

Ordinance
on safety and health protection
at work involving biological agents
(Biological agents ordinance - BioStoffV)*

of 27 January 1999 (Federal Gazette I p. 50) as amended by Article 8 of the Ordinance of
23 December 2004 (Federal Gazette I p. 3758)

Based on sections 18 and 19 of the Act on Health and Safety at Work of 7 August 1996 (Federal Gazette I p. 1246), on section 19 para. 1 and 3 and on section 20b of the Chemical Substances Act as published in the communication of 25 July 1994 (Federal Gazette I p. 1703) and on section 13 of the Home Work Act in the amended version published in the Federal Gazette Part III, order no. 804-1, as amended by Article I No. 9 of the Act of 29 October 1974 (Federal Gazette I p. 2879), the Federal Government issues the following ordinance:

Section 1
Scope and objective

This ordinance shall apply to activities involving biological agents including activities in their risk area. The purpose of this ordinance is to protect workers from risks to their safety and health while performing these activities. This ordinance does not apply to activities subject to legislation governing genetic engineering insofar as this legislation provides for equivalent or more stringent regulations.

^{*}) In conjunction with the Act on Health and Safety at Work this ordinance serves to transpose Council Directive 90/679/EEC of 26 November 1990 on the protection of workers from risks related to exposure to biological agents at work (seventh individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC (OJ EC No. L 374 p.1), as amended by Council Directive 93/88/EEC of 12 October 1993 (OJ EC No. L 268 p. 71), as amended by Commission Directives 95/30/EC of 30 June 1995 (OJ EC No. L 155 p. 41), 97/59/EC of 7 October 1997 (OJ No. L 282 p. 33) and 97/65/EC of 26 November 1997 (OJ EC No. L 335 p. 17)

Section 2
Definitions

(1) Biological agents shall mean micro-organisms, including those which have been genetically modified, cell cultures and humanopathogenous endoparasites, which may be able to provoke any infection, sensitizing or toxic effects in human beings. A biological agent within the meaning of the first sentence shall also mean to include agents associated with transmissible, spongiform encephalopathy which may be able to provoke an infection or a communicable disease in human beings.

(2) Micro-organisms shall mean a microbiological entity, cellular or noncellular, capable of replication or of transferring genetic material.

(3) Cell cultures shall mean the in-vitro growth of cells derived from multicellular organisms.

(4) Activities within the meaning of this ordinance include the production and use of biological agents, in particular the isolation, production and replication, the breaking up, the use and consumption, treatment and processing, filling and re-filling, mixing and separating as well as the transport on the company premises, stocking including storage, inactivation and disposal. Activities shall also include the work-related handling of human beings, animals, plants, biological products, materials and agents provided that while performing these activities biological agents may be released and workers may have direct contact with these biological agents.

(5) Activities are deemed to be specific activities if

1. the biological agents are at least known as a species
2. the activity is directly related to one or several biological agents and
3. the workers' exposure under normal operation conditions is sufficiently known or predictable

Activities are not deemed to be specific activities if at least one of the prerequisites pursuant to sentence 1, No. 1, 2 or 3 is not fulfilled.

(6) A strain exceeding the harmless base strain to workers' health caused by biological agents at work shall be deemed to be contamination.

(7) A protection level comprises the technical, organisational and personal containment measures which have been determined or recommended for activities involving biological agents according to their inherent risks in order to protect the workers. Containment measures

are special protective measures listed in Annex II and III and which are allocated to the respective protection levels.

(8) A business owner with no staff as well as principals and intermediaries within the meaning of the Home Work Act shall be deemed to be employers. Home workers, pupils, students, persons employed at scientific institutions, and any other persons who work with biological agents shall be deemed to be workers. The provisions of this ordinance related to worker participation do not apply to pupils and students.

Section 3

Risk groups for biological agents

Biological agents shall be classified into four risk groups according to their level of risk or infection emanating from them:

1. Risk group 1: Biological agents which are unlikely to cause human disease.
2. Risk group 2: Biological agents which are unlikely to cause human disease and may be a hazard to workers; they are unlikely to spread to the community; there is usually effective prophylaxis or treatment available.
3. Risk group 3: Biological agents which may cause severe human disease and are a serious hazard to workers; 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 which cause severe human disease and are a serious hazard to workers; they may present a high risk of spreading to the community; there is usually no effective prophylaxis or treatment available.

Section 4

Classification of biological agents into risk groups

(1) For the classification of biological agents into risk groups 2 to 4 Annex III of Council Directive 90/679/EEC of 26 November 1990 (OJ EC No. L 374 p.1), as amended by Council Directive 93/88/EEC of 12 October 1993 (OJ EC No. L 268 p. 71), last amended by Commission Directive 97/65/EC of 26 November 1997 (OJ EC No. L 335 p.17) shall apply. In the case that Annex III of Directive 90/679/EEC is amended in the light of technical progress pursuant to the procedure laid down in its Article 19, the Annex shall apply in its amended version after expiry of the

deadlines for transposition laid down in the amended directive. The amended version may be applied already as from the entry into force of the amended directive.

