SWEDISH
WORK
ENVIRONMENT
AUTHORITY

AFS 2005:1

Microbiological Work Environment Risks – Infection, Toxigenic Effect, Hypersensitivity

Provisions of the Swedish Work Environment Authority on Microbiological Work Environment Risks, together with General Recommendations on the implementation of the Provisions

Translation
In the event of disagreement concerning the interpretation and content of this text, the printed Swedish version shall have priority.

The Work Environment Authority's Statute Book

The Swedish Work Environment Authority was formed through a merger of the Swedish National Board of Occupational Safety and Health and the Labour Inspectorate, on 1st January 2001.

Provisions adopted by the Swedish Work Environment Authority are published in the Statute Book of the Swedish Work Environment Authority. Provisions earlier published in the Statute Book of the Swedish National Board of Occupational Safety and Health simultaneously still apply. Both Statute Books' names are abbreviated AFS.

Please note that references to statutes always give the original number of the document concerned, regardless of any subsequent amendments and reprints.

Concerning amendments to and reprints of Provisions of the Swedish National Board of Occupational Safety and Health and of the Swedish Work Environment Authority, reference is made to the latest Statute Book Register (in Swedish). A list of Ordinances, General Recommendations, Directions and Notices is also published in English.

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Provisions of the Swedish Work Environment Authority on Microbiological Work Environment Risks – Infection, Toxigenic Effect, Hypersensitivity

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The following Provisions are issued by the Swedish Work Environment Authority pursuant to Section 18 of the Work Environment Ordinance (SFS 1977:1166).[1]

Scope and definitions

Section 1
These Provisions apply to activity involving the use of biological agents. They also apply to other activity in which there are risks to health or safety which may be caused by biological agents at work.

Section 2
For the purpose of these Provisions, a party engaging in professional activity singly or together with a family member, but without any employees and parties engaging jointly in such activity are equated with employees.

Definitions

Section 3
For the purpose of these Provisions, the following definitions shall apply.

Biological agents	Agents/influential factors of the following kinds: (a) micro-organisms, i.e. micro-biological entities capable of replication or of transferring genetic material, (b) cell cultures of multicellular organisms, (c) inferior replicable entities, such as viruses and prions, (d) human endoparasites and (e) components of or substances produced from

[1] *Cf. Directive of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (OJ L 262, 17.10.2000, p. 21, Celex 32000 L0054).*

	agents as per (a) to (d) when occurring in conjunction with those agents.
Ill-health	Infection, toxigenic effect, hypersensitivity or other harmful effects due to biological agents.
Use of biological agents	Culture, enrichment and suchlike intentional use of biological agents.
Working area	A delimited area within the workplace where a risk of a certain kind of harmful exposure to biological agents has been judged to exist.
Risk group	The group to which a biological agent is referred when classified in accordance with the criteria stated in App. 2 A concerning ability to cause infection and the potential gravity of the consequences.
Biosafety level	The array of protective measures, as stated in App. 3 C, adapted to the use of biological agents involving similar risks.
Infectious agent	A biological agent capable of causing infection in man, i.e. a biological agent placed in group 2 or above according to the criteria in App. 2 A.
Infective dose	The quantity of an infectious agent usually required to establish an infection.
Unwanted event	An event which has or could have led to ill-health or an accident being caused by a biological agent.
Decontamination	Treatment to kill, inactivate or reduce the quantity of biological agents so that they will not cause injury.
Disinfection	Treatment reducing the number of viable biological agents.
Sterilisation	Treatment to achieve the absence of viable biological agents.
Microbiological air contaminant	A biological agent present in the air in a concentration which can entail ill-health.

General Provisions

Risk assessment, documentation

Section 4
The employer shall judge whether there are risks to workers' health and safety which can be caused by biological agents in the workplace. If harmful exposure to biological agents can occur, the nature, degree, extent and duration of the exposure shall be established as far as is possible.

The risk assessment shall proceed in accordance with the procedure set forth in App. 1, so that all microbiological work environment risks can be identified as far as possible and an assessment made of the measures needing to be taken. The employer shall have access to the competence needed for the assessment of risks.

The assessment of risks shall be renewed regularly and when any change occurs in the conditions which may affect the risk. It shall also be renewed when new information appears which can affect the assessment of risks.

Section 5
The results of the risk assessment shall be documented in writing, in a manner appropriate to the character of the risks. The documentation shall also show when the risk assessment was made, who took part in it, what was assessed, the risks, if any, identified, whether measures need to be taken and, if so, which measures, and the time of the next regular review.

The documentation shall be kept available to the employees and safety delegates concerned and shall be available for presentation at the request of the Work Environment Authority.

Planning of work, risk limitation

Section 6
Work shall be planned, organised and conducted in such a way that biological agents are eliminated or reduced to a low enough level not to cause ill-health or accidents.

In this connection the measures indicated in points 1-6, below, shall be considered in the order given.

1. Biological agents shall be selected which entail as little risk as the activity permits.
2. The unwanted occurrence and growth of biological agents shall be prevented.
3. Working methods, processes and technical devices shall be selected and designed in such a way as to counteract the occurrence of microbiological air contaminants.
4. Measures shall be taken as near as possible to the source, to limit the spread of biological agents.
5. The number of persons who can be affected shall be kept as low as possible.
6. Personal protective equipment shall be used.

Protective measures

Section 7
Following risk assessment and considerations as indicated in Sections 4-6, necessary protective measures shall be taken according to the nature of the work.

Facilities, fittings and equipment

Section 8
Facilities, fittings and equipment shall be designed in such a way that risks associated with biological agents are avoided, the spread of biological agents is limited and the necessary decontamination facilitated.

Section 9
Control and maintenance shall be carried out to the extent and by the methods necessary in order to prevent biological agents causing ill-health or accidents.

Decontamination, handling and transfer of contaminated material

Section 10
Decontamination shall be carried out to the extent necessary in order to prevent biological agents causing ill-health.

Decontamination shall normally be carried out as early as possible, using agents and methods appropriate to the need.

The methods used shall be designed to avoid microbiological air contaminants or other risks to health.

Section 11
Waste and other contaminated material shall be handled and transferred in accordance with predefined routines, in such a way that risks to health are avoided. The party transporting or disposing of such material shall previously be supplied with necessary information concerning the material, the risks entailed by handling it and the need for protective measures.

Personal hygiene

Section 12
Good personal hygiene shall be observed so as to prevent exposure to biological agents from causing ill-health. No procedure may occur which entails a risk of infectious agents coming into contact with mucous membranes in the eyes, mouth or nose.

The equipment needed for maintaining good hygiene shall be readily available. In connection with work entailing a risk of infection, hand-washing facilities and a skin disinfectant shall be provided in immediate conjunction

with the workplace. In connection with work which can entail exposure of the eyes, an eyewash facility shall be readily available.

Personal protective equipment

Section 13
Protective clothing shall be used for work which can entail exposure to infectious agents, and when otherwise needed. Protective clothing shall be stored separately from other clothing. Protective clothing and other personal protective equipment shall be removed when leaving the working area. They shall be managed in such a way that the spread of biological agents is avoided.

Protective gloves shall be used for work entailing a risk of skin contact with biological agents, if technical measures are not sufficient to prevent such air contamination causing ill-health.

Other suitable personal protective equipment shall be used when necessary.

Knowledge, information and instructions

Section 14
The employer shall see to it that the person directing the work and all employees who may come to be exposed to microbiological work environment risks have sufficient training and sufficient knowledge concerning the biological agents occurring in the activity.

Everyone doing work which can entail risks caused by biological agents in the workplace shall be sufficiently informed of these risks and how to avoid them.

Section 15
The employer shall see to it that the employees have received handling and safety instructions on how the work is to be done with adequate safety. The employer shall ascertain that the instructions have been properly understood by all concerned and are complied with.

The instructions shall also include measures needed for the protection of others than those to whom the instructions are addressed.

Instructions shall be repeated when necessary and reviewed jointly by employer and employees in order to adapt them to new or changed conditions. If shortcomings are observed, the instructions shall be amended.

Handling and safety instructions shall be in writing for the use of infectious agents and otherwise when necessary for the prevention of ill-health or accidents. The instructions shall always include the measures to be taken in the event of unwanted events.

Measures and reporting in connection with ill-health and unwanted events

Section 16
Employees shall report to the work supervisory staff without delay both unwanted events and ill-health which may be connected with the biological agents occurring in the workplace.

The employer shall see to it that routines exist for

- reporting as aforesaid, and documentation of the same,
- measures to limit the consequences of unwanted events,
- interaction with those concerned, in order to investigate the causes of unwanted events, and
- measures to avoid repetition of unwanted events or of ill-health.

Measures in connection with unwanted events shall be practised regularly. The exercises shall be made to vary in accordance with events conceivable.

A special contingency plan shall exist for measures to be taken in the event of occurrences which can result in group 3 or 4 infectious agents causing serious or extensive harm. This contingency plan shall include an evacuation plan. Everyone who can be involved shall be informed of the plan. Measures provided for in the contingency plan, the evacuation plan included, shall be practised at least annually.

Medical preventive measures and checks

Section 17
The employer shall, when necessary and at no cost to the employees, offer medical preventive measures and checks if the employees ay have been, or are in danger of being, subjected to harmful exposure to biological agents.

Further Provisions on work involving a risk of infection

Signage and marking

Section 18
Warning signs shall be put up at the entrances to facilities or working areas where infectious agents are used. Signs shall display a biohazard symbol as per AFS 1997:11 (Safety Signs and Warning Signals at Workplaces). In addition, particulars of risk group and biosafety level shall be displayed, together with the text “Smittrisk” and such other additional information as is needed. Signs referring to group 3 and 4 biological agents according to the criteria in App. 2 A shall also include information concerning access restrictions and a person to contact.

Signs as aforesaid shall also be put up at the entrances to nursing units where there are humans or animals infected or suspected of being infected by group 4 biological agents and by group 3 biological agents, if there is a risk of airborne infection or if there is otherwise a great risk of infection.

Section 19
Materials, containers and other equipment containing infectious agents shall be marked. The marking shall comply with the biohazard sign as indicated in AFS 1997:11 Safety Signs and Warning Signals at Workplaces, the text “Smittrisk” or “Smittförande” and particulars of contents, the person responsible and other information needed for the prevention of ill-health.

Marking with such particulars as are common knowledge at the place where they occur may be excluded if this can be done without any risk to health.

Packaging for the carriage of dangerous goods need not be marked as provided in subsection one if it is marked in accordance with the rules on transport of dangerous goods, class 6.2, infectious substances.

Pregnant employees

Section 20
An employee who has informed the employer that she is pregnant may not be employed on work where she risks exposure to rubella or toxoplasma, if assessment as provided in Section 2 of AFS 1994:32 Pregnant and Breast-Feeding Employees has shown exposure to entail a risk of harmful effects on the pregnancy or of other ill-health.

Registers

Section 21
The employer shall keep a register of the employees who may have been exposed to group 3 or 4 infectious agents as per the criteria in App. 2 A. The register shall indicate the type of work done and, where possible, the infectious agent to which the employee may have been exposed. A physician carrying out a medical check as provided in Section 17 shall be allowed access to the information in the register.

Health care and veterinary care

Section 22
Good health care work environment practice as per App. 3 A shall be applied in health care and nursing and also, where applicable, in veterinary medical activity.

Further measures shall be taken if the risk assessment shows them to be necessary. There shall be special routines for sampling and handling biological material from humans or animals, having regard to possible infection risks.

Section 23
In the nursing and care of humans and animals infected or suspected of being infected with group 3 or 4 infectious agents, protective measures at biosafety level 3 or 4 as per App. 3 C shall be taken to a suitable extent.

Further Provisions for laboratories and use of biological agents on animals and in large-scale processes

Protective measures and biosafety level

Section 24
General principles of good microbiological practice, as stated in App. 3 B, shall be applied to all use of biological agents.

Section 25
Protective measures shall be applied as follows in connection with activities stated in the tables of App. 3 C:

Use of biological agents in	shall occasion protective measures on at least
risk group 1	safety level 1
risk group 2	safety level 2
risk group 3	safety level 3
risk group 4	safety level 4

Section 26
Protective measures as per App. 3 V, table 1, shall be applied to a suitable extent in laboratories where material is handled which may contain infectious agents. The biosafety level shall be adapted to the risk associated with the infectious agents and to the exposure to them which is possible. At least biosafety level 2 shall be applied.

Section 27
Where there is uncertainty in the matter of biosafety level when applying Sections 25 and 26, the high level shall be chosen until it has been made clear that the lower level is sufficient. At least biosafety level 3 shall be applied if the work is judged to entail a serious risk to health.

Notification and permits

Section 28
An employer intending first-time use of risk group 2 infectious agents as per the criteria in App. 2 A shall notify the Work Environment Authority to this effect not less than 30 days before the work begins, unless the activity requires a permit under Section 29. The notice shall contain the particulars indicated in App. 4.

Significant changes which can affect the risk shall be notified to the Work Environment Authority not more than one month after being effected.

Section 29
The following activity may not be conducted without a permit from the Work Environment Authority.

1. An activity involving the use of risk group 2 infectious agents, as per the criteria in App. 2 A, with a total culture volume exceeding 500 litres.
2. An activity involving the use of risk group 3 or 4 infectious agents, as per the criteria in App. 2 A, or storage of the same.

Significant changes which can affect the risk, with regard to facilities, equipment and processes/procedures and the use of new biological agents in the activity, shall be notified the Work Environment Authority before the change is effected. If necessary for safety reasons, the measures shall instead be taken immediately. In such cases the change shall be notified without delay and on no account more than one month after being effected.

The permit may be revoked by the Work Environment Authority if necessary for safety reasons.

Liability

Section 30
The following Provisions constitute stipulations under the sections of the Work Environment Act (SFS 1977:1160) as indicated.

The Provisions	**Work Environment Act**
Section 20, pregnant employees	Chap. 4, Section 6
Section 21, registers	Chap. 4, Section 3 (1) (2)
Section 28, notification	Chap. 4, Section 8 (1)
Section 29 (1), permits	Chap. 4, Section 2
Section 29 (2), notification of changed conditions	Chap. 4, Section 8 (1)

Breaches of these Provisions are punishable with fines under Chap. 8, Section 2 (1) of the Work Environment Act.

Entry into force. Interim Provisions

These Provisions enter into force on 1st June 2005.

The Ordinances of the National Board of Occupational Safety and Health containing provisions on Hazardous Waste (AFS 1989:2) and Work Involving Infection Risks (AFS 1991:2), together with the Provisions of the National Board of Occupational Safety and Health on Biological Substances (AFS 1987:12) are repealed with effect from the same date.

Permits granted pursuant to the repealed Provisions (AFS 1987:12) on Biological Substances shall apply as permits under the Provisions (AFS 2005:1) on Microbiological Work Environment Risks. General stipulations in Provisions AFS 2005:1 shall, however, be complied with, saving where exemptions have been granted by the Work Environment Authority.

BERTIL REMAEUS

Anna Billgren Maria Hagberg Forss

Appendix 1

Risk assessment procedure under Section 4

The risk assessment involves systematically identifying risk sources and judging the likelihood of the work, and where relevant particular work operations, entailing, by reason of biological agents, a risk to health or safety, and judging the potential gravity of the consequences.

A. Risk identification

(1) Are there conditions favouring the unwanted growth of biological agents?
(2) Is the work of a kind in which ill-health or accidents connected with biological agents are a common occurrence?
(3) Do biological agents occur in large quantities, high concentrations and/or particular agents?
(4) Do certain work operations entail a greater likelihood of exposure and/or particular risks?
(5) Is there a risk of prolonged or frequent exposure in the workplace?
(6) Does ill-health which may conceivably be due to exposure to biological agents occur in the workplace?
(7) Can many employees be affected?
(8) Are there employees needing special consideration?

B. The nature of the exposure

When the nature of the exposure is going to be established, available information concerning all known or possibly occurring biological agents shall be taken into account. This includes:

(1) concerning infectious agents, as far as possible
    (a) infective dose and other factors affecting the likelihood of the agents causing infection,
    (b) infection paths
    (c) the severity of the disease,
    (d) the possibility of disease prevention,
    (e) the possibility of treatment, and
    (f) classification as per the criteria in App. 2 a,
(2) other available knowledge concerning ill-health which may be caused by biological agents occurring, including the triggering of hypersensitivity and toxigenic effects,
(3) the resistance of the biological agents occurring to dehydration, heat, disinfectants etc., and
(4) information concerning work injuries which may be connected with biological agents occurring.

C. Measurement/determination by sampling and analysis

Where necessary and technically possible, measurement/determination shall be conducted by means of sampling and analysis of biological agents to

establish the nature and degree of exposure. In the event of measurement/determination, it shall be ensured:

(1) that the party planning and conducting sampling and analysis of biological agents has sufficient knowledge for the purpose,
(2) that the purpose of sampling and analysis, including the use to be made of the results, has been ascertained,
(3) that sampling is planned in association with the employer and safety delegate, or, failing a safety delegate, the employees affected,
(4) that the sampling is representative of normal conditions and/or particular situations,
(5) that sampling and analysis are performed using a method and equipment appropriate to the purpose, and
(6) that sampling and analysis are documented in such a way as to facilitate replication and comparison with other measurements/determinations.

