.	not for water from washbasins or showers or similar waste water	recommended for water from washbasins or showers	mandatory
18. An observation window, or similar equipment, shall be present so that working area can be seen.	mandatory	mandatory	mandatory
19. An emergency call facility shall be provided when employees work alone.	recommended	mandatory	mandatory
20. It must be impossible to open windows.	no; windows shall be kept closed during the activity	mandatory	mandatory
21. Emergency power supply shall be provided for safety-critical installations.	recommended	mandatory	mandatory
22. Biological agents shall be kept under lock and key.	mandatory for listed biological agents* containing human pathogens	mandatory for listed biological agents* containing human pathogens	mandatory
23. An effective control of vectors (such as rodents and insects) shall be implemented.	recommended	mandatory	mandatory

24. Safe disposal of infected animal carcasses for instance by thermal inactivation, in incinerators for animal carcasses or other suitable sterilisation/inactivation facilities.	mandatory	mandatory	mandatory on site
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Note: Pursuant to section 10 para. 1, the protective measures designated as recommended shall be taken if the risk to employees can be reduced as a result.

* Human pathogens listed under 1C351 and genetically modified organisms listed under 1C353 in Annex I of Regulation (EU) No. 388/2012 of the European Parliament and of the Council of 19 April 2012 amending Council Regulation (EC) No 428/2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items. (Official Journal L 129 dated 16 May 2012, p. 12).

Annex III

Additional protective measures for biotechnological activities

The requirements of Annex II shall apply. For activities involving biological agents in biotechnological apparatuses such as bioreactors or separators, the following shall apply in addition:

A Protective measures	B Protection levels		
	2	3	4
1. The apparatus shall physically separate the process from the environment.	mandatory	mandatory	mandatory
2. The apparatus or a similar facility must be located in an appropriate area with an assigned protection level.	mandatory	mandatory	mandatory
3. The process exhaust air from the apparatus shall be treated so that a release of biological agents	is minimised.	is prevented.	is reliably prevented.
4. Opening the apparatus for sampling, adding substances or transferring biological agents, for example must be performed so that a release of biological agents	is minimised.	is prevented.	is reliably prevented.

5. Culture fluids may only be taken from the apparatus for further processing when their removal is handled in a closed system or when the biological agents have been inactivated by effective physical or chemical processes.	recommended	mandatory	mandatory
6. The seals of the apparatus must be designed so that an inadvertent release of biological agents	is minimised	is prevented	is reliably prevented.
7. It must be possible to collect the entire content of the apparatus.	mandatory	mandatory	mandatory

Note: Pursuant to section 10 para.1, the protective measures designated as recommended shall be taken if the risk for employees can be reduced as a result.