(2) Where biological agents are not covered by para. 1, the employer shall classify them in respect of specific activities into risk groups according to the state of the art in science and technology. In addition the notifications pursuant to section 17 para. 4 shall be observed.

(3) Where a classification into several risk groups is possible in respect of specific activities the agent shall be classified in the highest risk group.

Section 5

Information for the purpose of risk assessment

(1) The employer shall gather sufficient information in order to assess the risks. The following information shall be taken into account in particular:

1. work-related information accessible to him about the identity, classification and infection potential of the biological agents as well as the sensitising and toxic effects
2. work-related information on operational processes and work procedures,
3. type and duration of activities and possible infection routes as well as information on the exposure of workers,
4. experience from comparable activities, strain and exposure situations and information on well-known work-related diseases as well as the countermeasures which have been taken.

(2) On the basis of information pursuant to paragraph 1 the information classification into specific or non-specific activities shall be made.

Section 6

Risk assessment in respect of specific activities

(1) The employer shall perform the risk assessment in case of specific activities pursuant to sentence 2 and 3 and para. 2 on the basis of the allocation pursuant to section 4 and the information gathered pursuant to section 5. In the case of mixtures of biological agents each individual biological agent shall be assessed separately. Where an activity involves several

biological agents from different risk groups the risk group of the biological agent with the highest risk shall be relevant for the determination pursuant to para. 2.

(2) In the framework of the risk assessment, possible protection measures shall be identified for all specific activities involving biological agents. At least the general hygiene measures of protection level 1 pursuant in accordance with Annex II or III shall be applied. Moreover for biological agents

1. of risk group 2, containment measures of protection level 2,
2. of risk group 3, containment measures of protection level 3,
3. of risk group 4, containment measures of protection level 4

shall be specified in accordance with Annex II or III. The containment measures designated as recommended measures shall be adopted if they contribute to reducing the exposure risks for workers. In the risk assessment process sensitizing and toxic effects shall be in addition taken into account and suitable protection measures envisaged.

Section 7

Risk Assessment in respect of non-specific activities

(1) The employer shall perform the risk assessment in case of non-specific activities pursuant to sentence 2 to 4 and paragraph 2 or 3. In this context it shall be examined whether information gathered pursuant to section 5 allows a final risk assessment and the allocation of the activity to one of the protection levels in accordance with Annex II or III. Where several biological agents are simultaneously involved, each individual biological agent shall be assessed separately, if possible. An overall assessment of the infection risk shall be carried out on the basis of this individual assessment.

(2) Where the activity can be allocated to a protection level, the possible protection measures shall be identified and the required containment measures from the respective protection level shall be selected and specified within the framework of a risk assessment for activities presenting a similar risk as activities pursuant to section 6 para. 2 sentence 3, No. 1 to 3 so that the risk of the workers' exposure is minimised as much as possible. At least general hygiene measures from protection level 1 in accordance with Annex II or III shall be required. In addition, sensitizing and toxic effects shall be taken into consideration and suitable protection measures shall be adopted.

(3) Where the activity cannot be allocated to a protection level, type, extent and duration of the exposure of workers to biological agents shall be identified and the risk shall be assessed in

accordance with the state of the art. The required protection measures shall be defined according to the state of the art. Para. 2 sentence 2 and 3 shall apply mutatis mutandis.

Section 8

Execution of risk assessment

The risk assessment shall be carried out prior to the beginning of work and shall be repeated in case of any substantial changes in working conditions or in the cases mentioned in section 15a para. 6 sentence 1 and section 15a para. 7 sentence 1. In carrying out the risk assessment, the employer shall seek expert advice if he does not himself have the required expert knowledge. Experts are in particular company doctors and occupational safety experts. In establishments with ten or fewer workers, records pursuant to section 6 para. 1 sentence 1 and 2 of the Act on Health and Safety at Work shall be available unless the activities carried out are limited to (a) specific activities with biological agents from risk group 1 without sensitising or toxic effects or (b) non-specific activities presenting an analogous risk in terms of workers' exposure. In the case of specific activities the records shall include a list of biological agents. In the case of non-specific activities this record shall be maintained insofar as the biological agents are relevant for the risk assessment pursuant to section 7.

Section 9

Activities involving biological agents of risk group 1

Sections 10 to 16, with the exemption of section 10 paras. 1, 3 and 4, as well as section 14 para. 1 shall not apply in cases where in the light of the risk assessment specific activities involving biological agents from risk group 1 without sensitizing or toxic effects or non-specific activities presenting similar risks are carried out.

Section 10

Protective measures

(1) In the light of the risk assessment and in accordance with other provisions of this ordinance and pursuant to other provisions of this ordinance including its annexes the employer shall take the required protection measures for the workers' safety and health protection. In this context the rules and findings, identified by the Biological Agents Committee and published by the Federal Ministry of Labour and Social Affairs in the *Bundesarbeitsblatt* shall be observed. They need not be observed if equivalent and reasonable protective measures have been taken; this shall be proven in each individual case at the request of the responsible authority.

(2) Biological agents presenting a health risk for workers, shall be replaced by biological agents which are less dangerous for workers insofar as this is reasonable and possible according to the state of the art in technology and science.