Appendix 2 A

A. Criteria for the classification of biological agents

The classification refers to the capacity of biological agents for causing infection and the potential gravity of the consequences. When biological agents are placed in a risk group, the likelihood of a person suffering infection after exposure is balanced against the severity of the diseases which the infection can lead to and the possibility of preventing and/or curing the disease. Where there is uncertainty regarding the infectiousness or severity of the disease, the higher risk group shall be chosen until it is ascertained that the risk justifies placement in a lower risk group.

App. 2 B contains a list of biological agents in risk groups 2, 3 and 4. The list is not exhaustive and there are variations between different strains, and so classification in the individual case is always decided by the criteria in App. 2 A.

Risk group 1

Risk group 1 contains biological agents which do not normally cause infections in humans, together with non-pathogenic strains of pathogenic biological agents. Risk group 1 also includes biological agents which do not cause infection but can cause other ill-health, such as hypersensitivity or toxigenicity, which is not connected with infections.

Risk group 2

Risk group 2 contains biological agents which can cause infections capable of giving rise to diseases of varying severity for which prophylaxis or treatment is available or which normally self-heal without any serious after-effects. Risk group 2 includes viruses which have been isolated from humans and do not come in a higher risk group. It also includes biological agents which are suspected of being able to cause cancer in humans but where the likelihood of exposure leading to cancer is very small, e.g. because a combination of many different factors is needed.

Risk group 3

Risk group 3 includes infectious agents, exposure to which is liable to have serious consequences, e.g. a severe disease for which the possibilities of prophylaxis and treatment are limited or which is highly infectious. Biological agents which can cause cancer and exposure to which is very likely to cause cancer in humans are placed in group 3.

Risk group 4

Risk group 4 includes infectious agents, exposure to which is liable to have very serious consequences. This can mean a combination of severe, possibly

fatal disease with little or no possibility of prophylaxis or treatment, a risk of spreading to the community and a high level of infectiousness. A biological agent capable of causing cancer in humans without the presence of additional factors is placed in risk group 4.

Appendix 2 B

B. List of certain infectious agents in risk groups 2, 3 and 4

This list of infectious agents is based on EC Directive 2000/54/EC. It is not exhaustive and there are variations between different strains. Accordingly, classification in the individual case will always hinge on the criteria stated in App. 2 A.

Under Section 3, biological agents capable of causing infections in humans are defined as infectious agents. These are classified as risk group 2, 3 or 4 in accordance with the criteria stated in App. 2 A.

Biological agents not normally causing infections in humans are placed in risk group 1 and are not listed here. They can, on the other hand, cause other kinds of ill-health such as hypersensitivity or toxigenicity. The classification in this list, therefore, does not provide a definitive rating of ill-health inducible by biological agents.

Biological agents not included in the list are not necessarily included in risk group 1. Normally all viruses which have been isolated from humans are placed, at the lowest, in risk group 2, except where there is evidence of their being unlikely to cause disease in humans.

Only biological agents known to cause infection in humans are included in the list. Animal pathogens which also cause infections in humans (zoonoses) are classified according to their effect on humans.

The classifications in the list refer to original forms. If the properties of a biological agent have been permanently changed by natural means, by genetic technology or by other means, a new risk assessment is performed and comparison made with the criteria in App. 2 A.

In the case of infectious agents where more than one species is known for causing disease in humans, the list includes the species which experience has shown to be capable of causing infections. This does not preclude the possibility of disease also being caused by other species belonging to the same family.

When a whole family is listed, this does not include the species and strains known to be incapable of causing infections.

The list also indicates certain properties of particular importance. These are coded as follows:
A. Allergic effects.
D. Long-term effects, e.g. long incubation time or latent infections.
T: Toxin production.
V : Effective vaccine available.
R : Harmful to reproduction, as indicated in Section 20.

Note that these additional designations are not exhaustive. There are many biological agents with known toxin production or possible harmful effects on reproduction which are not marked T or R in the list. Allergic reactions can occur in sensitised persons following inhalation of virtually any kind of micro-fungus and bacteria. The availability of effective vaccine cannot be altered. The protective measures to be taken must always be decided according to the state of science and assessment of risk in the workplace.

Bacteria *Read the introduction on pp. 20-21*

Biological agent	Classification			Notes
	2	3	4	
Actinobacillus actinomycetemcomitans	2			
Actinomadura madurae	2			
Actinomadura pelletieri	2			
Actinomyces gerencseriae	2			
Actinomyces israelii	2			
Actinomyces pyogenes	2			
Actinomyces spp.	2			
Arcanobacterium haemolyticum (Corynebacterium haemolyticum)	2			
Bacillus anthracis		3		
Bacteroides fragilis	2			
Bartonella bacilliformis	2			
Bartonella quintana (Rochalimaea quintana)	2			
Bartonella (Rochalimea)spp.	2			
Bordetella bronchiseptica	2			
Bordetella parapertussis	2			
Bordetella pertussis	2			V
Borrelia burgdorferi	2			
Borrelia duttonii	2			
Borrelia recurrentis	2			
Borrelia spp.	2			
Brucella abortus		3		
Brucella canis		3		
Brucella melitensis		3		
Brucella suis		3		
Burkholderia mallei (Pseudomonas mallei)		3		
Burkholderia pseudomallei (Psedumonas pseudomallei)		3		
Campylobacter fetus	2			
Campylobacter jejuni	2			
Campylobacter spp.	2			
Cardiobacterium hominis	2			
Chlamydia pneumoniae	2			
Chlamydia trachomatis	2			
Chlamydia psittaci (avian strains)		3		
Chlamydia psittaci (other strains)	2			
Clostridium botulinum	2			T
Clostridium perfringens	2			
Clostridium tetani	2			T, V
Clostridium spp.	2			
Corynebacterium diphtheriace	2			T, V
Corynebacterium minutissimum	2			

Read the introduction on pp. 20-21

Biological agent	Classification			Notes
	2	3	4	
Corynebacterium pseudotuberculosis	2			
Corynebacterium spp.	2			
Coxiella burnetii		3		
Edwardsiella tarda	2			
Ehrlichia sennetsu (Rickettsia sennetsu)	2			
Ehrlichia spp.	2			
Eikenella corrodens	2			
Enterobacter aerogenes/cloacae	2			
Enteropbacter spp.	2			
Enterococcus spp.	2			
Erysipelothrix rhusiopathiae	2			
Escherichia coli (with the exception of non-pathogenic strains)	2			
Escherichia coli, verocytotoxigenic strains (e.g. O157:H7 or O103)		3(**)		T
Flavobacterium meningosepticum	2			
Fluoribacter bozemanae (Legionella)	2			
Francisella tularensis (Type A)		3		
Francisella turalensis (Type B) (a)	2			
Fusobacterium necrophorum	2			
Gardnerella vaginalis	2			
Haemophilus ducreyi	2			
Haemophilus influenzae	2			
Haemophilus spp.	2			
Helicobacter pylori	2			
Klebsiella oxytoca	2			
Klebsiella pneumoniae	2			
Klebsiella spp.	2			
Legionella pneumophila	2			
Legionella spp.	2			
Leptospira interrogans (all serovars)	2			V
Listeria ivanovii	2			
Listeria monocytogenes	2			
Morganella morganii	2			V
Mycobacterium africanum		3		
Mycobacterium avium/intracellulare	2			
Mycobacterium bovis (except BCG strain)		3		
Mycobacterium chelonae	2			
Mycobacterium fortuitum	2			
Mycobacterium kansasii	2			
Mycobacterium leprae		3		
Mycobacterium malmoense	2			

(**) Certain protective measures at biosafety level 3 as per App. C can be dispensed with by permission of the Work Environment Authority.
(a) Classified in risk group 3 pending confirmation of a lower classification by typing.

Read the introduction on pp. 20-21

Biological agent	Classification			Notes
	2	3	4	
Mycobacterium marinum	2			
Mycobacterium microti		3(**)		
Mycobacterium paratuberculosis				
Mycobacterium scrofulaceum	2			
Mycobacterium simiae	2			
Mycobacterium szulgai	2			
Mycobacterium tuberculosis		3		V
Mycobacterium ulcerans		3(**)		
Mycobacterium xenopi	2			
Mycoplasna caviae	2			
Mycoplasma hominis	2			
Mycoplasma pneumoniae	2			
Neisseria gonorrhoeae	2			V
Neisseria meningtidis	2			
Nocardia asteroides	2			
Nocardia brasiliensis	2			
Nocardia farcinica	2			
Nocardia nova	2			
Nocardia otitidiscaviarum	2			
Pasteurella multocida	2			
Pasteurella spp.	2			
Peptostreptococcus anareobius	2			
Plesiomonas shigelloides	2			
Porphyromonas spp.	2			
Prevotella spp.	2			
Porteus mirabilis	2			
Proteus penneri	2			
Proteus vulgaris	2			
Providencia alcalifaciens	2			
Providencia rettgeri	2			
Providencia spp.	2			
Pseudomonas aeruginosa	2			
Pseudomonas mallei and pseudomallei (see Burkolderia)				
Rhodococcus equi	2			
Rickettsia akari		3(**)		
Rickettsia canada		3(**)		
Rickettsia conorii		3		
Rickettsia montana		3(**)		
Ricettsia typhi (Rickettsia mooseri)		3		
Rickettsia prowazekii		3		
Rickettsia tsutsugamushi		3		

(**) Certain protective measures at biosafety level 3 as per App. C can be dispensed with by permission of the Work Environment Authority.

Read the introduction on pp. 20-21

Biological agent	Classification			Notes
	2	3	4	
Rickettsia spp.	2			
Rochalimaea quintana (see Bartonella)	2			
Salmonella arizonae	2			
Salmonella enteritidis	2			
Salmonella typhimurium	2			
Salmonella paratyphi A, B, C	2			V
Salmonella typhi		3(**)		V
Salmonella (other serovars)	2			
Serpulina spp.	2			
Shigella bodyii	2			
Shigella dysenteriae (Type 1)		3(**)		T
Shigella dysenteriae (other than Type 1)	2			
Shigella flexneri	2			
Shigella sonnei	2			
Staphylococcus aureus	2			
Streptobacillus moniliformis	2			
Streptococcus pneumoniae	2			
Streptococcus pyogenes	2			
Streptococcus suis	2			
Streptococcus spp.	2			
Treponema carateum	2			
Treponema pallidum	2			
Treponema pertenue	2			
Treponema spp.	2			
Vibrio cholerae (including El Tor)	2			
Vibrio parahaemolyticus	2			
Vibrio spp.	2			
Yersinia enterocolitica	2	3		V
Yersinia pestis				
Yersinia pseudotuberculosis	2			
Yersinia spp.	2			

(**) Certain protective measures at biosafety level 3 as per App. C can be dispensed with by permission of the Work Environment Authority.

Biological agent	Classification			Notes
	2	3	4	
Adenoviridae	2			
Arenaviridae				
LCM-Lassafeberviruskomplex				
(Old world arenaviruses):				
Lassafevervirus			4	
Lymphocyctyc choriomeningitis virus (neurotropic strains)		3		
Lymphocyctic choriomeningitis virus (other strains)	2			
Mopeiavirus	2			
Andra LCM-Lassafeberviruskomplex	2			
Tacaribeviruskomplex				
(New world arenaviruses):				
Guanaritovirus			4	
Juninvirus			4	
Sabiavirus			4	
Mchupovirus			4	
Flexalvirus				
Andra tacaribeviruskomplex	2			
Astroviridae	2			
Bunyaviridae				
Bunyamweravirus	2			
Oropouchevirus		3		
California encephalitis virus	2			
Germiston	2			
Sin Nombre (formerly Muerto Canyon)				
Belgrad (also known as Dobrava)				
Bhanja	2			
Hantaviruses:				
Hantaan (Korean haemorrhagic fever)		3		
Seoul virus		3		
Puumalavirus	2			
Prospect Hill virus	2			
Other hantaviruses	2			
Nairoviruses:				
Crimean-Congo haemorrhagic fever			4	
Hazaravirus	2			
Phleboviruses:				
Rift Valley fever		3		V
Sandfly fever	2			
Toscanavirus	2			
Other *bunyaviridae* known to be pathogenic	2			
Caliciviridae				
Norwalk virus	2			
other *Caliciviridae*	2			

Read the introduction on pp. 20-21

Biological agent	Classification			Notes
	2	3	4	
Hepatit E-virus		3(**)		
Coronaviridae				
SARS virus		3		
Other *coronaviridae*	2			
Filoviridae				
Ebola virus			4	
Marburg virus			4	
Flaviviridae				
Australia encephalitis (Murray Valley encephalitis)		3		
Central European tick-borne encephalitis virus (TBE) (b)		3		V
Absettarov		3		
Hanzalova		3		
Hypr		3		
Kumlinge		3		
Dengue virus type 1-4		3		
Hepatitis C-virus		3(**)		D
Hepatitis G-virus		3(**)		D
Japanese B encephalitis		3		V
Kyasanur Forest		3		
Louping ill		3(**)		
Omsk		3		V
Powassan		3(*)		
Rocio		3		
Russian spring-summer encephalitis (TBE) (b)		3		
St. Louis encephalitis		3		
Wesselsbron virus		3		
West Nile fever virus		3		V
Yellow fever		3		
Other flaviviruses known to be pathogenic	2			
Hepadnaviridae				
Hepatitis B virus		3(**)		V, D
Hepatitis D virus (Delta) (c)		3(**)		V, D
Herpesviridae				
Cytomegalovirus (CMV)	2			
Epstein-Barr virus (EBV)	2			
Herpesvirus simiae (B virus)		3		
Herpes simplex virus types 1 and 2	2			
Herpesvirus varicella-zoster	2			

(**) Certain protective measures at biosafety level 3 as per App. C can be dispensed with by permission of the Work Environment Authority.
(b) Tick-borne encephalitis.
(c) Hepatitis D virus is pathogenic in workers only in the presence of simultaneous or secondary infection caused by hepatitis B virus. Vacicnation against hepatitis B virus will therefore protect workers who are not already affected by hepatitis B virus against hepatitis D virus (Delta).

Read the introduction on pp. 20-21

Biological agent	Classification			Notes
	2	3	4	
Human B-lymphotropic virus (HBLV-HHV6)	2			
Humant herpesvirus 7	2			
Humant herpesvirus 8	2			D
Orthomyxoviridae				
Influensavirus typ A, B och C	2			V (d)
Tick-borne *orthomyxoviridae:*				
Dhori and Thogoto viruses	2			
Papovaviridae				
BK and JC viruses	2			D
Human papillomaviruses	2			D
Paramyxoviridae				
Measles virus	2			
Mumps virus	2			
Newcastle disease virus	2			
Parainfluenza viruses types 1 to 4	2			
Respiratory syncytial virus	2			
Parvoviridae				
Human parvovirus (B 19)	2			
Picornaviridae				
Acute haemorrhagic conjunctivitis virus (AHC)	2			
Coxsackie viruses	2			
Echo viruses	2			
Heptaitis A virus (human enterovirus type 72)	2			V
Polioviruses	2			V
Rhinoviruses	2			
Poxviridae				
Buffalopox virus (e)	2			
Cowpox virus	2			
Elephantpox virus (f)	2			
Milkers' node virus	2		4	
Molluscum contagiosum virus	2		4	
Monkeypox virus		3		V
Orf virus	2			
Rabbitpox virus (g)	2			
Vaccinia virus	2		4	V
Variola (major minor) virus			4	V
Whitepox virus ("Variola virus")			4	
Yatapox virus (Tana & Yaba)	2			

(d) Only for types A and B.
(e) Two viruses are identified: one a buffalopox type and the other a variant of the Vaccinia virus.
(f) Variant of cowpox virus
(g) Variant of vaccinia.

Biological agent	Classification			Notes
	2	3	4	
Reoviridae				
Coltivirus	2			
Human rotaviruses	2			
Orbiviruses	2			
Reoviruses	2			
Retroviridae (h)				
Human immunodeficiency viruses (HIV)		3(**)		D
Human T-cell lymphotropic viruses virus (HTLV) types 1 and 2		3(**)		D
Simian immunodifiviency virus (SIV) (h)		3(**)		
Rhabdoviridae				
Rabies virus		3(*)		V
Visicular stomatitis virus	2			
Togaviridae				
Alfaviruses:				
Eastern equine encephalomyelitis		3		V
Bebaru virus	2			
Chikungunya virus		3(**)		
Everglades virus		3(**)		
Mayaro virus		3		
Mucambo virus		3(**)		
Ndumu virus		3		
O'nyong-nyong virus	2			
Ross River virus	2			
Semliki Forest virus	2			
Sindbis virus	2			
Tonate virus		3(**)		
Venezuelan equine encephalomyelitis		3		V
Western equine encephalomyelitis		3		V
Other known alphaviruses	2			
Rubivirus (rubella)	2			V, R
Toroviridae	2			
Unclassified viruses:				
Hepatitviruses not yet identified		3(**)		D
Equine morbillivirus			4	

(**) Certain protective measures at biosafety level 3 as per App. C can be dispensed with by permission of the Work Environment Authority.
(h) At present there is no evidence of disease in humans caused by retroviruses of simian origin. As a precaution containment level 3 is recommended for work with them.