(3) In home work only biological agents from risk group 1 without sensitizing or toxic effects shall be made available or used. Sentence 1 shall apply mutatis mutandis to non-specific activities presenting similar risks.

(4) In all activities involving biological agents general hygiene measures of protection level 1 in accordance with Annex II or III shall be observed.

(5) Workers shall only be assigned to specific activities involving biological agents of risk group 3 or 4 if they are sufficiently knowledgeable and instructed. This shall apply mutatis mutandis to non-specific activities presenting similar risk. Prior to the assignment of activities the employer shall seek expert advice if he does not himself have the required expert knowledge on the required protection measures.

(6) The work procedures and the technical precautions shall be designed in such manner that biological agents are not released at the workplace. If this cannot be avoided or if biological agents are released according to the intended purpose, in particular the following technical and organisational precautions shall be taken in order to minimise the exposure of the workers:

1. Selection and design of suitable and safe work procedures for activities involving biological agents including their disposal,
2. Limitation of the number of exposed workers in the light of the risk assessment.

Moreover, the following further protective measures shall be taken:

1. The biohazard signs are to be posted workplaces and risk areas pursuant to Annex I in the light of the risk assessment,
2. Provisions against accidents and incidents prior to the beginning of work with biological agents,
3. Development of a plan to avert risks which may occur in case of a failure of the containment measure by the release of biological agents in case of specific activities involving biological agents of risk group 3 or 4 as well as with non-specific activities presenting similar risks.

(7) Where a serious risk for the workers emanating from biological agents is expected due to extraordinary circumstances or due to the fact that an installation has not been operated according to the intended purpose, and where it is not possible to assess the type, extent and

duration of the exposure, containment measures which must at least comply with protection level 3 shall be identified forthwith and adopted in accordance with Annex II or III.

(8) Where procedures are used requiring work with biological agents in technical installations or procedures involving the use of technical work equipment, the employer shall take the state of the art measures and precautions required to protect the workers.

(9) Where the technical safety of a work procedure has been further developed, and where it has proven reliable and where safety at work has hence increased considerably, this work procedure shall be adjusted to this advanced development within a reasonable delay.

(10) Biological agents shall be stored safely. For the storage, transport or disposal of biological agents only containers shall be used which by their nature are suited to ensure the safe enclosure of their content. The containers shall be labelled to indicate in a suitable and clearly visible manner the risks to the workers emanating from the containers. Biological agents must not be stored in containers whose form or label may lead to the workers mistaking the content for food.

Section 11

Hygiene measures, protective equipment

(1) In the light of risk assessment the necessary hygiene measures for disinfection and decontamination shall be taken and protective equipment including suitable protective clothing shall be provided. Appropriate measures shall be taken and the necessary facilities shall in particular be made available to ensure that personal protective equipment can be removed on leaving the place of work and be kept separately from other clothing and that its condition can be checked. In the light of the result of the checks personal protective equipment shall be disinfected and cleaned. Where protective equipment is defective it shall be repaired, replaced or destroyed where necessary.

(2) In order to keep contamination of the work place and exposure of workers at a minimum, the functioning and effectiveness of technical precautions shall be regularly checked. Where the release of biological agents cannot be safely prevented, it shall be ascertained whether the workplace has been contaminated. In doing so account shall be taken of microbial air pollution at the workplace.

(3) Workers shall not be permitted to eat, drink or smoke at workplaces where there is a risk of contamination by biological agents. For this purpose suitable areas shall be installed prior to the beginning of the activities.

Section 12
Information of workers

(1) In the light of risk assessment operating instructions relating to the working area and working agents shall be drawn up prior to the beginning of work. They shall contain information on the risks presented by the envisaged activities. They shall also indicate the necessary protection measures and rules of conduct and contain instructions to be followed in the case of accidents and incidents, as well as first aid instructions. The operating instructions shall be written in a form and language understandable to the workers and they shall be made known in a suitable location at the workplace and shall be displayed for consultation or be put up on the notice board.

(2) Workers due to work with biological agents shall receive training on the basis of the operating instructions relating to existing risks and protective measures. Training shall be given orally and with specific reference to the workplace prior to the beginning of work and shall be repeated in the cases referred to in Section 8, first sentence. After the training, time and content of training shall be recorded in writing and shall be signed and approved by the trainee.

2a) The employer shall ensure that all workers that carry out activities with biological agents are provided with general medical counseling within the context of the training pursuant to para. 2. Workers shall also be advised of the option to undergo a medical examination pursuant to section 15a para. 5, and shall furthermore be advised of particularly high risks such as that entailed by long-term weakening of the body's immunological mechanisms. The medical counseling shall be realized with the participation of a doctor pursuant to section 15 para. 3 sentence 2.

(3) In the case of work where experience has shown that a risk of infection is likely to arise because there is a higher risk of accident, or where serious infections are likely to occur as a result of an accident, instructions for the prevention of accidents shall in addition be made available at the place of work. This applies also in the case of

1. Procedures for taking, handling and processing samples of human or animal origin,
2. Maintenance, cleaning, modification or demolition activities in or on contaminated plants, equipment or installations.

(4) Workers employed in the risk area and the works council or staff representation shall be informed forthwith about any incidents presenting a potential risk for the workers' health or

safety as well as about any accidents. The information referred to in Section 13 paragraph 1 to 3 shall be made available to the works or staff council.

Section 13

Obligation to notify and to keep records

(1) The employer shall notify the competent authority of specific activities involving risk group 2, 3 or 4 biological agents, which are carried out for the first time, at least 30 days before the beginning of work. The notification shall include:

1. Name and address of the employer and the persons in charge within the meaning of paragraph 13, paragraph 1 No. 1 to 3,
2. Name and qualification of the persons responsible for safety and health at work,
3. the result of risk assessment in accordance with paragraph 6,
4. the type of biological agent,
5. the safety and health measures that are envisaged.

(2) Renotification must take place in the case of:

1. Substantial changes of importance to the workers' health or safety,
2. the beginning of work involving each subsequent group 3 biological agent inasfar as the agent is not contained in Annex III of Directive 90/679/EEC as amended,
3. the beginning of work involving each subsequent group 4 biological agent.

(3) A list of workers due to work with group 3 or 4 biological agents shall be maintained, indicating the type of work done, the biological agents involved as well as any accidents and incidents. The workers concerned or their authorized representatives shall have access to information concerning them.

(4) The list referred to in paragraph 3 shall be kept for at least ten years after the termination of the activities. The list shall be kept for up to 40 years if this is required by the nature of an illness or the period of time elapsing between the exposure and possible occurrence of an infectious disease. The list shall be made available to the competent authority at its request. In the case of closure of the establishment, the list shall, without request, be transferred for further keeping to the competent industrial accident insurance fund.

(5) Paragraphs 1 to 4 shall apply mutatis mutandis for non-specific activities presenting risks comparable to the activities referred to in paragraph 6, paragraph 2 sentence 3 No. 2 or 3.

(6) Where the particulars to be specified in the notification are contained in an equivalent way in notifications pursuant to other legal provisions, the obligation to notify may be fulfilled by submitting a copy of these notifications to the competent authority.

Section 14

Official delegations

(1) Upon written application of the employer the competent authority may permit derogations from the provisions of section 10 including Annexes II and III if

1. the employer has taken other equally valid protective measures, or
2. if the implementation of the provision would in individual cases lead to unreasonable hardship and the derogation is compatible with the safety of the workers concerned.

(2) In the case of establishments with less than ten workers the competent authority may, upon written application of the employer, grant a derogation from the obligation to document risk assessment. Sentence 1 above does not apply to specific activities involving biological agents of group 3 or 4 and for non-specific activities presenting similar risks.

Section 15

Preventive medical check-ups

(1) The employer shall ensure that workers are provided with adequate preventive medical check-ups pursuant to section 3 of the Act on Health and Safety at Work. The check-ups shall include any preventive medical measures that are necessary in order to protect workers against work related hazards. For any worker whose activities involve biological agents, medical check-ups shall include the following in particular:

2. A medical assessment of the health risks arising from the work activities and biological agents of interest, and recommendations in regard to suitable protective measures.
3. The health risk attributable to the worker's activities shall be explained to him, and he shall receive counseling in regard to such risk, including risk that might arise from any existing health problem.
4. The realization of specific preventive check-ups with a view to detecting any health problem or work related illness at an early stage.

5. Recommendations as to how work place safety can be audited, as well as repetition of the risk assessment.
6. The elaboration of further or enhanced measures at the work place, on the basis of relevant findings, with a view to protecting workers who carry out activities with biological agents.

(2) Specific preventive medical check-ups shall be either requested or offered by the employer, and shall be realized as follows:

1. Initial medical examination prior to the beginning of any work involving a health risk
2. Check-ups at regular intervals while the worker is performing work involving a health risk
3. Check-ups upon termination of such work
4. Medical examinations for specific purposes or in specific settings.

Preventive check-ups shall as a rule consist of the following:

1. The doctor shall either inspect, or obtain information regarding, the work place
2. The worker shall complete a medical questionnaire and shall undergo a medical examination
3. The worker's state of health shall be assessed in light of his working conditions
4. The worker shall discuss his medical condition with the company doctor.
5. The results of the preventive check-up shall be recorded

(3) The employer shall ensure that preventive check-ups are realized by engaging the services of a doctor to perform the check-ups. The doctor shall either be a specialist in occupational medicine (i.e., an occupational physician), or his field of expertise shall be officially designated as "occupational medicine". When performing preventive check-ups that require specialized expertise or equipment, the attending physician shall enlist the aid of medical specialists that have competency in the relevant disciplines or expertise with the relevant equipment. If the services of a specialist in occupational medicine pursuant to the Act on Health and Safety at Work are engaged, whenever possible the employer shall request that the specialist also carry out specific preventive check-ups. The doctor shall be provided with all necessary information regarding working conditions, particularly risk assessment results, and shall be given the opportunity to visit the work place. Upon request, the doctor shall be authorized to examine the records referred to in section 13 para. 3 and 5, as well as the prevention files referred to in par. 6 hereunder.