Read the introduction on pp. 20-21

Biological agent	Classification			Notes
	2	3	4	
Prions				
Unconventional agents associated with the transmissible spongiform encephalopathies (TSE)				
Creutzfeldt-Jakob disease		3(**)		D
Variant Creutzfeldt-Jakob disaese		3(**)		D
Bovin spongiform encephalopathy BSE) and Other related animal TSEs (i)		3(**)		D
Gerstmann-Sträussler-Scheinker syndrome		3		D
Kuru		3		D

(**) Certain protective measures at biosafety level 3 as per App. C can be dispensed with by permission of the Work Environment Authority.
(i) In the case of laboratory work involving an identified scrapie agent, Biosafety level 2 may be applied without a permit from the Work Environment Authority.

Parasites *Read the introduction on pp. 20-21*

Biological agent	Classification			Notes
	2	3	4	
Acanthamoeba castellani	2			
Ancylostoma duodenale	2			
Angiostrongylus cantonensis	2			
Angiostrongylus costaricensis	2			
Ascaris lumbricoides	2			A
Ascaris suum	2			A
Babesia divergens	2			
Babesia microti	2			
Balantidium coli	2			
Brugia malayi	2			
Brugia pahangi	2			
Capillaria philippinensis	2			
Capillaria spp.	2			
Clonorchis sinensis	2			
Clonorchis viverrini	2			
Cryptosporidium parvum	2			
Cryptosporidium spp.	2			
Dipetalonema streptocerca	2			
Diphyllobothrium latum	2			
Dracunculus medinensis	2			
Echinococcus granulosus		3(**)		
Echinococcus multilocularis		3(**)		
Echinococcus vogeli		3(**)		
Entamoeba histolytica	2			
Fasciola gigantica	2			
Fasciola hepatica	2			
Fasciolopsis buski	2			
Giardia lamblia (Giardia intestinalis)	2			
Hymenolepis diminuta	2			
Hymenolepis nana	2			
Leishmania brasiliensis		3(**)		
Leishmania donovani		3(**)		
Leishmania ethiopica	2			
Leishmania mexicana	2			
Leishmania peruviana	2			
Leishmania tropica	2			
Leishmania major	2			
Leishmania spp.	2			
Loa loa	2			
Mansonella ozzardi	2			

(**) Certain protective measures at biosafety level 3 as per App. C can be dispensed with by permission of the Work Environment Authority.

Read the introduction on pp. 20-21

Biological agent	Classification			Notes
	2	3	4	
Mansonella perstans	2			
Naegleria fowleri		3		
Necator americanus	2			
Onchocerca volvulus	2			
Opisthorchis felineus	2			
Opisthorchis spp.	2			
Paragonimus westermani	2			
Plasmodium falciparum		3(**)		
Plasmodium spp. (human and simian)	2			
Sarcocystis suihominis	2			
Schistosoma haematobium	2			
Schistosoma intercalatum	2			
Schistosoma japonicum	2			
Schistosoma mansoni	2			
Schistosoma mekongi	2			
Strongyloides stercoralis	2			
Strongyloides spp.	2			
Taeinia saginata	2			
Taeinia solium		3(**)		
Toxocara canis	2			
Toxoplasma gondii	2			R
Trichinella spiralis	2			
Trichuris trichiura	2			
Trypanosoma brucei brucei	2			
Trypanosoma brucei gambiense	2			
Trypanosoma brucei rhodesiense		3(**)		
Trypanosoma cruzi		3		
Wuchereria bancrofti	2			

(**) Certain protective measures at biosafety level 3 as per App. C can be dispensed with by permission of the Work Environment Authority.

Fungi *Read the introduction on pp. 20-21*

Biological agent	Classification			Notes
	2	3	4	
Aspergillus fumigatus	2			A
Blastomyces dermatitidis (*Ajellomyces dermatitidis*)		3		
Candida albicans	2			A
Candida tropicalis	2			
Cladophialophora bantiana (*tidigare: Xylohypha bantiana, Cladosporium bantianum* eller *trichoides*		3		
Coccidioides immitis		3		A
Cryptococcus neoformans var. *neoformans* (*Filobacidiella neoformans* var. *neoformans*)	2			A
Cryptococcus neoformans var. *gattii* (*Filobasidiella bacillispora*)	2			A
Emmonsia parva var. *Parva*	2			
Emmonsia parva var. *crescens*	2			
Epidermophyton floccosum	2			A
Fonsecaea compacta	2			
Fonsecaea pedrosoi	2			
Histoplasma capsulatum var. *capsulatum* (*Ajellomyces capsuulatus*)		3		
Histoplasma capsulatum duboisii		3		
Madurella grisea	2			
Madurella mycetomatis	2			A
Microsporum spp.	2			
Neoteostudina rosatii	2			
Paracoccidioides brasiliensis		3		
Penicillium marneffei	2			A
Scedosporium apiospermum (*Pseudallescheria bodyii*)	2			
Scedosporium prolificans (inflatum)	2			
Sporothrix schenckii	2			
Trichophyton rubrum	2			
Trichophyton spp.	2			

Appendix 3 A

A. Good health care work environment practice as per Section 22.

- observe cleanliness and tidiness.
- avoid rings, bracelets, untied hair and other things which can impede good hygiene and contribute to the spread of infection
- wear gloves whenever there is a risk of contact with body fluids
- use protective clothing for nursing and caring work in close contact with people and, for veterinary activity, in close contact with animals
- if necessary, use a visor or suchlike if there is a risk of body fluids splashing
- use a respiratory protective device if there is a risk of serious airborne infection
- disinfect, and if necessary wash, the hands after dirty work, when work is finished and after using gloves
- use the technical devices needed for the avoidance of infection
- handle syringes and sharp objects which have been in contact with body fluids in a safe manner and transfer them immediately to containers intended for infectious waste/sharps without recapping syringe needles and
- have routines for dealing with unwanted events

Appendix 3 B

B. Good microbiological practice as per Section 24.

- observe cleanliness and tidiness,
- avoid rings, bracelets, untied hair and other things which can impede good hygiene and contribute to the spread of infection,
- not eating, drinking, applying cosmetics, using tobacco products or handling foodstuffs within the working area,
- not pipetting by mouth or otherwise working in such a way that biological agensts are liable to enter the mouth,
- avoid formation and spread of aerosols, spillage and spatter,
- as far as possible avoid using syringes and sharp objects,
- handle syringes and sharp objects which have been in contact with infectious agents in a safe manner and transfer them immediately to containers intended for infectious waste/sharps without recapping syringe needles,
- handle cultures in closed vessels or in som other way to prevent them from spreading,
- use protective clothing in but not outside the working area
- wash and/or disinfect the hands after dirty work, when work is finished and after using gloves
- have routines for dealing with unwanted events

Appendix 3 C Table 1

C. Protective measures when using biological agents at different biosafety levels as per Sections 25 and 26

Table 1
Protective measures when using biological agents in laboratory and animal activities

Facilities and equipment	Containment level 1	Containment level 2	Containment level 3	Containment level 4
1. Isolation	No	Segregated from other activities	Yes	Yes, in separate building or as a completely isolated unit in a building for other activities
2. Entry to lab by airlock only	No	No	Yes, in the event of airborne infection or otherwise, subject to risk assessment	Yes
3. Biohazard sign with additional information according to section 18	No	Yes	Yes	Yes
4. Separate ventilation system with HEPA filtration of extract air	No	No	Yes, in the event of airborne infection or otherwise, subject to risk assessment	Yes, and also HEPA filtration of input air. For virus not trapped by HEPA filter, additional air handling measures etc.
5. The laboratory has negative pressure relative to the pressure of the immediate environment	No	No	Yes, in the event of airborne infection or otherwise, subject to risk assessment	Yes
6. The laboratory is sealable for decontaminatio n through fumigation	No	Subject to risk assessment	Yes, in the event of airborne infection or otherwise, subject to risk assessment	Yes

Facilities and equipment	Containment level 1	Containment level 2	Containment level 3	Containment level 4
7. Hand-washing facilities provided	Yes	Yes, preferably with hands- free control and hand disinfection	Yes, with hands-free control and hand disinfection	Not relevant, since total physical isolation is applied
8. Shower directly adjoining lab	No	No	Subject to risk assessment	Yes
9. Surfaces resistant to water, acids, alkalis, solvents and disinfectants and easy to clean	Yes (bench)	Yes (bench, floor)	Yes (bench, floor)	Yes (bench, floor, ceiling, walls)
10. Facility equipped for disinfection of effluent from hand-washing sink, showers and drains	No	No	If there is a risk of infections substances escaping into the drainage system	Yes
11. Observation window or the equivalent provided so that occupants can be seen.	Subject to risk assessment	Subject to risk assessment	Yes	Yes
12. Autoclave provided	Subject to risk assessment	Yes, adjoining the activity	Yes, inside the controlled area, possibly double ended	Yes, inside the controlled area, double ended
13. Laboratory's own equipment inside the controlled area	No	Subject to risk assessment	Yes	Yes
14.Functionally checked microbiological safety cabinet with HEPA filter or corresponding enclosure provided within the working area	No	Yes, for handling infected material if there is a risk of aerosol generation or otherwise subject to risk assessment	Yes, safety cabinet class I or II for handling infected material material if there is a risk of aerosol generation or otherwise subject to risk assessment	Yes, safety cabinet class III if there is no other solution available for achieving total containment

Facilities and equipment	**Containment level 1**	**Containment level 2**	**Containment level 3**	**Containment level 4**
15. Alarm system provided to indicate whether technical safety equipments are out of order	No	Yes, for safety cabinet and otherwise subject to risk assessment	Yes	Yes
16. Reserve power supply provided for technical safety equipments in the laboratory	No	No	Subject to risk assessment	Yes
17. Effective pest control (e.g. for rodents and insects)	Subject to risk assessment	Yes	Yes	Yes
Working routines and organisation	**Containment level 1**	**Containment level 2**	**Containment level 3**	**Containment level 4**
18. Restricted access	No	Yes, access only for persons informed of the risks	Strict, access only for authorised personnel. Locking routines	Strict, access only for authorised personnel. Locking routines
19. Protective clothing used within the working area and removed when leaving it	Generally	Suitable protective clothing	Full protective clothing, change of footwear and use of shower when necessary	Complete change of protective clothing and footwear, shower before exit
20. Gloves are worn for manual handling of biological agents	No	Subject to risk assessment	Yes	Yes
21. Secure storage of biological agents	Subject to risk assessment	So that no-one is in-advertently exposed and no un-authorised person can gain access to the material	So that no-one is inadvertently exposed and no unauthorised person can gain access to the material. Storage primarily in the controlled area.	So that no-one is inadvertently exposed and no unauthorised person can gain access to the material. Storage in the controlled area.

Facilities and equipment	Containment level 1	Containment level 2	Containment level 3	Containment level 4
22. Routines exist for the prevention of exposure and for dealing with unwanted events	Yes, Subject to risk assessmens	Yes, including written instructions	Yes, including written instructions	Yes, including written instructions
23. Specific measures to control aerosol dissemination	Yes, subject to risk assessment	Yes, minimised	Yes, prevented	Yes, prevented
24. Used material containing biological agenst is decontaminated before being washed, re-used, discarded (waste included)	Subject to risk assessment	Yes	Yes, before leaving the laboratory	Yes, before leaving the laboratory
25. Routines exist for for solitary work	Subject to risk assessment	Yes, design according to risk assessment	Yes, if solitary work is permitted there must be strict routines for rapid relief when needed	Solitary work is not permitted
26. Isolator or other HEPA-filtered containment provided	No	Optional, subject to risk assessment	For airborne infection or otherwise subject to risk assessment	Yes
27. Animal facilities are segregated with restricted access	Optional, subject to risk assessment	Yes	Yes	Yes
28. Measures taken to limit the possibility of the animals escaping from the controlled area	Yes	Yes	Yes	Yes
29. Material and equipment designed for easy cleaning and decontaminatio n	Subject to risk assessment	Yes	Yes	Yes

Facilities and equipment	Containment level 1	Containment level 2	Containment level 3	Containment level 4
30. Surfaces easy to clean, over and above the requirements of item 9	Subject to risk assessment	None above the requirements of item 9	Walls	None above the requirements of item 9
31. Incineration of animal cadavers	Recom-mended	Yes	Yes	Yes, on the spot if sterilisation by a validated method has not preceded transfer to an incineration furnace.
32. Disposable clothing used, unless the animals are isolated, for example in an isolator. Changed every time.	No	Subject to risk assessment	Yes	Yes, complete change
33. Bedding and waste decontaminated	Subject to risk assessment	Yes	Yes	Yes

Table 2

Containment and other protective measures for use of biological agents in large-scale processes

Facilities and equipment	Containment levels			
	Containment level 1	**Containment level 2**	**Containment level 3**	**Containment level 4**
34. Viable organisms handled in a system which separates the process from the environment (closed system)	Subject to risk assessment	Yes	Yes	Yes
35. Access to the controlled area through airlock only	No	Subject to risk assessment	Yes	Yes
36. The controlled area has specific ventilation to minimise air contamination.	Subject to risk assessment	Subject to risk assessment	Subject to risk assessment	Yes
37. Extract and input air from the controlled area HEPA-filtered	No	Subject to risk assessment	Yes, for extract air, subject to risk assessment for input air	Yes
38. The controlled area maintained at an air pressure negative to the immediate surroundings	No	Subject to risk assessment	Subject to risk assessment	Yes
39. The controlled area sealable to permit fumigation	No	Subject to risk assessment	Subject to risk assessment	Yes
40. Surfaces resistant to water, acids, alkalies, solvents and disinfectants and easy to clean	Yes, bench if any	Yes, bench, if any, and floor	Yes, bench, if any, and floor	Yes, bench, floor, ceiling and walls

Facilities and equipment	**Containment levels**			
	Containment level 1	**Containment level 2**	**Containment level 3**	**Containment level 4**
41. The controlled area is designed so that spillage and the entire contents of the closed system can be contained and decontaminated in the event of an accident	Subject to risk assessment	Yes	Yes	Yes
42. Exhaust gas from closed systems is handled in such a way that emissions:	Do not harm health	Are minimised	Are prevented	Are prevented
43. Seals are designed so that release:	Does not harm	Is minimised	Is prevented	Is prevented
44. Alarm system provided to indicate whether technical safety equipments are out of order	No	Yes	Yes	Yes
45. Reserve power supply provided for technical safety equipments on the premises	No	Subject to risk assessment	Yes	Yes
46. Biohazard sign posted	No	Yes	Yes	Yes
47. Hand-washing facilities provided	Yes	Yes, preferably with hands- free control and hand disinfection	Yes, preferably with hands-free control and hand disinfection	Yes, with hands-free control and hand disinfection
48. Shower provided within the controlled area	No	No	Subject to risk assessment	Yes

Facilities and equipment	**Containment levels**			
	Containment level 1	**Containment level 2**	**Containment level 3**	**Containment level 4**
49. Restricted access	No	Yes, access only for authorised personnel.	Strict, access only for authorised personnel. Locking routines	Strict, access only for authorised personnel. Locking routines
50. Special protective clothing used	Yes	Yes	Yes	Yes, complete change
51. Personnel use shower before exit from the controlled area	No	No	authorised personnel.	Yes
52. Decontamination of biological agents in contaminated material and waste including those in process effluent and waste before final discharge	Subject to risk assessment	Yes, decontamin-ation by validated inactivation methods	Yes, decontamin-ation by validated inactivation methods	Yes, decontamin-ation by validated inactivation methods
53. Sample collection, addition of material to a closed system and transfer of viable organisms to another closed system are performed in such a way that release:	Does not cause harm to health	Is minimised	Is prevented	Is prevented
54. Decontamination of bulk culture fluids before removal from the closed system for further handling	Subject to risk assessment	Yes, decontam-ination by validated inactivation methods	Yes, decontamin-ation by validated inactivation methods	Yes, decontamin-ation by validated inactivation methods

Facilities and equipment	**Containment levels**			
	Containment level 1	**Containment level 2**	**Containment level 3**	**Containment level 4**
55. Effluence from hand-washing sinks, showers etc collected and inactivated before being released.	No	No	If there is a risk that infectious agents can be released to the sewer	Yes
56. Subject to risk assessment	Subject to risk assessment	Yes, if solitary work is permitted there must be strict routines for rapid relief when needed	Solitary work is not permitted	Solitary work is not permitted

Appendix 4

Information to accompany notification under Section 28

1. The employer's name and corporate registration number.

2. The name and address of the workplace.

3. The name of the person or persons allotted tasks relating to health and safety in the workplace, and particulars of their capabilities relevant to the task. Availability of advisory competence for risk assessment.

4. Description of the nature of the activity. General particulars of the infectious agents which will be used, of the maximum volume to be handled and of handling procedures.

5. Risk assessment documentation as per Sections 4-5.

6. Description of facilities and technical devices material to safety, together with protective measures and other preventive measures planned.

7. Programme of medical preventive measures and controls.

8. The number of persons to be employed in the activity.

Appendix 5

Information to accompany notification under Section 29

1. The employer's name and corporate registration number.

2. The name and address of the workplace.

3. The name of the person or persons allotted tasks relating to health and safety in the workplace, and particulars of their capabilities relevant to the task. Availability of advisory competence for risk assessment.

4. Description of the nature of the activity. General particulars of the infectious agents which will be used, of the maximum volume to be handled and of handling procedures.

5. Risk assessment documentation as per Sections 4-5.

6. Handling and safety instructions drawn up for the work, including measures to be taken in the event of unwanted events.

7. Description of facilities and technical devices material to safety, together with protective measures and other preventive measures planned.