(4) The following requirements shall be met in regard to preventive medical check-ups:

1. The results of the check-ups shall be recorded in writing
2. The worker shall be informed of the results of the check-up

3. A certificate shall be issued to the worker indicating whether and/or to what extent there are medical objections to the activities being carried out by the worker
4. A copy of the check-up results certificate pursuant to no. 3 shall be transmitted to the employer only in the case of a check-up pursuant to section 15a para. 1.

Any findings obtained as a result of preventive medical check-ups pursuant to the present Ordinance shall be taken into consideration in fulfilling the requirements of section 3 of the Act on Health and Safety at Work.

(5) The employer shall maintain a prevention file for any worker that is to undergo regular medical check-ups pursuant to section 15a para. 1. The prevention file shall contain the information specified in section 13 para. 3, as well as the results of the worker's preventive medical check-ups, and shall be submitted to the competent authority upon request. It shall be permissible for prevention files to be kept in lieu of the records pursuant to section 13 para. 3 and 5. Prevention files are to be kept in such a way that they can be evaluated at a later time. The worker concerned or his authorized representative shall be entitled to examine the relevant information in the records. Application of sentence 1 shall be excluded if a worker does not require medical check-ups owing to his lifelong immunity to an inoculable biological agent.

(6) The employer shall store a worker's prevention file until such time as the worker leaves his job, whereupon the worker shall be given the extract of the prevention file that pertains to him. The employer shall apply human resource record archiving procedures to the extract of any record transmitted to a worker.

Section 15a

Requesting and offering preventive medical check-ups

(1) The employer shall request medical check-ups pursuant to section 15 para. 2 sentence 1 nos. 1 and 2 on a regular basis in the following instances:

1. Specific activities involving the following:

risk group 4 biological agents.

the inoculable or chronically deleterious biological agents mentioned in Annex IV, para. 2, column 1

and

2. Non-specific activities that meet the following criteria:

a) protection level 4 activities

b) the conditions stipulated in Annex IV, par. 2, columns 2 and 3, insofar as the inoculable or chronically deleterious biological agents mentioned in column 1 are likely to occur or continue occurring in connection with specific activities, and insofar as the risk of infection from these

biological agents is substantially higher for the workers who are exposed to them than for the general population.

(2) At the conclusion of an activity pursuant to para. 1, the employer shall offer the worker the opportunity to undergo a medical examination as specified in section 15 para. 2 sentence 1 no. 4.1 Sentence 1 shall also apply for activities involving inoculable biological agents if the worker already has sufficient immunity against the agent.

(3) Medical examinations shall not be required for activities involving an inoculable biological agent if the worker already has sufficient immunity against the agent. In all other cases, the employer shall request that the worker be offered the opportunity to be vaccinated within the framework of the medical examination. In so doing, the employer shall provide the worker with information regarding the disorder against which he is to be vaccinated and regarding any possible adverse events and complications associated with the vaccination. If the worker declines to be vaccinated, this alone shall not constitute grounds for asserting that the worker is unfit to carry out specific work duties for medical reasons.

(4) No worker shall take up or resume his work duties unless and until he has undergone a medical check-up pursuant to para. 1.

(5) If the employer is not required to request that the medical examination pursuant to para. 1 be performed, the employer shall nonetheless offer the worker the opportunity to undergo a medical examination pursuant to section 15 para. 2 nos. 1 and 2 in the following instances:

1. In the case of specific activities involving risk group 3 biological agents and non-specific protection level 3 activities.
2. In the case of specific activities involving risk group 2 biological agents and non-specific protection level 2 activities, providing that the risk assessment and protective measures that have been realized do not indicate that a risk of infection exists.

(6) If a worker contracts an infection or illness that could be attributable to activities involving a biological agent, the worker shall immediately be offered a medical examination pursuant to section 15 para. 2 no. 4.2 The foregoing shall also apply to workers who engage in similar activities, insofar as there is reason to believe that such workers may also be at risk. The foregoing shall not apply if the infection or illness is attributable to an individual injury, and transmission to other workers can be ruled out. Sentence 1 shall also apply insofar as (a) it

¹ **Hinweis:** Der richtige Bezug lautet: § 15 Abs. 2 Satz 1 Nr. 3

² **Hinweis:** Der richtige Bezug lautet: § 15 Abs. 2 Satz 1 Nr. 4

appears certain that an acute infection or disease will result from exposure to a biological agent and (b) it is possible to realize post-exposure prophylactic measures.

(7) If it comes to the employer's attention that, for health reasons, specific working conditions make it inadvisable for a worker to continue their present activities, the employer shall realize additional protective measures forthwith. Such measures may include assigning the affected worker to activities that entail no risk of further exposure. The employer shall notify the works or staff council as well as the competent authority of any protective measures taken and shall repeat the risk assessment. Where, in the case of the setting referred to in section 15 para. 4, the person examined or the employer believe the results of the examination to be incorrect, the competent authority shall take a decision if so requested.