8. Description of technical controls, planned and accomplished, material to safety.

9. Programme of medical preventive measures and controls.

10. The number of persons to be employed in the activity.

11. The time for which a permit is requested.

12. A statement by the safety delegate(s) representing the employees who are to take part in the work.

13. Where relevant, the following particulars of a contingency plan as provided in Section 16:
    (a) Risk sources and circumstances in which events are liable to occur which can result in risk group 3 or 4 infectious agents causing serious or extensive harm.
    (b) Conceivable consequences for human health.
    (c) The preventive measures applied, e.g. protective equipment, alarm systems and an evacuation plan.
    (d) A description of the contingency preparedness information given to the employees.
    (e) An assurance that the competent authorities charged with rescue measures have been informed of the contingency plan.

A permit renewal application shall also be accompanied by an account of compliance with the conditions attaching to the permit granted previously.

General Recommendations of the Work Environment Authority on the implementation of the Provisions on Microbiological Work Environment Risks

The following General Recommendations are issued by the Swedish Work Environment Authority on the implementation of the Provisions (AFS 2005:1) on Microbiological Work Environment Risks

Background

General recommendations have a different legal status from Provisions. They are not mandatory. Instead they serve to elucidate the meaning of the Provisions, e.g. by explaining suitable ways of meeting the requirements, by instancing practical solutions and procedures, and by furnishing recommendations, background information and references. The Work Environment Authority and other agencies can also issue other material for the guidance of those tasked with assessing risks and choosing measures of compliance with the Provisions.

Council Directive 2000/54/EC is an amalgamation of Directive 90/679/EEC on the protection of workers from risks related to exposure to biological agents at work and the Directives amending it through Directives 93/88/EEC, 95/30/EC, 97/59/EC and 97/65/EC.

Examples of ill-health

Biological agents can cause various kinds of ill-health. Hypersensitivity and toxigenicity can be caused by both living and dead organisms and substances produced by them, while infection normally requires viable organisms. See the definition of biological agents in Section 3 and guidance on the same. Some examples of ill-health will now be given.

Hypersensitivity

Allergy and other hypersensitivity mean a person reacting to exposure which usually causes no discomfort. Allergy is a type of hypersensitivity which, following repeated exposure, is transmitted by reactions in the body’s immune system. Unlike the usual course of infections, the activities of the immune system do not lead to recovery but instead give rise to symptoms of illness, such as snuffles and rhinitis, asthma and eczema. Allergy and other hypersensitivity develop more rapidly and easily in connection with high and/or prolonged exposure, but can occasionally occur even at a very low level of exposure.

Sensitisation can result from repeated exposure to an allergenic substance and implies a permanent change in the immune defence, leading to allergy. Once sensitisation has occurred, it generally takes very little renewed exposure indeed to provoke a hypersensitivity reaction.

The quantity of biological agents in the inspiratory air makes an important difference to the development of hypersensitivity. Fungal spores are one example of biological agents which spread easily by air.

The boundary between hypersensitivity and toxigenicity is not always self-evident. Inhalation of large quantities of organic dust, e.g. with high concentrations of mould fungus or bacteria, can trigger an acute reaction in the form of an inflammatory reaction in the lungs (known as ODTS, Organic Dust Toxic Syndrome), the symptoms of which are fever and a feeling of illness, often combined with couching and pain in the joints and muscles. The discomfort mostly subsidies relatively quickly if the exposure was temporary, but repeated exposure can lead to chronic disorders including severe coughing and dyspnoea.

Toxigenicity
Toxins – harmful substances or "poisons" – produced by certain biological agents can contribute towards the harmful effects of infections but can also be a direct cause of ill-health, without any living organisms having to invade the body. Toxins can be formed by biological agents of various kinds, e.g. bacteria, fungi and algae. They include endotoxins and exotoxins, which may, for example, be enzymes or other biologically active substances. They can, for example, obstruct the body's defence mechanisms or cause tissue damage making it easier for them to spread in the body. Toxin production depends partly on specific growth conditions.

Endotoxins are lipopolysaccharides, a component of the outer membrane of what is termed a gram-negative bacterium. Lipopolysaccharides consist of a complex lipid, lipid A, which is bonded with a polysaccharide. "Free endotoxin" is released after the cell dies or by budding from living cells. Lipid A is the active (toxic) part and can cause fever, disorders of the upper respiratory tract and other symptoms in persons exposed. The composition and toxicity of endotoxins vary from one species to another. Endotoxins have for example been implicated in the pathogenesis of "humidifier fever", hacking cough ("printer's fever" in Swedish) and health problems among wastewater processing plant workers.

Exotoxins are formed by certain bacteria and usually secreted into the environment. They include some extremely toxic substances, such as botulinum toxin, which is produced by the Clostridium botulinum bacterium in anaerobic conditions, e.g. in home-made preserves which have not been sufficiently heat-treated.

Other harmful effects
Microbial volatile organic compounds (MVOCs) have sometimes been linked with the "sick building syndrome" (SBS). The relations between MVOCs and ill-health or discomfort are not wholly uninvestigated, but studies are in progress, particularly concerning individual substances which can be present in MVOCs.

Oxygen deficiency due to biological agents consuming oxygen is another instance of harmful effects.

Infection
Infections are caused by infectious agents invading the body, multiplying and being able to cause harm, e.g. by producing toxins of various kinds. Infectiousness is affected partly by the ability of the infectious agent to cause infection and survive, and by its infection paths. In addition, different infectious agents require different doses of infection in order to become established and possibly cause illness.

If an infection does occur, the gravity of the consequences will depend, for example, on the duration of the illness, on mortality and on whether the illness can cause permanent harm or secondary diseases.

The risk of infection is affected by the use and availability of effective vaccines or other immune prophylaxis. The possibility of antibiotic treatment, in the event of a person becoming infected despite precautions, affects the consequences of an infection. Antibiotic-resistant strains can develop, especially in environments where antibiotics are much used, the reason being that the infectious agents which are sensitive to antibiotics have been removed, leaving room for the more resistant ones.

Infectious agents are placed in risk groups 2-4 as per the criteria in App. 2 A. Classified infectious agents are listed in App. 2 B. That list cannot be mechanically applied. See also App. 2 B and the accompanying guidance.

Infection paths

The risk of infection depends very much on how the infectious agents can spread, i.e. the infection paths. Various examples of infection paths are given below. Sometimes a number of infection paths may occur simultaneously.

Airborne infection
The infection is spread through inhalation of the infectious agents. The latter can, for example, emanate from the airways of humans or animals carrying the infection. Transmission of infectious agents deposited on the ground or on objects and capable of being included in dust which can be stirred up and inhaled can perhaps also be classed as airborne infection, albeit of a more indirect kind. Diseases which can be spread through airborne infection include chicken pox, psittacosis, tularaemia and tuberculosis.

Droplet infection, splashing
Infection can be transmitted through inhalation or by the infectious agent reaching the mucous membranes, e.g. in the eyes. Aerosols – droplets containing infectious agents – can sometimes be spread and cause infection without the infectious agent normally being transmitted as an airborne infection. The risk of aerosol infection is greatest with infectious agents having a small infective dose.

Contact infection
The infectious agents are transmitted through direct contact between two persons or through indirect contact via objects. Ringworm, threadworm, scabies, intestinal diseases and venereal infections etc. can spread through direct contact. Indirect contact infection requires the infectious agent to be capable of surviving for some time outside the body. Intestinal diseases, for example, can sometimes be spread through indirect infection.

Bloodborne infection
Infected blood or other body fluids mingled with blood have to reach the recipient's bloodstream. Diseases which can be spread through blood include, for example, hepatitis B and C and HIV infection. There are special Provisions concerning Protection against Bloodborne Infections (AFS 1986:23).

Vector-borne infection
The inspection is spread by insects or arachnids – vectors – either through indirect contact, as for example when dysentery bacteria are spread by flies, or when the infectious agent is present in the vector and can be transmitted through its bite. In Sweden, for example, Borrelia and tick-borne encephalitis (TBE) are spread in this way, as are malaria and yellow fever in certain other countries.

Food-borne infection
Disease results from foodstuffs having contained an infectious agent, e.g. Campylobacter, Salmonella or Listeria. Infection can be transmitted due to inadequate hygiene. Certain infectious agents can multiply in foodstuffs, especially when the foodstuffs are incorrectly prepared, e.g. if they are insufficiently heated or are wrongly handled after heating. Food-borne infection can also be caused by bladderworm of tapeworm, such as Taenia.

Water-borne infection
Waterborne infection: This is communicated through the ingestion of infected water or, for example, vegetables that have been watered or rinsed with such water. Hepatitis A, dysentery and typhoid fever give rise to infections having such a mode of entry, even with very small infective doses. *Giardia* and *Campylobacter* are other examples of infectious substances spread by water.

Accident risks

Biological agents can cause accidents, e.g. by producing explosive gases or consuming oxygen in confined spaces. Microbiological activity can also cause a risk of slipping or the degradation of materials, with effects on mechanical strength. Accidents not directly caused by biological agents, e.g. pricks or cuts, can lead to ill-health as a result of the wound becoming a portal of entry for an infectious agent.

Guidance on certain sections

Guidance on Section 1, Scope
These Provisions cover a very wide scope. Microbiological work environment risks can occur in the most varied activities.

Biological agents occur naturally to a great extent in humans, animals and the environment, but only in certain circumstances do they present a work environment risk. Environments/jobs with microbiological work environment risks in activities where biological agents as defined in Section 3 are not used include agriculture, sewerage systems, abattoirs, demolition work, care and treatment of humans and animals, printing works and sawmills. People in such environments can be exposed, for example, to infectious agents, mould fungus or endotoxins.

Microbiological activity using biological agents occurs, for example, in scientific and medical research, in diagnostic laboratories, control laboratories, analytical laboratories, teaching and the industrial production of enzymes, foodstuffs (e.g. yoghurt), pharmaceuticals and other substances or for degradation purposes.

The Provisions under the heading “General Provisions” apply to the entire scope of this instrument, i.e. both to microbiological activity involving the use of biological agents or some other kind of activity in which people may be exposed to biological agents, e.g. the handling of contaminated material. The purpose of the requirements, however, can vary from one activity to another, partly depending on the results of the risk assessment.

In addition to the General Provisions there are further Provisions applying to particular areas, under the headings “Further Provisions on work involving a risk of infection” and “Further Provisions for laboratories and use of biological agents on animals and in large-scale processes”. Thus laboratory activities involving an infection risk come under the Provisions relating to laboratory activities but also the General Provisions and the Provisions on work involving a risk of infection. Certain sections contain provisos applying solely to the section concerned.

Harmful substances produced by biological agents also count as biological agents if they occur in conjunction with the organisms they are produced by, in which case they too come under these Provisions. Otherwise Provisions for the chemical sector apply. See the definition of “biological agent” in Section 3 and guidance on the same.

The Provisions apply regardless of whether the biological agents concerned are genetically modified or not. Contained use of genetically modified micro-organisms also comes under AFS 2000:5, issued by authority of the Environmental Code. Those Provisions include many stipulations agreeing with those in the Work Environment Authority’s Provisions on Microbiological Work Environment Risks, but they also include stipulations relating to

protection of the environment generally. The Provisions on Microbiological Work Environment Risks, on the other hand, contain certain stipulations specific to the work environment. The administrative stipulations concerning notification, permits and furnishing of information differ between the two sets of Provisions.

Guidance on Section 2, Employers and employees

Failing indication to the contrary, a Provision applies to everyone who, under the Work Environment Act, may incur a responsibility of the kind which the Provision describes. The persons concerned may belong to one of the following categories:

- Employers.
- Employees.
- Two or more persons jointly engaging in professional activity.
- One-person businesses.
- Family businesses.
- A party outsourcing manpower.
- The person in control of a worksite.
- The party conducting an activity at a common worksite.
- The party commissioning construction or civil engineering work.
- The party taking part in pre-planning.

Legal persons with employer responsibilities include enterprises, universities, county councils and municipalities.

Many Provisions are also addressed to the party responsible for co-ordinating measures of protection against ill-health and accidents at a common worksite (the party with co-ordinating responsibility). This is the case with all Provisions to do with co-ordination of protective measures between different enterprises active at the common worksite. The co-ordination is above all concerned with risks which occur in the activities of one enterprise but are liable to affect people working for other enterprises at the common worksite. See Chap. 3 of the Work Environment Act.

Thus all the groups which have now been enumerated need to study all Provisions of the prescriptions and to decide how far the Provisions affect their activities. An employer needs to take into account all Provisions except those expressly referring to some other party.

It is important that the employer should be aware that the Provisions also include, for example, school pupils, trainees, students, guest researchers and outsourced manpower.

Chap. 3, Section 12 of the Work Environment Act lays down: “A person hiring rented labour to work in his activity shall take the safety measures which are needed in that work.” The purpose of this stipulation is for responsibility to match the employer’s responsibility for the work environment, but only with

regard to the work occurring at the external worksite. Under Section 1 of the Provisions on Systematic Work Environment Management, “Persons renting manpower are equated with employers.” Thus a party outsourcing manpower is bound – with respect to the work to which the outsourcing refers – to comply with the Provisions on Systematic Work Environment Management. This can, for example, mean investigating working conditions, assessing risks, taking remedial measures and issuing instructions, and assuming responsibility for the occupational health care which the working conditions demand being available. Corresponding duties are incurred by the party organising training or engaging trainees in his activity.

Guidance on Section 3, Definitions

Definition of biological agent
Biological agents include, for example, micro-organisms such as bacteria, including actinomycetes and rickettsias, blue-green algae, microfungi, e.g. yeast and mould, and micro-algae and protozoa. Inferior replicable units which are only capable of reproducing with the aid of a host organism are also included, e.g. virus and viroids, but also prions, i.e. infectious, self-reproducing protein structures, and infectious nucleinic acids.

Cell cultures are often used for cultivating virus or other intracellular parasites, but they can also contain them accidentally. Virus can appear unexpectedly, e.g. in primary cultures, hybrid cultures and cell fusions. Cell cultures can also become infected, for example, with mycoplasma. Sometimes cells are genetically changed, in which case they are regarded as genetically modified micro-organisms as referred to in AFS 2000:5.

Human internal parasites are organisms which dwell in and derive benefit from humans without themselves being of any benefit to the host. They are often unicellular but can also be multicellular, e.g. intestinal worm. Scabies is caused by a parasite and is contagious. Certain animal parasites can also be harmful to humans, e.g. *Echinococcus multilocularis* and *Toxocara canis* (common dog roundworm). If so, they are considered human in accordance with the definition of biological agents in these Provisions. Infections which can be transmitted between animals and humans are usually termed zoonoses. The biological agents which can cause zoonoses are classified in App. 2 B according to their effects on humans.

Harmful substances produced by biological agents are counted as biological agents only if they occur in conjunction with the organisms they are produced by. The enzyme subtilisin can be counted as a chemical agent, e.g. if it is used as a detergent additive without the bacteria (*Bacillus subtilis*) producing the enzyme being present. Among other things there is an occupational exposure limit for subtilisin and suchlike proteolytic enzymes. In the production of the enzyme, on the other hand, subtilisin counts as a biological agent, because active subtilisin bacteria are included in the manufacturing process. The products termed “biotechnical organisms” in Chap. 14 of the Environmental Code are also biological agents, because active micro-

organisms are included in the product itself. In environments favouring the growth of gram-negative bacteria, large quantities of endotoxins can be formed, and these are active biological agents even if the bacteria have died. See under the heading *Toxigenic effects* in the section giving examples of ill-health.

Definitions of ill-health
Ill-health can comprise disease, bodily functional impairment or discomfort. Examples of ill-health caused by biological agents, including their components or substances produced by them, are given under a separate heading above. Biological agents can cause ill-health but need not always do so. For assessment of possibly harmful exposure, see the guidance on Section 4 and App. 1.

Definition of the use of biological agents
Use of biological agents can be instanced with cultivation, e.g. for diagnosis or research, vaccine production, fermentation processes with subsequent processing for the production of different substances, silage with the aid of starter cultures, and introduction into laboratory animals.

If a diagnostic sample is suspected of containing an infectious agent and confirmation of this is desired by means of cultivation or some other enrichment procedure, this constitutes use of a biological agent.

Microbiological work environment risks can also occur without a biological agent being used. Work can. for example, proceed in an environment where conditions – such as damp – can cause unwanted growth, leading to harmful exposure. Nursing and animal husbandry are other examples. Handling of contaminated material, e.g. waste or, mouldy hay, can entail great risks without involving the use of biological agents.

Examination of a diagnostic sample, e.g. for clinical chemical analysis or direct microscopy, does not amount to use of biological agents and is not subject to a permit under Section 29, but the handling of such a specimen can imply an infection risk, which has to be taken into account in risk assessment and when choosing protective measures; see, e.g., Sections 26 and 27.

Definition of working area
Tasks of different kinds may occur at one and the same workplace. In the assessment of risks, areas are identified in which it is believed that microbiological work environment risks may occur. These areas may also need to be subdivided into a greater number of areas with different risks involved. A workplace may, for example, include laboratories with different biosafety levels and, moreover, other spaces where biological agents are not used at all. An area within a workplace may be temporarily demarcated while decontamination is in progress. Wastewater processing plants include a variety of working areas, e.g. aerated tanks and spaces with belt filter presses or other sludge dewatering.

Risk group definition
See App. 2 A and guidance on the same.

Definition of biosafety level
App. 3 lists an array of protective measures for facilities, equipment, routines and organisation, adapted for the use of biological agents classified in one of four risk groups according to their ability to cause infection and the potential gravity of the consequences. Under Section 25, a biosafety level of at least 2 shall be applied to the use of biological agents in risk group 2 etc. See also the guidance on App. 3 C.

Definition of infectious agent
In these Provisions the term is applied solely to biological agents which can cause infections, i.e. risk group 2 and above.

Definition of infective dose
Different infectious agents need to be present in different quantities to cause an infection. This can depend on many factors, e.g. the resistance of the infectious agent to the body's defence mechanisms. The infective dose of an infectious agent cannot be stated exactly; most often an approximate estimate is made. For one thing, the dose is hard to verify experimentally, and secondly there are great variations in the sensitivity of different individuals. Very often, however, there is a certain amount of experience on which to base an assessment of infective dose. The infective dose is usually stated as the number of viable units of an infectious agent which it is believed is required to infect a susceptible subject.

Definition of unwanted event
An unwanted event can, for example, be an accident or incident. In certain cases an unwanted event can lead to ill-health. See also the guidance on Sections 15 and 16.

Definition of decontamination
Decontamination is a collective term and can refer to different levels such as cleaning, disinfection or sterilisation. The term "disinfection" is used in other connections for the kind of decontamination referring solely to infectious agents. In these Provisions, the term "decontamination" denotes treatment of biological agents of all kinds. The extent of the decontamination needed is decided following risk assessment in accordance with current Provisions. See also the guidance on Section 10.

Definition of disinfection
Disinfection can be carried out, for example, using heat or chemical agents, disinfectants. See also the guidance on Section 10.

Definition of sterilisation
Total decontamination cannot be established by measurement but can be described in statistical terms, e.g. that the theoretical likelihood of a living micro-organism being present in a test material is equal to or less than one in

10^6. To ascertain that a sterilisation has the effect intended, the process has to be validated. See also the guidance on Section 10.

Guidance on General Provisions

These Provisions apply whatever the kind of microbiological work environment risk occurring in the workplace, but their implementation will vary a great deal, depending on the type of activity involved. There are certain fields, moreover. to which additional Provisions apply. See also the guidance on Section 1, concerning the scope of the Provisions.

Guidance on Section 4 and on App. 1, Risk assessment

One of the first steps in risk assessment is to judge the likelihood of biological agents also being capable of causing ill-health or accidents in the workplace.

Activities which may involve risks of this kind include, for example:

- Activity involving the use of biological agents.
- Activity of such a kind that harmful exposure to biological agents is a common occurrence.
- Activity in an environment which favours the growth of biological agents.

Examples of work environments where microbiological work environment risks occur can be found on the Work Environment Authority website www.av.se under the subject heading “Mikrobiologiska arbetsmiljörisker”. This collection of examples is not exhaustive and further examples and guidance material may be added to it if necessary. There are also links to other authorities and organisations publishing guidance in this field. Guidance material includes the Prevent publication entitled “Mikroorganismer i arbetsmiljön” and National Board of Health and Welfare Report 1998:12, containing facts on the prevention of infections in health services and medical care. Genetically modified micro-organisms (GMMs) are subject to special risk assessment stipulations under AFS 2000:5 Contained Use of Genetically Modified Micro-Organisms. See guidance at www.av.se, subject field *Genteknik, GMM* www.av.se/english/topics/gmm . At the subject field *sjuka hus* (on sick buildings, in swedish) there is an action plan with guidance on procedure for dealing with microbial problems in buildings.

The occurrence of biological agents need not in itself imply a work environment risk. Most biological agents are harmless in normal quantities and many are beneficial or necessary, e.g. for the ecocycle and digestion. Some are normally pathogenic, while others are harmful only under certain conditions. Factors deciding whether biological agents constitute a health hazard include their inherent properties, quantity, entry path and recipient sensitivity.

If the employer does not have access to risk assessment competence within his own organisation, then occupational health care and occupational medical

expertise, for example, may need to be engaged. For the assessment of infection risks, assistance can for example by requested from the county medical officer, nursing hygiene expertise, the Swedish Institute for Infectious Disease Control, the National Veterinary Institute or other microbiological expertise.

In larger organisations, such as county councils, universities or certain business enterprises, a unified advisory competence on assessment of microbiological risks can be achieved by forming a biosafety committee or some other such group of persons representing different expert fields. Different organisations can also join forces to form advisory groups of this kind.

Guidance on App. 1, point A, Risk identification

Since the work environments forming the subject of risk assessment are so very different, one must begin with an inventory of risk sources, in order to arrive at a general picture before going into details. In an activity where biological agents are used, it may be appropriate to start with the nature of exposure under point B before going on to consider relevant factors as per point A. In other cases it may be preferable to start by reviewing the factors in point A. Other work areas in the workplace, e.g. different operations and processes, may require separate risk assessment. Risks can also vary in magnitude according to the personnel categories or individuals concerned. In the assessment of risks, allowance may need to be made for students, trainees and others with little experience of the work or persons who may be particularly sensitive. Pregnant employees and minors are the subject of special Provisions which among other things forbid their employment on work liable to involve certain kinds of exposure to biological agents.

Guidance on App. 1, point B, The nature of the exposure

Section 4 requires the investigation to provide, as far as possible, a basis for the assessment of all risks and of the protective measures needed. In certain activities where experience has shown that large quantities of organic dust are liable to occur containing, for example, spores of mould fungus or actinomycetes, the risk assessment needed for taking risk limitation measures can often be carried out without any determination of individual agents. Determination of this kind may, however, be essential in order to establish whether an employee has developed hypersensitivity to an agent of this kind.

When biological agents are used their identity is often known, in which case information is obtainable concerning their inherent properties, so that the risk assessment can be factored in together with handling and other factors. In special cases of use of biological agents, e.g. for diagnosis or control activity, or when use is made of agents selected from nature, it cannot be known with certainty which agents are being used. Often, though, there is a suspicion or experience which can furnish guidance, and knowledge can improve as work proceeds.

In an activity where biological agents are not used but where personnel may still be exposed to them, the possibilities of knowing which agents occur in the workplace may vary. When, for example, a patient is being treated in an infectious diseases ward, the diagnosis may be known. In other activity too, the occurrence of infection risks may be known and the type of agent liable to be involved may be reasonably predictable. In certain cases species is less important than the degree of exposure. Exposure to heavy concentrations of biological agents can trigger an acute pathological conditions as a non-specific reaction to organic dust (Organic Dust Toxicity Syndrome, ODTS).

See also App. 2 A, containing criteria for the classification of biological agents, and App. 2 B, listing certain infectious agents and offering guidance on App. 2.

Guidance on App. 1, point C, Measurement/determination

The work environment can be investigated by various methods in order to assess the risks which are present and the measures which may be needed to reduce any work environment problems.

Different strategies are needed, depending on whether the task is to investigate the presence of heavy concentrations of unspecified agents, to identify agents or carry out serological tests for infection tracing or exposure control, or sampling and analysis of environmental specimens for the presence of, say, mould spores or endotoxins.

It is only in special cases that measure of the atmospheric concentration of biological agents yields adequate data on which to base an assessment of suitable measures. There may be adequate foundation of another kind for the immediate deployment of risk limitation measures without any very extensive investigation of the extent of exposure.

Measures to prevent unwanted growth can only be taken if the factors favouring growth are known, e.g. by eliminating problems of damp. Measures to prevent the spread of biological agents, e.g. from aerated tanks or belt filter presses in wastewater processing plants, or the measures indicated in App. 3, can be based on experience from elsewhere. AFS 1994:11 Organic Dust in Agriculture gives many examples of measures to prevent the occurrence and spread of such dust, which often contains biological agents.

Occupational exposure limit values for biological agents are hard to define, due partly to the lack of standardised methods of measurement, which are a *sine qua non* of studies and comparisons of relations between health effects and concentrations, e.g. when biological agents are inhaled. Which concentrations of biological agents are harmful to health depends very much on the agents and the types of environment involved, but individual factors also make a difference, especially where hypersensitivity is concerned.

When risk-limiting measures have been taken, investigations may be necessary to verify that the measures have had the effect intended. One way of doing this may be to establish whether ill-health or discomforts have diminished. Another way can be to verify the efficacy of measures taken by means of before-and-after measurement. When using biological agents which have to be kept contained, a check can be made to see whether they occur outside the containment.

In certain cases there may be predefined values for comparison. Protection factor testing of microbiological safety cabinets is a standardised procedure for deciding how much of an aerosol created inside the safety cabinet spreads from it through the opening. Protection factor testing methods are described in the standard SS-EN 12469, “Safety Biotechnology – Performance criteria for microbiological safety cabinets”. See also Section 9 and guidance on the same, concerning inspection and maintenance of equipment.

In cases where it has been concluded that occupational hygiene measurements are justified, it is essential that these should be taken correctly, given that they are relatively expensive. There are often great variations involved, and it is hard to draw conclusions from isolated measurements. Competence may be needed for both ordering had planning measurements, as well as for carrying out sampling and analysis and documenting and interpreting the results. It is important, for example, that sampling should be carried out using the right equipment in accordance with a properly thought-out sampling strategy and that various sources of error should be known. A standardised procedure must be followed if conclusions are to be drawn from, and comparisons made between, measurements taken in different places and on different occasions.

The standard SS-EN 13098, “Workplace atmosphere – Guidelines for measurement of airborne micro-organisms and endotoxin”, gives examples of measurement strategies and general principles for different kinds of measurement in connection with sampling, analysis, documentation, presentation of results etc. A method for measuring endotoxins is described in the standard SS-EN 14031, “Workplace atmospheres - Determination of airborne endotoxins”. Arbete och hälsa 1983:4, “Sampling of micro-organisms in air” (published in Swedish) and 1991:44, “Micro-organisms” (also in Swedish) review, among other things, sampling equipment and measurement in different environments and discuss sources of error etc.

Guidance on Section 5, Documentation of the risk assessment

The extent of documentation can vary according to the nature of the activity. If the risks are small and commonly known, it may be sufficient to make reference to known facts and only to note risk sources which are specific to the activity concerned. Review and ticking-off of factors to be taken into account according to App. 1 A is an appropriate starting point. If no special protective measures are considered necessary, a note is made to this effect. Otherwise a note is made of the measures which are going to be taken in the

light of the risk assessment findings. Section 10 of AFS 2001:1 Systematic Work Environment Management requires measures which will not be taken immediately to be entered in a written action plan.

It is the overall situation that is assessed; cf. App. 1 and the guidance on Section 4. If there are special risks involved, depending on the biological agents occurring in the activity, these may need to be assessed individually and in relation to the manner of their occurrence or use.

Where greater or more complex risks are involved, more documentation will be needed. Where written handling and safety instructions and other documents, e.g. technical descriptions, exist, reference can be made to them. Where activity is subject to the grant of a permit, App. 5 requires documentation to be enclosed with the application.

It is especially valuable for the documentation to be readily available when the persons acquainted with the risks are not present, e.g. in the event of an accident. A list of the agents occurring and of the whereabouts of risk assessment documentation is one way of meeting the availability requirement.

The risk assessment review required under Section 4 is documented in various ways, depending on the magnitude of the changes. When the review shows the conditions prevailing according to the previous documentation to be still relevant, a note to this effect may suffice. If there is any change with regard to biological agents, working methods, facilities, equipment etc., or if new knowledge appears, it is important that the original risk assessment be renewed. If the change is of a limited kind, the earlier documentation can be supplemented with particulars of what has changed, what assessment has been made and whether the change gives occasion for any action to be taken. A name and date must always be given under Section 5. If major changes, such as reorganisation, a change of direction in the activity, or the commissioning of new equipment and new facilities, or if many changes have occurred since the last complete risk assessment, a completely new risk assessment will normally be needed.

Guidance on Section 6, Planning of Work

Prevention of ill-health and accidents depends on adequate resources being set aside for the purpose. See also AFS 2001:1 Systematic Work Environment Management.

Points 1-6 of Section 6 could be described as a ladder or staircase of measures, describing the order in which different measures are to be considered. Measures of various kinds are specifically stipulated elsewhere in these Provisions.

Sometimes measures may need to be taken on more than one level of the “staircase”, but it remains important to have a strategy whereby suitable

protective measures are reviewed in a certain order. Measures early on in the chain can reduce the risks, often making further measures unnecessary.

It is important to note that not only the employees directly involved in the activity but all employees liable to be exposed need to be protected. See also Chap. 3, Sections 1 a, 6 and 7 of the Work Environment Act, concerning co-operation and co-ordination, and the guidance on Sections 2 and 14.

Under Chap. 6, Section 4 of the Work Environment Act, safety delegates shall participate in planning for the use of substances which can entail ill-health or accidents. This concerns all aspects, e.g. facilities, devices, working processes, working methods and work organisation.

1. Where suitable, risks shall be reduced primarily through suitable choices of biological agents. In large-scale production, non-pathogenic biological agents should be the first preference. This is not always feasible in vaccine production, but the risks can be reduced by using attenuated strains. Another way of reducing the risks is by expressing only minor portions of pathogenic organism, with the aid of gene technology. In diagnosis one cannot choose the agents in the samples, but on the other hand one can decide not to actively cultivate agents which cannot be safely used in one's own laboratory and forward them to a specialised laboratory instead.

2. Unwanted occurrence of biological agents can be prevented by conditioning one or more growth factors. Nutrition supply can be influenced by cleaning and the removal of organic material which could otherwise become a breeding ground for microbial growth. Water supply is an important growth-limiting factor. Damp is a common cause of the occurrence of unwanted biological agents, e.g. in sick buildings or in the form of wood mould. Sometimes it is desirable to permit one type of biological agent while avoiding others, e.g. when silage and lactic acid fermentation are used as preserving methods. If so, it is important that the preconditions for avoiding unwanted growth should be known.

3. See, for example, the guidance on Section 10, concerning the avoidance of decontamination methods which give rise to high atmospheric concentrations of mould spores and should therefore not be used. The retrieval of bacteria colonies with a heated platinum loop entails a risk of aerosol formation. The risk can be counteracted by using disposable loops.

4. There are many different ways of limiting the spread of biological agents, and the methods used can vary according to the nature of the activity.

   Decontamination at an early stage is one example of measures taken near the source. Process ventilation is another.

Measures to limit the spread of biological agents include the use of suitable equipment and the establishment of an operation or process capable of causing the spread of biological agents in a closed system or space, a special facility, part f a facility or a separate place. It is important to ensure that the contaminants are not passed on to another space. See also the section on facilities, fittings and equipment in these Provisions.

AFS 1988:6 Wood Mould contains rules for preventing the spread of wood mould where measures to prevent its occurrence in the first place have been unsuccessful. See also AFS 1994:11 Organic Dust in Agriculture.

5. Measures to limit the number of persons exposed can involve allocation of a special time or place for the work or ensuring that only personnel needed for the work will be present. It is important to segregate activities involving major risks from activities involving lower risks.

6. Chap. 2, Section 7 of the Work Environment Ordinance lays down that personal protective equipment shall be used when other measures are insufficient. In other words, the use of personal protective equipment instead of other protective measures is not acceptable. Respiratory protective devices and protective clothing can, for example, be needed by persons directly engaged in mould clearance, but other measures may be needed to protect other persons from exposure, e.g. evacuation or screening-off and efficient process ventilation.

Guidance on Section 7, Protective measures

The risks and the need for protective measures vary considerably from one area of activity to another. Section 4 and App. 1 A are the point of departure. Other parts of App. 1 are checked to the extent necessary, after which a review as per Section 6 is appropriate.

If sufficient competence is not available within the organisation, help will be needed, e.g. from occupational health care services and trade organisations. Protective measures appropriate to risks of different kinds in different environments are described in guidance material from the Work Environment Authority and other organisations; cf. the subject page on microbiological work environment risks and sick buildings at the Work Environment Authority website on www.av.se.

Other Provisions and General Recommendations may also apply, e.g. AFS 1988:6 Wood Mould. AFS 1994:11 Organic Dust in Agriculture contains many examples of ways in which the risks of harmful exposure to biological agents in the agricultural environment can be prevented and limited. AFS 1999:3 Building and Civil Engineering Work stipulates a work environment plan for all construction work where biological substances may occur which are a danger to health, e.g. demolition of mouldy material. For laboratory work, see also AFS 1997:10 Laboratory Work with Chemicals.

AFS 2001:1 Systematic Work Environment Management lays down that measures which cannot be implemented immediately are to be entered in a written action plan for implementation as soon as is practically possible. If there are great risks involved, work may need to be stopped until the measures have been taken.

Protective measures include the design of facilities, technical devices, assistive devices, routines and organisational measures such as reduction of stress and congestion. See also the guidance on other sections of these Provisions.

The protective measures in App. 3 are mainly concerned with activities under the special headings “Further Provisions on work involving a risk of infection” and “Further Provisions for laboratories and use of biological agents on animals and in large-scale processes”, but they can also be consulted in other cases.

Guidance on Section 8, Facilities, Fittings and equipment

See also AFS 2000:42 Workplace Design, in which many fundamental stipulations are set forth.

The spread of microbiological air contaminants can be counteracted if the air flow is steered from a space with a lower to a space with a higher degree of contamination. This can be achieved, for example, by creating negative pressure with safety ventilation on the premises where microbiological air pollutants may occur, in relation to neighbouring facilities or spaces. If the spread implies a risk of harmful exposure, the functioning of the ventilation system should also be investigated in the event of malfunctions. The ducting system and heat recovery system of the ventilation plant are to be designed to prevent the spread of microbiological air contaminants between different parts of the same building.