Section 16

Information to the authority

(1) Without prejudice to section 22 of the Act on Safety and Health at Work the competent authority, at its request, shall be informed of:

1. the results of risk assessment and the information used for making the assessment,
2. the activities in which workers have been exposed or may have been exposed to biological agents and the number of workers concerned,
3. the persons responsible within the meaning of Section 13 of the Act on Safety and Health at Work,
4. the protective and preventive measures taken including operating and working instructions, and
5. the measures taken pursuant to section 10, para. 6, sentence 3, number 2 and the plan drawn up pursuant to section 10 para. 6, sentence 3, number 3.

(2) The competent authority shall be informed forthwith of any accident or incident during activities involving group 3 and 4 biological agents or non-specific activities presenting similar risks which may lead to a health hazard for the workers. Information of cases of illness or death attributable to activities involving biological agents, together with a specification of the activity concerned, shall be forthwith supplied to the competent authority.

Section 17

Biological Agents Committee

(1) For consultation in all matters of health and safety at work involving biological agents, a Committee on Biological Agents shall be set up at the Federal Ministry of Labour and Social

Affairs, comprising an appropriate representation of public and private employers, trade unions, Land authorities, statutory accident insurance institutions, universities and science. The Committee members shall not have more than 16 members. Membership in the committee shall be exercised as an honorary function.

(2) The Federal Ministry of Labour and Social Affairs shall appoint the members of the committee as well as a deputy for each member. The committee shall adopt its rules of procedures and elect a chairman from among its members. The rules of procedure and the election of the chairman shall be subject to the approval of the Federal Ministry of Labour and Social Affairs.

(3) The Committee's tasks shall include:

1. establishing rules and findings in conformity with Section 4 of the Act on Safety and Health at Work, for work involving biological agents as well as rules and findings concerning classification in accordance with Section 4, para. 1 and 2, sentence 1,
2. identifying ways of fulfilling the requirements of this ordinance,
3. proposing provisions corresponding to the state-of-the-art in the field of science, technology and medicine,
4. advising the Federal Ministry of Labour and Social Affairs on general questions of biological safety.

(4) The Federal Ministry of Labour and Social Affairs may decide to publish in the *Bundesarbeitsblatt* the rules and findings established by the Biological Agents Committee in accordance with para. 3, number 1 and the procedural rules established in accordance with para. 3, number 2.

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

(6) The committee's business shall be conducted by the Bundesanstalt für Arbeitsschutz und Arbeitsmedizin.

Section 18

Administrative and criminal offences

(1) Persons who, deliberately or through negligence,

1. violate Section ... para. 1, sentence 1 or Section 7, para. 1, sentence 1, by not carrying out risk assessment, by carrying out incorrect or incomplete risk assessment or risk assessment not taking account of the requirements specified in Section 8, sentence 1, number 2 or 3,
2. violate Section 11, para. 1, sentence 3 or 4 by not disinfecting, cleaning, repairing, replacing or destroying personal protective equipment or by not doing so properly and in time,
3. violate Section 11, para. 2 by not regularly checking the effectiveness of technical precautions,
4. violate Section 11, para. 3, sentence 2 by not installing the areas specified in that provision or by not installing them in time.
5. violate Section 12, para. 1, sentence 1 or 4 by not drawing up operating instructions or by not drawing up operating instructions properly, completely or as required or not in due time, by not making the operating instructions known, or by not making them known in due time, or by not displaying the operating instructions for consultation or by not doing so in due time or by not putting them up on the board, or by not putting them up on the board in due time,
6. violate Section 12, para. 2, sentence 1 or 3 by not training workers or by not training workers as required or in due time, or by not recording in writing the time and content of training, or by not recording time and content of training as required and in due time,
7. violate Section 12, para. 4, sentence 1 by not informing about incidents or accidents or by not informing about incidents and accidents accurately, completely and in due time,
8. violate Section 13, para. 1, sentence 1 by not notifying or by not notifying accurately, completely or in due time,
9. violate Section 13, para. 3, sentence 1 by not maintaining a list, or by not maintaining a list accurately and completely,
10. violate Section 13, para. 4 by not keeping the list, or by not keeping the list for the period of time required, or by not making it available, or by not making it available in due time, or by not handing the list over, or not handing it over in due time,

- 10a. violate section 15 para. 3 sentence 1 by not taking steps to ensure that preventive medical check-ups are realized

- 10b. violate section 15 para. 5 sentence 1 by not maintaining prevention files (Vorsorgekartei)

11. violate section 15a para. 1 by not requesting medical check-ups, or by not requesting them in due time

12. violate section 15a para. 5 by not offering preventive medical check-ups, or by not offering them in due time

13. violate section 15a para. 3 sentence 2 or para. 6 sentence 1 by not offering a vaccination or a preventive medical check-up, or by failing to do so in due time
14. violate Section 15, para. 5, sentence 2 by not allowing an inspection of the work place, or by not allowing it in due time,
15. violate Section 16, para. 1 or 2, sentence 1 by not informing the competent authority, or by not informing the competent authority accurately, completely or in due time,
16. violate Section 16, para. 2, sentence 2 by not giving notification, or by not giving notification accurately, completely or in due time,

shall be guilty of an administrative offence within the meaning of Section 25, para. 1, number 1 of the Act on Safety and Health at Work.