Excessively low temperature in hot water systems or a wrongly designed system, e.g. one where water with a suitable growth temperature can remain standing, may result in legionella bacteria multiplying and being able to spread, e.g. through showers.

Decontamination of facilities and equipment is facilitated by smooth, tight surfaces and by ensuring that there are no nooks and crannies. Where infectious agents can occur, it is important to choose material which will tolerate disinfectants in common use.

Equipment which can give rise to microbiological air contaminants includes, for example, belt filter presses for dewatering sewage sludge, waste screening belts and solid fuel installations. It is important to design and position such equipment in a way which will minimise the spread of microbiological air contaminants. AFS 1984:15 Sewer Systems contains

Provisions on measures to counteract the spread of aerosols, e.g. from aerated tanks.

Under AFS 2000:42 Workplace Design, a special facility, segregated from other facilities, must as a rule be arranged for a work process entailing a special risk to health and safety. See also App. 3 C. Nursing in an infectious diseases ward is another instance where a segregated facility is needed.

Guidance on Section 9, Control and maintenance

A check may need to be made concerning the unwanted occurrence of biological agents, to investigate whether equipment is spreading biological agents or whether safety equipment is sufficiently effective to limit the spread of biological agents. Checks may also need to be carried out in connection with malfunctions or other events which may entail inadvertent emissions, or to check the efficacy of decontamination. Checks of this kind can form part of the employer's systematic work environment management.

AFS 2000:42 Workplace Design includes stipulations concerning written instructions for the operation and maintenance of ventilation systems and requires operating and maintenance personnel to have adequate knowledge of the system. The Provisions also stipulate that ventilation systems are to be inspected and serviced regularly and that newly installed ventilation systems are to be checked to ensure that they are in proper working order before being taken into service. Where process ventilation is needed, any faults in the working of the ventilation system shall be shown by a control system.

Maintenance (servicing) can mean very different things, e.g. regularly emptying and cleaning air humidifier water tanks so as to guard against the growth of biological agents, which can otherwise result in the air humidifier spreading microbiological air contaminants.

If an eyewash device is fitted with a water tank, biological agents may start to grow if the water is left standing for too long. The device, therefore, ought preferably to be connected to running water, and it needs to be flushed regularly. See also AFS 1999:7 First Aid and Crisis Support.

Autoclaves normally need to be inspected as pressure vessels under AFS 1999:6. The sterilisation capacity of the autoclave is checked by a validated method.

It is very important to check safety equipment systematically and with adequate knowledge of suitable methods. Checks should be made annually, or more often if necessary.

App. 3 C contains specific stipulations concerning the use of functionally tested microbiological safety cabinets. See also the guidance on App. 3 C, point 14.

It is important for maintenance, repairs, servicing and inspection of ventilation systems and other technical devices to be able to proceed without risk. The risk assessment needs to be based partly on what the device has been used for and in what type of activity. For example, it is appropriate that a filter in a microbiological safety cabinet can be enclosed in such a way that the person replacing it will not need to come into contact with the filter if it could not be decontaminated before replacement. A centrifuge, culture vessel and other equipment which may be contaminated with infectious agents need to be decontaminated before being sent for repair. The equipment should then be accompanied by a certificate showing that this has been done.

The Work Environment Authority may come to require special control measures, e.g. as a condition for permits or in other cases where they are judged necessary.

Guidance on Section 10, Decontamination

The nature of the work and the risks entailed by the biological agents occurring will decide the extent to which decontamination is needed. Normally, however, decontamination must be carried out at the earliest possible stage. This can, for example, mean decontaminating spillage immediately or decontaminating waste before it leaves the work area or the workplace.

In certain cases departures from the main rule may be justified, especially if decontamination on site can entail greater risks than removal of the material. The material in sick buildings, attacked by mould or some other substance, ought primarily for example to be removed instead of disinfectant being used on the spot. If so, of course, it is then very important to limit the spread of the biological agents.

Cleaning may be needed to impede the growth of biological agents, e.g. in air humidifiers, stables, worktops (in the food industry etc.), in medical care or in swimming baths. Very often, cleaning may be sufficient to achieve an acceptable effect. In particular, flooring, safety devices, controls, tools and other implements or instruments often need to be thoroughly cleaned. Rules on cleaning are contained in AFS 2000:42 Workplace Design.

Sometimes disinfection or sterilisation needs to be resorted to if the risks associated with the organisms occurring are of such a kind that cleaning will not suffice, e.g. if there is a risk of infection.

Suitable decontamination agents and methods need to be available. In the first instance, heat treatment should be used if possible, e.g. a washer disinfector or an autoclave, depending on the degree of decontamination needed. When choosing a chemical treatment method, one needs to consider the effect of the agent on the biological agents used and its deleterious effects when inhaled, touched etc.

The effect of chemical treatment can also vary a great deal, depending on concentration, active time, presence of organic material, the age of the solution to be applied etc. In standardised conditions, a disinfectant can reduce the concentration of certain test organisms by a factor of at least 10^5. It is important, though, to remember that biological agents are also sensitive to various disinfectants. Whether reduction by a factor of 10^5 gives sufficient effect for decontamination depends among other things on the initial concentration of an infectious agent and on the infective dose required to trigger infection.

It is important that the sterilisation methods should be validated. Total killing is in practice not always possible, but for certain areas there are statistics showing how low the probability must be of an infectious agent having survived the treatment. Autoclaving is one example of a sterilisation method. There are tests with spores of extra heat-resistant bacteria spores for checking the efficacy of autoclaving, but this is not sufficient for prions, which are even more heat-resistant.

It is important to make sure that the decontamination treatment is sufficiently effective under the prevailing conditions. The choice of decontamination agent and method may in certain cases need to be made in consultation with expertise in the field, e.g. nursing hygiene, clinical microbiology or suchlike.

Decontamination can give rise to microbiological air contaminants if an unsuitable method is used. There are various ways of avoiding this. Sweeping, e.g. of mouldy chips or organic dust, can spread biological agents and must therefore be avoided, as must cleaning with a high-pressure jet in environments contaminated with biological agents. When vacuum-cleaning it is important that the exhaust air should be removed from the space or filtered with sufficient efficacy. If a culture containing an infectious agent has been spilled, the risk of aerosol spreading will be less when the spillage is covered with a cloth soaked in disinfectant than if the disinfectant is poured straight onto the spillage.

When biological agents are cultivated in large quantities, special devices and routines are needed to ensure that the volumes which might escape in the event of a leakage can be collected and neutralised.

Equipment contaminated with biological agents needs to be decontaminated in a suitable manner before being washed, re-used, discarded or suchlike. Steam sterilisation, or possibly use of an effective rinse/wash disinfector, is preferable to chemical treatment, because the efficacy of chemical treatment can be impaired by organic material.

In the transport sector, it is important that vehicles such as lorries and trucks should be kept clean so as to avoid any spread of infection or growth of micro-organisms. Ambulances or other passenger vehicles are an example of vehicles which may need to be cleaned with special care (see SoS-rapport

1989:31). See also the manual Desinfektion på arbetsplatsen H338), published by the Work Environment Authority.

Guidance on Section 11, Handling and transfer of waste and other contaminated material

Handling may, for example, include packing, carriage, storage, sorting, processing and disposal.

Manual sorting of waste can involve great risks, and it is important to prevent such risks, e.g. through careful planning in accordance with Section 6 and through knowledge, information and instructions as per Sections 14-15. If a consignment of mouldy timber or wood fuel is to be delivered for incineration, measures need to be taken to prevent mould spores spreading, and the persons taking charge of the material need to be informed so that they can take appropriate protective measures.

Information concerning the contents can, for example, be provided through labelling. It is important for information concerning risks and protective measures to accompany the material at all stages and for material constituting a potential hazard not to be left in such a way that unauthorised persons can come into contact with it, both in the workplace and outside.

It is important that packagings should be sufficiently tight and durable for biological agents not to escape from them. The safety requirement for packagings depends on their contents. Containers for sharps need to be puncture-proof. Packagings meeting the stipulations for carriage of dangerous goods, class 6.2 infectious substances, may also be suitable for the carriage of contaminated material not coming under those Provisions.

The rules on the carriage of dangerous goods concern external transport operations. They are based on international rules which differ somewhat as between different kinds of transport (e.g. ADR for road transport, issued by the Swedish Rescue Services Agency). The rules are all similar and are based on a common classification devised by the UN. Under that classification, biological agents which can cause infections in humans and animals come in class 6.2, infectious substances. Genetically modified organisms come in class 6.2 if they are infectious, otherwise they are referred to class 9. The transport provisions include special stipulations concerning marking and labelling as well as packagings.

Where the work environment is concerned, Section 16 requires the employer among other things to see to it that contingency preparedness exists for dealing with unwanted incidents in transit. Drivers need to know the risks and to be sufficiently trained.

The Provisions and General Recommendations of the National Board of Health and Welfare (SOSFS 1999:27) include rules on infectious waste from medical care. The Waste Disposal Ordinance and the Animal By-Products

Ordinance also contain provisions on infectious waste. In certain cases the rules for the work environment have more far-reaching stipulations than these other rules where the work environment is concerned.

The Work Environment Authority can make the grant of a permit conditional on waste being decontaminated before delivery. Even in cases where no permit from the Work Environment Authority is necessary, it follows from Section 10 that waste shall normally be decontaminated as soon as possible.

Once infectious waste has been sufficiently decontaminated, it does not need to be handled with any special consideration for infection risks. On the other hand it may entail other risks which have to be allowed for. Cuts and punctures, for example, can be inflicted from sharp waste even after it has been decontaminated. Radioactivity and chemical hazards are other examples. Certain biological agents, e.g. mould spores and endotoxins from gram-negative bacteria, can still cause ill-health after the organisms producing them have been killed off.

App. 3 C specifies stipulations for the handling of waste from certain activities in which biological agents are used on various biosafety levels.

Guidance on Section 12, Hygiene

Good personal hygiene is important in connection with microbiological work environment hazards of all kinds, but especially where there is a risk of infection.

See App. 3 for certain definitions regarding good work environment practice for nursing hygiene, good microbiological practice and use of biological agents at different biosafety levels.

When washing one’s hands, a softening hand lotion is often advisable, to keep the skin from cracking. Rings, bracelets and suchlike are an obstacle to hand hygiene.

Hand disinfection can in certain case be substituted for hand-washing. It is important that agents used for decontaminating the skin should be gentle on it. Glycerol, for example, added to alcohol-based hand disinfectants can reduce the risk of desiccation or other adverse effects on the skin.

A hand-washing facility should be located as near as possible. To avoid spreading infection, the facility can be designed in such a way that the taps do not have to be operated with the hands and the hands themselves can be washed in running water. It is advisable to use liquid soap and disinfectant in dispensers designed in such a way that the agents will not get into people’s eyes; this is otherwise a type of occurrence often figuring in work injury reports. Disposable towels should be supplied.

Good hygiene also means using workwear of suitable design, made of a material which can washed at a high enough temperature.

An emergency shower may be needed in certain cases. See, for example, AFS 1997:10 Laboratory Work with Chemicals. A shower may also be needed in other cases; see AFS 2000:42 Workplace Design. See also App. 3 C for more detailed stipulations concerning showers at different biosafety levels.

AFS 1997:7 First Aid and Crisis Support contains rules on eyewash facilities and emergency showers, among other things. See also the guidance on Section 9, Control and maintenance.

Guidance on Section 13, Personal protective equipment

AFS 2001:3 Use of Personal Protective Equipment contains general Provisions on PPE. In addition, the Work Environment Authority has published books on PPE, dealing among other things with the selection, care and use of PPE of different kinds.

Section 12 of AFS 2001:3 requires the employer to supply the PPE needed for the work, at no expense to the employee. In addition, “The employer shall see to it that the personal protective equipment is maintained, inspected, repaired and stored in such a way that its protective effect and hygienic quality are preserved.” Among other things, this means the employer arranging for the laundering of protective clothing.

Protective clothing needs to be adapted to the nature and particular hazards of the tasks involved. Lab coat, plastic (rubberised) apron and arm guards are examples of protective clothing.

When handling material attacked by mould or suchlike, e.g. during decontamination work, both breathing protection and full-length protective clothing may be needed.

Clothing which has been used as protection from biological agents needs to be washable at high enough temperatures. In certain cases it may need to be autoclaved or put in a self-dissolving laundry bag before being sent for washing, depending on the risk assessment.

Contaminated protective clothing must be changed. Removal of protective clothing and other protective equipment when leaving the work area means, for example, not wearing these items when visiting “clean premises”, e.g. personnel rooms or, where applicable, premises with a lower biosafety level.

AFS 2000:42 Workplace Design stipulates a special space for the storage of protective clothing used as protection against infection and other dangers to health. See also the specific stipulations in App. 3 C.

Small cuts and scratches and eczema on the hands, barely visible to the naked eye, can provide an entry portal for infectious agents, aggravating the risk of ill-health. AFS 2001:3 Use of Personal Protective Equipment requires the employer to analyse and evaluate the risks and to judge the properties which the protective equipment must have in the work situation concerned. This makes it important to choose safety gloves according to the nature of the work. The handling of mouldy timber, for example, calls for a different kind of gloves than laboratory work. If safety gloves are also expected to afford protection against chemical substances, it is important to check that they are really intended for this purpose. Disposable gloves are not intended for re-use and will not stand up to disinfection.

Safety gloves have been shown capable of reducing the amount of blood or culture fluid transmitted by an inadvertent needle prick. It is also appropriate to investigate whether gloves exist of a quality affording a certain degree of protection against penetration by syringe needles and against cuts. Double gloves can give better protection from infection.

When choosing gloves one should also consider the risk of allergy and hypersensitivity entailed by the material which they are made from. Latex allergy, i.e. allergy to natural rubber latex, is not exactly uncommon and can produce serious symptoms, at worst in the from of anaphylactic shock, which is a life-threatening condition. It is therefore important to have routines for deciding when natural rubber latex gloves need to be used. Powder used to facilitate the putting on and removal of gloves can also carry allergenic proteins and trigger reactions from latex-allergic persons working in the same room.

Safety gloves may also cause other forms of hypersensitivity. Most commonly, gloves cause irritative dermatitis due to the skin being enclosed in the glove, or perhaps because of the powder which the gloves contains. Contact allergy may also occur, due to the chemicals added during the production process. This makes it even more important to have routines for the use of gloves at work. Inner gloves of cotton, the choice of a glove material other than latex or with a low content of soluble natural rubber proteins and powder-free gloves are among the possible means of risk abatement.

Respiratory protective devices may be needed when dangerous concentrations of biological agents are feared, e.g. in connection with safety equipment malfunction. They ma also be needed when personnel enter premises where there is a risk of airborne infection, during close contact with patients secreting infectious agents which re spread through the air, and when endotoxins or spores from mould fungi or actinomycetes are present in large quantities.

It is important to realise that a surgical mask is not the same thing as a respiratory protective device and, consequently, affords no protection against airborne agents. See the Work Environment Authority’s guidance on respiratory protective devices etc., which can, for example, be accessed on

www.av.se under the subject heading Mikrobiologiska arbetsmiljörisker. Apart from choosing the right product, it is important that respiratory protective devices should be personally tested and should be stored out of the way of contamination.

The training required under Section 14 also includes the handling of PPE. AFS 2001:3 Personal Protective Equipment also requires the employer to provide instruction and practice.

Other personal protective equipment includes, for example, a visor or safety goggles to ward off splashing.

Guidance on Section 14, Knowledge and information

Chap. 3, Section 3 of the Work Environment Act requires the employer among other things to inform his employees of the risks which may be associated with the work and to ensure that the employee has the training needed for the work. It is important that necessary knowledge, e.g. concerning risks, hygiene requirements, protective equipment and personal protective equipment, be kept up to date. In addition, the employees need to know which symptoms of infections, allergies etc. can be related to the activity concerned.

The extent of information depends among other things on the risks associated with handling, and on previous experience and training. Detailed information is especially important in connection with the hiring of new employees, the hiring of temporary employees and changes of job content, and also when introducing new routines, new equipment or new biological agents.

A regular review is needed in order to meet the stipulation of everyone having the knowledge and instructions that are needed. See also Section 15, on handling and safety instructions.

For laboratory work in schools, it is important that teachers should have sufficient training and sufficient access to expertise to be able to make the risk assessments necessary and adapt their teaching to the capabilities of the pupils and the facilities.

Work of a certain kind, such as the cleaning of premises where infectious agents in the higher risk groups are used, should only be done by persons with microbiological training and a thorough knowledge of the risks.

Chap. 3, Section 6 of the Work Environment Act requires “Two or more persons simultaneously engaged in activities at a common worksite” to “… co-operate with a view to achieving satisfactory safety conditions. Each of them shall also ensure that he does not, through his activity or his devices at the common worksite, expose any person working there to the risk of ill-health or accident.” Chap. 3, Section 7 of the work Environment Act contains rules concerning co-ordinating responsibility. See also the guidance on Section 2.

The stipulations under Section 14 include seeing to it that the person apprised of risks informs others needing to know about them. The person using biological agents knows more about the risks than, say, personnel casually entering the workplace to carry out maintenance work or suchlike. In other cases the opposite may apply. For example, a company carrying out decontamination work may know more about the risks than the people working in a mould-damaged building.

In order to meet the stipulations in Section 14, the employer needs to have routines and instructions ensuring that sufficient information is supplied, for example, when employees relieve one another in different shifts or when infectious material is transmitted to someone else. See also Section 11.

Guidance on Section 15, Handling and safety instructions

The design of handling and safety instructions may need to vary, depending on the nature of the activity. Both verbal and written instructions may be needed. Risk assessment under Section 4, specified in App. 1, and Section 5 forms the basis of the instructions.

To meet the stipulation of ascertaining that the instructions have been properly understood, the instructions may need to be put down in different languages, so that persons with no proper command of Swedish will be able to understand them. Different instructions may be needed for different personnel categories. It is important, for example, not to forget those who attend to washing up, laundry and waste disposal, or cleaning, operating and maintenance staff. Special instructions may also be needed for security personnel etc.

Deficiencies which may occasion amendment of instructions can be the observation of new risks or conditions possibly entailing risks. The amendment of instructions can also be prompted by unwanted events or practice as per Section 16. In such eventualities, there is cause to consider the need for written instructions. AFS 2001:1 Systematic Work Environment Management mentions the importance of having written instructions on what is to be done in the event of breakdowns, disruptions, incidents and accidents.

An accident risk may exist due to oxygen deficiency or the development of explosive gases in close spaces with microbial activity, e.g. cess pits. Instructions may be needed on how to investigate whether such spaces can be entered safely and on what needs to be done if someone meets with an accident. A person entering a space where the oxygen is exhausted in order to rescue someone must have fresh air supply in order not to meet with the same fate themselves. See also AFS 1999:3 Work in Confined Spaces.

Activities for which written handling and safety instructions may be needed include, for example, activities with a potential risk of infection. Methods books capable of forming the basis of handling and safety instructions are widely used in the medical sector. Handling of specimens from humans and animals

can involve an infection risk, and Section 23 stipulates special routines which call for written instructions.

Written handling and safety instructions may also be needed in other activity, if using the right working method is important for the prevention of ill-health and accidents. This can be the case in an activity where there is a risk of exposure to large quantities of biological agents, e.g. when handling mouldy timber, during decontamination work or in certain industrial activities. In connection with mould clearance it is also important to consider how persons other than those working on the decontamination need to be protected. For example, the work area may need to be screened off or measures taken to ensure that spores do not spread to other parts of the building through the ventilation system.

AFS 2001:3 Use of Personal Protective Equipment requires suitable written instructions to be provided for each item of PPE needed in the activity.

Experience of workplaces resembling one's own can furnish guidance for instructions. Sometimes experience of this kind can be gathered in guidance material from trade organisations or expert bodies. Handbooks such as the WHO Laboratory Biosafety Manual, methods books etc., can furnish useful guidance for laboratory activities. The protective measures indicated in App. 3 can form the basis of handling and safety instructions for the activities for which the appendices are designed, but to a certain extent for other activities too. See, e.g., Sections 22-27.

It is important, however, that local conditions and the assessment of risks in the individual workplace should always from the basis on which the instructions addressed to the personnel are designed. It is also essential that handling and safety instructions should be appropriately co-ordinated with methods descriptions and procedures included in any QA systems existing.

Written handling and safety instructions can serve many important purposes, among them the following:

- When the instructions are drawn up, the work planned with biological agents has to be thought through step by step, so that the risks of the different operations can be evaluated and suitable protective measures chosen. This reduces the likelihood of unwanted events.
- Misunderstandings can be avoided by combining verbal reviews with written instructions. With written instructions one can look up and check in the event of uncertainty and can make sure that vital stages have not been overlooked. This, for example, is an advantage when introducing new associates.
- Routines can be maintained over long periods of time. Many workplaces now have a quality management system which regulates activities in detail, so as to ensure that the results of work will be of consistently acceptable quality. Similarly, an activity can be quality-assured for the prevention of ill-health and accidents by having written instructions which take into account the risks which the work entails.

Important elements of handling and safety instructions include, for example:

- working methods,
- disinfection and cleaning routines,
- use of equipment,
- care and inspection of equipment,
- access restrictions,
- handling of waste and laundry,
- use of personal protective equipment,
- measures in the event of unwanted events, and
- routines for reviewing the instructions and practising unwanted events.

An unwanted event is defined in Section 3 as “an event which has or could have led to ill-health or an accident being caused by a biological agent.” If anything of this kind occurs, it is of the utmost important to have considered beforehand what to do in such situations, instead of having to start wondering when the event is already a fact. Section 16 stipulates practice of unwanted events. Experience shows that exercises of this kind often give cause to revise the instructions, after measures as described in the instructions have been found to work less well in practice. When framing the instructions it is important to consider what unwanted events are possible, e.g. a fault in ventilation or other equipment, human error, spillage, splashing or cuts.

Handling and safety instructions for work can include a detailed description of work procedure and of suitable ways of protecting oneself, as well as what to do in response to unwanted events. The detailed instructions can very well be combined with notices in bullet form or suchlike dealing with particular tasks, such as cleaning, handling of specimens, entry control routines, unpacking of specimens, handling of goods for washing or safety cabinet work. Certain tasks in response to unwanted events may also be suitable subjects for notices.

AFS 2001:3 Use of Personal Protective Equipment requires the employer to arrange practice and, if necessary, to demonstrate how the PPE is to be used so as to achieve the protection intended.

Chap. 3, Sections 3 and 4 of the Work Environment Act lay down among other things that the employer shall see to it that only employees who have been given sufficient instructions can gain access to areas where there is a palpable risk of ill-health or accidents and that the employee shall take part in work environment management and shall comply with the Provisions issued.

Guidance on Section 16, Measures and reporting in connection with ill-health and unwanted events

Work-related ill-health which may be connected with the biological agents occurring in the workplace can occur without any unwanted event having been noticed. This can, for example, be the case with airborne infection or use of biological agents having a low infective dose. Ill-health may also have resulted

from prolonged exposure to endotoxins or mould. The employer's duty of information under Section 14 means, for example, ascertaining that the employees have a knowledge of symptoms of infection, hypersensitivity etc. which could be connected with the activity concerned. This is an important prerequisite of the employees' ability to report such ill-health.

Unwanted events include puncture wounds, malfunctions and spillage of bacterial culture. A puncture wound can be classed as an accident but can also be an incident constituting a threat of infection or else actually lead to infection. An unwanted event can also refer, for example, to the unscheduled reception of a consignment of mouldy timber or of a patient with an infectious disease. Unwanted growth of biological agents and gas development are other examples of what may be unwanted events.

Routines for reporting unwanted events and ill-health mean, for example, the employees knowing what has to be reported under Section 16 and who has been appointed by the employer to receive such reports. This is a natural stage of systematic work environment management.

It is important that there should be routines for promptly taking action if necessary to deal with unwanted events, e.g. in the event of acute oxygen shortage, anaphylactic shock or risk of infection demanding prompt post-exposure treatment. In order for this to work, the employees also need to know whom to turn to in an emergency. See also AFS 1999:7 First Aid and Crisis Support.

Section 16 requires unwanted events to be reported and documented regardless of whether or not they lead to ill-health. The documentation makes the risks visible and can among other things identity an unsuitable working method and equipment and thus lead to preventive measures. It is also a good instrument for ascertaining whether measures have had the effect intended and for revolving unnecessary repetition of unwanted events.

Stipulations of interaction between work supervision and other employees follow from Chap. 3, Section 1 as of the Work Environment Act. Interaction of this kind is a major prerequisite of achieving an improvement once a work environment problem has been observed. Those directly affected often have the kind of previous experience of the problem that makes a solution easier to find. Besides, discussions of this kind generate a better knowledge of the problems, which in itself usually reduces the number of incidents.

The ongoing documentation referred to in Section 16 can form a basis of the annual compilation required from the employer under AFS 2000:1 Systematic Work Environment Management.

Internal reporting as per Section 16 independent of a work injury being reported to the Insurance Office. It is also independent of any reporting under Section 2 of the Work Environment Ordinance, whereby the employer has to notify the Work Environment Authority, normally in his own district, without

delay of any accident or incident involving serious danger to life or health or of a harmful effect involving several employees.

Practising of unwanted events could very well begin with handling and safety instructions, where Section 125 requires such measures always t be included. See also the guidance on Section 15.

A suitable interval for practice can be once annually, more frequently if the unwanted events can be serious or if there are several different kinds of event needing to be practised. The exercises can show whether the measures as per the instructions work or are unclear. In such cases there may be cause to amend the instructions. Past events not foreseen in the instructions also provide occasion for amending the instructions. Section 15 requires the instructions to be amended if deficiencies are noticed.

The special contingency plan refers to occurrences which may demand special initiatives, e.g. from rescue services and ambulance crews. Normally no contingency plan is needed for the risk group 3 agent which does not constitute a hazard of airborne infection. In the list in App. 2 B these are marked (**). Of course, routines for dealing with unwanted events are still needed.

The contingency plan is a support in coping with serious occurrences or extraordinary conditions and can, for example, contain checklists, clarify responsibilities and powers, and indicate internal and external alarm lists. If, for example, fire safety or ambulance personnel know what risks a certain activity entails, they can prepare themselves appropriately so that a response will not be delayed and they will not be exposed to unnecessary risks.

See also Section 29, concerning particulars to be furnished when applying for a permit.

AFS 2000:4 Workplace Design contains general stipulations concerning alarms and evacuation.

The Accident Protection Act lays down that, in the event of an emission of toxic or harmful substances, the party carrying on the activity shall notify the county administrative board, the police authority, the county council and the municipality if the emission occasions special measures for the protection of the general public. Notification shall also be effected if there is an imminent danger of such an emission. It is the incident commander who decides whether an operation is to be regarded as a rescue service. In order for the neutralisation or other disposal of biological agents constituting a potential danger to be possible, contingency plans are needed indicating which risks can occur in different situations and what action is to be taken together with other authorities and organisations. The tasks of the rescue services include alerting, when necessary, all other parties that may be affected and if necessary issuing an “important public announcement” (VMA).

Guidance on Section 17, Medical preventive measures and checks

Medical checks and preventive measures include, for example, health screening before and/or after exposure and, if necessary, at regular intervals thereafter, immunity examination, serological follow-up in connection with exposure, immunoglobulin prophylaxis and vaccination. Investigation of allergic reactions and lung function tests are examples of examinations which may be needed when employees are, or are suspected of being, exposed to microbiological air contaminants.

It is essential to have access to occupational health care services and occupational medicine expertise with a knowledge of the exposure conditions in the workplace and exposure conditions affecting the individual employees, so as to be able to understand connections between symptoms and any exposure to biological agents and to advise on suitable measures for individual employees and the work environment. Other medical expertise should be consulted if necessary. If an employee presents symptoms which may be a consequence of exposure to biological agents in the workplace, it is vital that an assessment be made of the need to offer medical checks to other employees who have been similarly exposed.

Certain persons may have special need of medical checks, e.g. persons with reduced immune defence or hypersensitivity to specific biological agents. In such cases the checks can hep to decide whether a particular kind of exposure to biological agents entails special risks. Control of rubella (German measles) immunity is one instance of a medical check which can have a bearing on assessment of the applicability of the prohibition in Section 20.

It is important to observe that students and pupils also come under the Work Environment Act, and accordingly that the party responsible for the education, e.g. a municipality, county council, university or private school management, is equated with an employer and incurs financial liability if an assessment shows that health examinations or immunisation need to be offered.

If necessary, the Work Environment Authority, exercising powers under Chap. 4, Section 5 of the Work Environment Act, can prescribe that in certain specified situations the employer must arrange a particular kind of medical examination, vaccination or other preventive treatment against infection for persons employed or about to be employed on the work concerned.

It is essential that the greatest possible use be made of the possibility of vaccinating personnel who are to work with infectious agents, and especially if there is a risk of exposure to infectious agents in risk groups 3 and 4. The classification list in App. 2 B indicates for certain infectious agents whether an effective vaccine is available, but the list is not exhaustive and the supply of vaccine can change. This makes it important to obtain up-to-the-minute information.

In cases of uncertainty, consult the Work Environment Authority. Advice on general matters of vaccination and infection avoidance is obtainable, for example, from the National Board of Health and Welfare and the Swedish Institute for Infectious Disease Control.

Vaccination can in certain cases endanger the health of the person vaccinated. It is essential that the employee be informed of both advantages and possible disadvantages of the vaccination concerned. If immunoglobulin treatment, vaccination or other preventive treatment is given after exposure, it is important that this be done as expeditiously as possible.

It is appropriate for a vaccination certificate to be issued. This should be available to the employee and, on request, to the Work Environment Authority or any other authority entitled to have access to such information.

Section 2 a of the Work Environment Ordinance requires a physician to notify the Work Environment Authority of diseases which may be connected with work and are of interest from a work environment viewpoint, and also to furnish the Authority with information and assistance.

Infectious diseases legislation includes rules on the duty of person infected, or suspected of being infected, with certain diseases to submit, among other things, to examination by a physician.

Special rules on medical checks are also contained in food legislation.

Guidance on Further Provisions on work involving a risk of infection

These Provisions apply over and above the General Provisions. Certain provisions also apply where laboratory work can entail a risk of infection or the use of infectious agents in activity with animals or in large-scale processes.

Guidance on Section 18, Signage

The text “Smittrisk” can be supplemented with the designation “Biohazard” if necessary for the information of persons unable to understand Swedish.

The names and phone numbers of persons to be contacted in the event of an accident, malfunction or suchlike are important, especially in the case of activities at biosafety levels 3 and 4.

If any particular kind of PPE needs to be used in the facility, additional signage to this effect is appropriate.

Particulars of access restrictions in connection with activities at biosafety levels 3 and 4 may, for example, take the form of a text stating that only persons with authorised access to the facility may enter. It is appropriate that

the names of the persons having access should be available. It may sometimes be necessary to indicate access restrictions for activities at biosafety level 2, e.g. if vaccination is required.

Information concerning risk group and biosafety level indicates the level of risk and protective measures respectively. The term “biosafety level” is normally applied to the activities indicated in App. 3 C. In the case of a hospital ward sign as referred to in the second subsection of this section, it may be more appropriate to state the risk grouping of the infectious agents to which the warning refers, since the protective measures tally only partly with those at the corresponding biosafety level as per App. 3 C.

Signage design, as regards colour, shape and symbol, is set forth in AFS 1997:11 Safety Signs and Warning Signals at Workplaces.

Additional information can be provided on an additional sign immediately adjoining the warning sign.

Guidance on Section 19, Marking

It is essential that infectious material be marked so as to convey sufficient information about the risks entailed by the contents. This is particularly important if such material is handled by persons who cannot be expected to be aware of the risks, e.g. in the handling of waste and laundry and the washing of infected goods.

Other particulars necessary for the prevention of ill-health may, for example, include particulars of antibiotic resistance.

If there is a sign at the entrance to a facility or, for example, on a thermostat or refrigerator, the information on the sign, e.g. a statement of biosafety level, may be considered common knowledge. If so, individual containers present in these spaces need not be marked with such particulars. Particulars of contents, however, are one instance of particulars which may need to be shown on a container, since they are not normally stated on signage.

Material handled under the surveillance of persons acquainted with the contents, e.g. test tubes containing dilution series while work is in progress, do not normally need to be marked with a warning.

The Swedish Rescue Services Agency issues rules on the marking of hazardous materials for transportation. See also the guidance on Section 11.

Guidance on Section 20, Pregnant employees

Other infectious agents than those covered by the prohibition, e.g. parvovirus B 19, chickenpox, hepatitis B virus and cytomegalovirus (CMV), can also constitute a potential risk in connection with pregnancy. Section 4 of these Provisions makes it incumbent on the employer to carry out a risk assessment as the basis for deciding what measures need to be taken. Provisions on risk assessment are also contained in AFS 1994:32 Pregnant and Breast-Feeding Employees. See also guidance material on infections which can entail special risk during pregnancy.

Harmful exposure of the kind referred to in Section 20 is not considered to exist if the employee has satisfactory immune protection.

In activity involving a risk of exposure to rubella, there may be cause for the employer to ascertain whether female employees of childbearing age are immune to rubella (German measles). Most Swedes are immune to rubella, either because they have had the illness or else because they have been vaccinated for it In a few cases immunity may need to be tested and perhaps vaccination provided. See also the website of the National Board of Health and Welfare.

Toxoplasma can infect through the consumption of raw meat, such as pork and mutton/lamb, or through the excrement of cats, causing mild, influenza-like symptoms. If a toxoplasma infection coincides with pregnancy, foetal injury can result. In Sweden there are between about 15 and 20 such cases every year. The likelihood of these persons having been infected at work is very small. Ordinary hand hygiene normally affords protection against the kind of harmful exposure in the work environment referred to in Section 20, unless the tasting of raw meat is a person’s job. Tasks of that kind could also imply other infection risks and are incompatible with the stipulations for preventing such hazards. There is no effective vaccine for toxoplasma at present. Immune protection can be tested.

Guidance to Section 21, Registers

Employees who may have suffered exposure include, for example, those employed in an activity where risk group 3 or 4 infectious agents are used. These need not have been any unwanted event. The stipulation also applies to activities for which permits have been granted. Employees not directly involved in such activity may also have been exposed if they handle infected material from the activity, e.g. by changing filters which have not been decontaminated. Employees who only handle infectious agents in fully contained systems or securely packaged, e.g. in accordance with transport regulations for infectious substances, do not normally need to be included in registers of the kind referred to in Section 21, unless something has happened which means that they may have been exposed. Handling of decontaminated

material cannot entail exposure to the infectious agents referred to in Section 21.