(2) Persons who violate Section 10, para. 3, sentence 1 or sentence 1 together with sentence 2, by making available or using a biological agent, deliberately or through negligence, shall be guilty of an administrative offence within the meaning of Section 32, para. 1, number 1 of the Home Work Act.

(3) Persons who, by a deliberate act referred to in para. 1 above, put at risk the life or health of a worker, shall be guilty of a criminal offence within the meaning of Section 26, number 2 of the Act on Safety and Health at Work.

(4) Persons who, by a deliberate act referred to in para. 2 above, put at risk the working capacity or health of persons engaged in home work, shall be guilty of a criminal offence within the meaning of Section 32, para. 3 or 4 of the Home Work Act.

Section 19

Transitional provision

Notifyable activities which have already been started at the time of entry into force of the Ordinance shall be notified to the competent authority within six months of the entry into force of the Ordinance. Section 13, para. 1, sentence 2 shall apply mutatis mutandis.

Annex I

Biohazard symbol



Design of the label: black symbol on yellow background

Annex II

Containment measures in the case of activities involving biological agents in laboratories and quasi-laboratories

(1) Protection level 1 includes general hygiene measures in accordance with the technical rules laid down by the Biological Agents Committee

(2) Safety levels 2, 3 and 4 include the following containment measures:

A Containment measures	B Protection levels		
	2	3	4
1. The workplace is to be separated from any other activities in the same building	No	obligatory, where infection by airborne route is possible	obligatory
2. Input air and extract air to the workplace are to be filtered using (HEPA) or likewise	No	obligatory, on extract air	obligatory, on input and extract air
3. Access is to be restricted to nominated workers only	obligatory	Obligatory	obligatory, via airlock
4. The workplace is to be sealable to permit disinfection	no	Recommended	obligatory
5. Specified disinfection procedures	obligatory	Obligatory	obligatory
6. The workplace is to be maintained at an air pressure negative to atmosphere	no	obligatory, where infection by airborne route is possible	obligatory
7. Efficient vector control e.g. rodents and insects	recommended	Obligatory	obligatory
8. Surfaces impervious to water and easy to clean	obligatory, for bench	obligatory, for bench and floor	obligatory, for bench, walls, floor and ceiling
9. Surfaces resistant to acids, alkalis, solvents, disinfectants	recommended	Obligatory	obligatory
10. Safe storage of a biological agent	obligatory	Obligatory	obligatory, secure storage
11. An observation window, or, alternative, is to be present, so that occupants can be	recommended	Obligatory	obligatory

seen			
12. A laboratory is to contain own equipment	no	Recommended	obligatory
13. Infected material including any animal is to be handled in a safety cabinet or isolation or other suitable containment	where appropriate	obligatory, where infection is by airborne route	obligatory
14. Incinerator for disposal of animal carcasses	recommended	obligatory, accessible	obligatory, on site

Annex III

Containment measures in the case of specific and non-specific activities which are not covered by Annex II

- (1) Protection level 1 includes general hygiene measures in accordance with the technical rules laid down by the Committee for Biological Agents
- (2) Protection levels 2, 3 and 4 include the following containment measures:

Containment measures	Protection levels		
	2	3	4
1. Viable organisms are to be handled in a system which physically separates the process from the environment	Obligatory	Obligatory	obligatory
2. Exhaust gases from the closed system are to be treated so as to:	minimize release	prevent release	prevent release
3. Sample collection, addition of materials to a closed system and transfer of viable organisms to another closed system are to be performed so as to:	minimize release	prevent release	prevent release
4. Bulk culture fluids are not to be removed from the closed system unless the viable organisms have been:	inactivated by validated means	Inactivated by validated chemical or physical means	inactivated by validated chemical or physical means
5. Seals are to be designed so as to:	minimize release	prevent release	prevent release
6. Closed systems are to be	recommended	recommended	obligatory

located within a controlled area			
(a) Biohazard signs are to be posted	recommended	obligatory	obligatory
(b) Access is to be restricted to nominated personnel only	recommended	obligatory	obligatory, via an airlock
(c) Personnel is to wear protective clothing	obligatory	obligatory	a complete change
(d) Decontamination and washing facilities are to be provided for personnel	obligatory	obligatory	obligatory
(e) Personnel is to shower before leaving the controlled area	no	recommended	obligatory
(f) Effluent from sinks and showers are to be collected and inactivated before release	no	recommended	obligatory
(g) The controlled area is to be adequately ventilated to minimize air contamination	recommended	obligatory, where infection by airborne route is possible	obligatory
(h) The controlled area is to be maintained at an air pressure negative to atmosphere	no	recommended	obligatory
(i) Input air and extract air to the controlled area are to be HEPA filtered	no	recommended	obligatory
(j) The controlled area is to be designed to contain spillage of the entire contents of the closed system	no	recommended	obligatory
(k) The controlled area is to be sealable to permit fumigation	no	recommended	obligatory
(l) Effluent treatment before final discharge	inactivated by validated means	inactivated by validated chemical or physical means	inactivated by validated chemical or physical means

Obligatory preventive medical check-ups pursuant to section 15a para. 1

- (1) Preventive medical check-ups shall be requested in the following cases:
1. for specific activities involving the biological agents mentioned in para. 2 column 1
 2. for non-specific activities involving the biological agents mentioned in para. 2 column 1, in the types of facilities mentioned in column 2, and under the exposure conditions mentioned in column 3.
- (2) Reasons for performing medical examinations

column 1	column 2	column 3
biological agent	non-specific activities	exposure conditions
Risk group 4 biological agents	in institutions that carry out medical investigations and provide medical treatment and in the field of human medicine	Activities involving contact with persons who are ill or in whom illness is suspected
	in pathology laboratories and departments	Autopsies or post-mortem examinations performed on persons who, or animals which, had an illness that was attributable to risk group 4 biological agents or in whom or which such an illness was suspected.
	in laboratories and research institutions	Regular activities that present opportunities for contact with (a) infected specimens or specimens suspected of being infected or (b) items or materials that are contaminated or that contain pathogenic organisms
Bordetella pertussis*) Measles virus *) Mumps virus *)	in institutions that provide the following services for children: medical investigations, medical treatment, medical care or preschool daycare	Regular and direct contact with children
Rubivirus*) Varizella-Zoster virus (VZV)*)	in laboratories and research institutions	Regular activities that present opportunities for contact with (a) infected specimens or specimens suspected of being infected or (b) items or materials that are contaminated or that contain pathogenic organisms
Borrelia burgdorferi	Forestry activities	Activities carried out in lower vegetation
Bacillus anthracis*) Bartonella - bacilliformis - quintana - henselae Borrelia burgdorferi sensu lato Brucella melitensis Burkholderia pseudomallei (Pseudomonas pseudomallei) Chlamydia pneumoniae Chlamydia psittaci (aviary strain) Coxiella burnetii Franciscella tularensis*) Yellow fever virus* Helicobacter pylori Influenza A+B*) Japanese encephalitis virus*) Leptospira species*) Treponema pallidum (Lues) Tropheryma whipplei Trypanosoma cruzii Yersinia pestis*) Poliomyelitis virus Schistosoma mansoni	in research institutions and reference laboratories	Regular activities that present opportunities for contact with (a) infected animal/specimens or animals/specimens suspected of being infected or (b) items or materials that are contaminated or that contain pathogenic organisms whose transmission pathway is known

column 1	column 2	column 3
biological agent	non-specific activities	exposure conditions
Streptococcus pneumoniae vibrio cholerae*)		
Early summer meningoencephalitis virus	in endemic areas:	
	Forestry and gardening	Regular activities in forests and lower vegetation
	Hunting, commercial activities involving animals	Activities involving regular and direct contact with animals living in the wild
	in laboratories and research institutions	Regular activities that present opportunities for contact with (a) infected specimens or specimens suspected of being infected or (b) items or materials that are contaminated or that contain pathogenic organisms whose transmission path is known
Hepatitis-A virus (HAV)*	in facilities for the disabled and elderly, in pediatric wards	Activities involving regular contact with faeces in the following settings:
		medical care for infants
		health care for elderly and disabled persons
	in faeces laboratories	Regular activities involving faeces specimens
	in sewage treatment plants in sewage systems	Activities involving regular contact with wastewater containing faeces or with items that are contaminated by faeces
	in research institutions and laboratories	Regular activities that present opportunities for contact with (a) infected specimens or specimens suspected of being infected or (b) contaminated items or materials containing pathogenic organisms
Hepatitis-B virus (HBV)* Hepatitis-C virus (HCV)*	in facilities that carry out medical examinations, medical treatment, and human healthcare, as well as care for disabled persons including facilities and services that supply or support such facilities emergency medical and rescue services in pathology labs or departments	Activities that could involve regular and extensive contact with body fluids, excretions, or body tissues, particularly activities involving a high risk of injury or a risk arising from body fluid discharges or body fluid aerosol..
	in laboratories and research institutions	Regular activities that present opportunities for contact with (a) infected specimens or specimens suspected of being infected or (b) contaminated items or materials containing pathogenic organisms
Mycobacterium - tuberculosis - bovis	in tuberculosis wards and other pulmonary institutions	Activities involving regular contact with persons who are ill or suspected of being ill
	in laboratories and research institutions	Regular activities that present opportunities for contact with (a) infected specimens or specimens suspected of being infected or (b) items or materials that are contaminated or that contain pathogenic organisms

column 1	column 2	column 3
biological agent	non-specific activities	exposure conditions
Salmonella typhi	in faeces laboratories	Regular activities involving faeces specimens
<i>Rabies virus</i> *)	in rabies areas	Activities involving regular and direct contact with animals living in the wild
	in laboratories and research institutions	Regular activities that present opportunities for contact with (a) infected specimens or specimens suspected of being infected (b) items or materials that are contaminated or that contain pathogenic organisms; or (c) infected animals

*) inoculable cases only

Approved by the *Bundesrat*.

Bonn, 27 January 1999

The Federal Chancellor
Gerhard Schröder

The Federal Minister of Labour and Social Affairs
Walter Riester