Workers who may be exposed as referred to in Section 21 also include those whose work brings them into direct contact with humans, animals or materials known to be, or very probably, carrying infectious agents in risk groups 3 or 4, e.g. through work in an infectious diseases department or as ambulance crews or police. Personnel whose work brings them into direct contact with blood which known to be, or suspected of being, infected are among the categories which may have been exposed.

Particulars of the type of work can, for example, state whether the work involved contact with infected material, persons or animals or the use of group 3 or 4 infectious agents for cultivation or suchlike. Other particulars which may be of interest are the frequency/extent of such use, the infectious agents used in the cases concerned and any accidents or incidents.

Provisions concerning the right of employers to inspect register particulars concerning them are contained in Chap. 4, Section 3 (3) of the Work Environment Act. Under Section 3 of the Work Environment Ordinance the register must be kept by the employer for at least 40 years from the day on which exposure ceased.

Guidance on Section 22, Good health care work environment practice and routines for handling samples etc.

See the guidance on App. 3 A, concerning good health care work environment practice.

The taking of specimens can involve a major risk of infection, due to the close contact occurring with the humans and animals the sample is to be obtained from and to the frequent use of syringes. The possibility must always be borne in mind of specimens and other biological material from humans and animals being infected. Work with animals, which may be infected, also implies an added risk of infection through bites and scratches, for example.

Guidance on Section 23, Nursing and care in higher risk groups

See the guidance on App. 3 C, which is above all designed with reference to the use of biological agents in laboratory and animal activity. Many of the protective measures at biosafety levels 3 and 4, however, may be relevant to other activity potentially involving exposure to infectious agents in risk groups 3 and 4. These activities are not subject to the grant of a permit, but it is appropriate that guidance material for applying this Provision should be jointly prepared by representatives of the employers concerned and the Work Environment Authority.

Guidance on Further Provisions for laboratories and use of biological agents on animals and in large-scale processes

These Provisions apply over and above the General Provisions. Certain provisions also apply where there is a risk of infection.

Guidance on Section 24, Good microbiological practice

See the guidance on App. 3 B, concerning good microbiological practice.

Guidance on Section 25, Protective measures at different biosafety levels

See the guidance on App. 3 C concerning protective measures at different biosafety levels. Many protective measures, especially at biosafety level 2, are of such a kind that implementation hinges on the risk assessment. It is important that the risk assessment documentation should show the deliberations underlying the choice of protective measures. Certain biosafety level 3 protective measures can be dispensed with when using group 3 infectious agents with the suffix (**), signifying that infection from the substances is not normally airborne. In the case of activities for which a permit is required, the protective measures to be applied in the individual case are decided after the permit application has been processed.

Guidance on Section 26, Protective measures in certain laboratories

The laboratories referred to in Section 26 may, for example, be laboratories for clinico-chemical diagnosis or laboratories otherwise handling material from humans and animals.

The risks may be great even if the activity does not require a permit. The possibilities of telling which infectious agents may occur can be more limited than in microbiological laboratories. The absence of enrichment can mean less risk of exposure. Factors of this kind are included in the assessment of risks and help to decide which of the protective measures in App. 3 C may be relevant. See also the guidance on App. 3 C.

Guidance on Section 27, Higher biosafety level in cases of uncertainty

This section applies both to the use of infectious agents as referred to in Section 25 and to laboratories handling material which may contain infectious agents as referred to in Section 27.

Guidance on Section 28, Notification

Significant and notifiable changes include, for example, the commissioning of new facilities for the use of risk group 2 biological agents, plans for a completely new kind of activity involving risk group 2 biological agents, or

other changes, compared to the description in the notification, which have a bearing on the risk.

For the particulars to be included in the notification, see the guidance on App. 4.

Guidance on Section 29, Permits

The list in App. 2 B is not exhaustive and strains may occur, for example, which have different properties. Sometimes too it may be unclear whether a certain activity implies the use of biological agents or not. If it is uncertain whether a particular activity requires a permit, the employer should consult the Work Environment Authority. Total culture volume is the volume which can be present simultaneously in all vessels for the entire activity.

Note that the permit requirement applies to the storage of risk group 3 or 4 infectious agents, even if there is no activity involving the use of such substances. This can apply, for example, to the freezer storage of cultures or to temporary storage during transit.

The permit application procedure includes an assessment of the suitability of facilities and equipment, and of handling and safety instructions, for the work planned. The activity is assessed in its entirety. Permits can be made subject to conditions, according to the risks which the work is judged to involve. Protective measures as per App. 3 may then need to be modified.

Permits can be granted, for example, for routine activity generally at a particular biosafety level, for particular infectious agents or for individual projects. In the case of a more clearly defined activity, e.g. using a particular infectious agent, the conditions can be adapted to the particular risks associated with that substance, while the conditions attaching to a general permit for a certain risk group are likely to be more comprehensive. The scope of the permit is indicated in the record of decision.

Significant and notifiable changes may, for example, comprise significant alterations to facilities or equipment or other changes to the activity compared with the description on which the permit is based, changes of such a kind as to affect the risk involved. Notification can also include work using other agents than those specified in the application, but still within the scope of the permit.

A new permit is needed if the party plans to commission new facilities or to use an agent outside the scope of the permit award.

Changes requiring immediate action may, for example, include the discovery of previously unknown risks or the discovery in some other respect that insufficient protective measures have been taken.

Concerning the particulars to be furnished in a permit application, see the guidance on App. 5.

Guidance on Section 30, Liability

The Provisions on liability for breaches of Section 28 apply both to subsection one concerning prior notification and to subsection two on notification of significant changes with a possible bearing on the risk involved.

Guidance on entry into force and transitional Provisions

The validity of permits under AFS 1997:12 as permits under AFS 2005:1 merely implies that a new permit application need not be made before the entry into force. General stipulations under AFS 2005:1 also apply, however, to activities covered by a valid permit.

Guidance on App. 1, Risk assessment

See guidance on Section 4 and App. 1.

Guidance on App. 2 B, Classification

The list in App. 2 B, based on that in Directive 2000/54/EC, is incomplete and may include inaccuracies. It may come to be continuously updated with regard to classification, supplementary designations of available vaccines etc. and nomenclature. In cases of uncertainty the Work Environment Authority should always be consulted. According to the classification criteria in App. 2 A, in the event of uncertainty concerning risk group the higher group is to be chosen until it has been made clear that the risk justifies placement in a lower risk group.

This classification covers only some of the factors to be taken into consideration when making a risk assessment and choosing protective measures. See Section 4 and App. 1.

A classification system dividing biological substances into a number of categories according to risk and the need for protection is bound to be schematic and can never convey precise information about an individual biological agent in every situation. There can be great differences between the risks entailed by a number of biological agents in one and the same risk group. The need for protective measures can vary in such a way that all protective measures in App. 3 C corresponding to the risk group concerned may at times be inapplicable. Different infection paths, for example, may call for different protective measures.

Risks may also differ between different strains of the same species. Certain strains may have become resistant to antibiotics, as for example with meticillin-resistant staphylococci (MRSA) and *M. tuberculosis* resistant to

several of the agents commonly used in the treatment of tuberculosis. This affects the treatment possibilities and can augment the risk substantially. A newly isolated organism may differ from one which has long been cultivated in the laboratory. Passage in laboratory animals can change the properties. Vaccine strains have been modified to reduce the risks. With gene technology the risk panorama can be modified by combining genetic material from different organisms. Certain biological agents in risk group 1 are commonly termed “opportunist” because they will only cause infectious diseases under certain circumstances.

Because the classification is based on risk assessment in a normal average population, special measures may be necessary in certain cases, e.g. for persons with impaired immune defence, pre-existing disease or certain medication, or for pregnant employees. See also Section 20 and AFS 1994:32 Pregnant and Breast-Feeding Employees.

Biological agents which do not cause infectious diseases may cause ill-health in other ways, e.g. by producing toxins or triggering hypersensitivity reactions.

Bacteria normally classed in risk group 1 include, for example, *Escherichia coli* K12, *Lactobacillus acidophilus* and *Leuconostoc mesenteroides*. Fungi belonging to risk group 1 include *Neurosopra crassa, Sachharomyces cerevisiae, Penicillium chrysogenum* and *Aspergillus oryzae*.

These Provisions also apply to genetically modified micro-organisms (GMM), and GMMs therefore need to be assessed with reference both to these Provisions and to AFS 2000:5 Contained use of Genetically Modified Micro-Organisms. Since the assessment of GMMs takes account of both health-related and environmental risks, the risks may be on a different level according to AFS 200:5 than according to classification as a biological agent under the present Provisions.

Guidance on App. 3 A, Good health care work environment practice

It has to be realised that the general Provisions of these prescriptions apply, for example, to risk assessment, waste disposal, hygiene and personal protective equipment.

Clothing used for protection from infection must, together with other personal protective equipment, meet the stipulations applying to such items. See, e.g., the guidance on Section 13.

It is important for work to be organised in such a way as to minimise the risks of infection, e.g. by avoiding stress. There are also Provisions requiring personnel to comply with instructions and to use PPE when it is needed. See, e.g., Sections 13-15 and guidance on the same.

Good health care work environment practice is fundamental, but there are certain situations in which extra measures need to be taken. Guidance on

hygiene routines in health care is issued by the National Board of Health and Welfare, e.g. concerning basic hygienic routines and specific hygienic routines for various fields – dentistry, for example – and facts on prevention of iatrogenic infections. The guidance material in question can be accessed on www.sos.se.

It is important to remember, however, that measures for the protection of patients do not always protect the staff. Surgical masks, for example, are not the same thing as respiratory protective devices. A respiratory protective device is needed to protect the wearer from airborne infection, while a surgical mask can protect the surroundings. A surgeon wears a surgical mask to protect the patient. In certain cases a surgical mask worn by a patient can protect the surroundings from infection. See, e.g., the guidance on respiratory protective devices and surgical masks at www.av.se, subject heading *mikrobiologiska arbetsmiljörisker (*in Swedish*)*.

The Swedish Board of Agriculture has issued Provisions on preventive measures concerning zoonoses (infectious diseases which can be transmitted between animals and humans). The purpose of the Provisions is to prevent the spread of zoonotic infectious agents between animals and humans, and they apply to all types of animal husbandry except non-professional keeping of animals in private homes.

See also the guidance on App. 3 B concerning good microbiological practice.

Guidance on App. 3 B, Good microbiological practice

Good microbiological practice (GMiP) can be acquired through basic and subsequent microbiology training, tuition at work and handling and safety instructions in the workplace in connection with practical performance of the tasks involved.

Good microbiological practice is the foundation of safe use of biological agents. The WHO Laboratory Biosafety Manual describes the basics of safe laboratory work. Much of this can also be applied to other activity involving similar exposure to biological agents.

When handling infected material it is important to avoid as far as possible the use of hypodermic needles and sharp objects, because these always imply a special risk. If they are used nonetheless, it is especially important that they should be handled safely. Many accidents have occurred when the needle has been re-capped after use and the needle has missed the cap or penetrated it and struck the user's hand. There are assistive devices for avoiding this, e.g. waste containers with cap removers. Risks can also be reduced by using needles with a special safety device.

When inoculating laboratory animals it is essential to wear safety gloves which afford a certain degree of protection from bites and scratches. The risk of injuries can also be reduced by sedating the animals beforehand.

Avoiding the formation of aerosols can, for example, mean not blowing a pipette clear or not inserting a hot platinum loop into a bacteria colony. Measures for avoiding the spread of aerosols include working in a safety cabinet and using safety cups for centrifuging.

See also the guidance on Section 22 and App. 3 A.

Guidance on App. 3 C, Protective measures at different biosafety levels

Section 7 lays down that the protective measures to be applied must always be based on the risk assessment and deliberations as per Sections 4-6. The link between risk group and biosafety level as per Section 25 is a rule indicating the minimum level of the measures to be taken with reference to the classification of biological agents, but it does not say anything about individual protective measures.

Classification is always based on the criteria in App. 2 A. When reading the list it has to be borne in mind that there are many variations between biological agents in the same risk group. See the guidance on App. 2 A.

It should also be noted that other stipulations under these Provisions apply even if not specified in App. 3 C.

It is important that protective measures should be selected with an open mind, so that the risks identified can be effectively prevented. If there is any uncertainty about the biosafety level, e.g. whether protective measures from different biosafety levels or tables are needed, it follows from Section 27 and App. 2 A that it is the higher level or table which is to be applied. Even if more lenient protective measures can be justified in individual cases, it is important to remember that no chain is stronger than its weakest link. Very often too it is both simpler and less expensive to have uniform routines and containment measures in an activity. Protective measures from different biosafety levels and tables can be justified in certain cases.

The phrase “depending on the risk assessment” occurs at a number of points in the tables. The reason why it is impossible in these cases to state unambiguously whether the protective measure in question is needed is that use of biological agents in the same risk group can still constitute a variety of risks. Consequently the protective measures needed may also differ. At biosafety level 1, for example, it may be the differing capacities of the organisms for inducing hypersensitivity, the mode of use etc. that decide whether a certain protective measure is needed. Activities at biosafety level 2 can involve anything from relatively safe organisms to relatively dangerous infectious agents, and so many of the protective measures will have to be applied according to the risk assessment.

The risk group 3 organisms which, according to the classification list in App. 2 B, are marked 3(**) do not normally represent any risk of airborne infection,

and certain protective measures can then be dispensed with. They may, however, be needed for operations involving a risk of splashing or aerosol formation. At biosafety level 3, and especially biosafety level 4, where very dangerous infectious agents are used, or in large-scale activity, further protective measures, over and above those in tables 1 and 2, may prove necessary. The processing of permit applications includes an *ad hoc* decision at to which protective measures are needed.

Guidance on the tables in App. 3 C

In the case of medium-sized activities involving the simultaneous use of less than 500 litres culture, a combination of protective measures from tables 1 and 2 may sometimes be appropriate.

Guidance on App. 3 C, table 1, Protective measures when using biological agents in laboratory and animal activity

1. Biosafety level 2
Demarcation normally means the laboratory being physically demarcated by doors and walls from other activities. With an assortment of activities going on in the same space, demarcation can mean activities at, say, biosafety levels 1 and 2 being separated in time or all activity taking place at biosafety level 2, even when normally protective measures at biosafety level 1 only would be needed. In this way one avoids inadvertently working at an excessively low biosafety level.

2. Biosafety level 3
An airlock is needed to maintain negative pressure in relation to surrounding facilities. Some form of “airlock/sluice” may also be needed in other cases, e.g. changing rooms for protective clothing and hand-washing facilities. Protective clothing needs to be stored in a special space, not in changing rooms where other clothing is kept.

3. Biosafety levels 2-4
See Section 18 concerning the additional information which may be needed over and above the symbol.

4. Biosafety levels 3-4
Separate ventilation systems mean that supply and exhaust air ducts serving laboratory facilities at a certain biosafety level may not be connected to a ventilation system serving facilities at a lower biosafety level or facilities where biological agents are not used.

HEPA (High Efficiency Particulate Air) filters are highly efficient for particle separation and are used among other things for filtering air entering and leaving premises where biological agents are being used. It is important that there should be routines for overhauling and replacing these filters. There are various filter classes. See classification as per Swedish Standard SS-EN

1822-1 High efficiency air filters (HEPA and ULPA) - Part 1: Classification, performance testing, marking.

As regards further stipulations concerning air handling at biosafety level 4, the measures needed have to be decided in the individual case, in the light of the risk assessment, e.g. concerning properties of the viruses used.

5. Biosafety levels 2-3
Negative pressure in the facilities is not stipulated for the use of risk group 2 and 3(**) (non-airborne infection) infectious agents, but care should be taken to ensure that the facilities are not subjected to positive pressure. Instead a neutral pressure should be aimed for.

7. Biosafety level 2
If there are no special devices to avoid touching the taps, instructions are needed concerning other ways of preventing the hands from coming into direct contact with the taps. Disposable towels can be used, for example, and discarded after use.

7. Biosafety levels 2-4
Devices for hands-free operation include light relay control and pedal- or elbow-operated cranes. Light relay control is preferable to mechanical control, given the greater possibilities of cleaning.

8. Biosafety levels 3-4
This is not to be regarded as an emergency shower, because in cases of this kind showers are taken as a preventive measure, not necessarily preceded by any unwanted event.

9. Biosafety levels 1-4
A bench is the worktop where work is usually done, e.g. an open bench or a safety cabinet. To be easily cleanable, surfaces need to be smooth and impervious, joins included, and carpeting needs to include a covered skirting area.

10. Biosafety level 3
At biosafety level 3 wastewater can if necessary pass through a buffer with a disinfection facility before being discharged, thus preventing any escape of infectious agents into the drainage system. Laboratory facilities do not normally have drains.

12. Biosafety level 2
Autoclaves used at biosafety level 2 should not be too far away from the activities in which the organisms are used. Normally this means having the autoclave in the same building or complex of buildings.

If infected material needs to be transferred over considerable distances within a building, it is important that this can be done safely. This can mean using special transport vessels with clear marking and instructions to the washing

staff and others concerned. It is important that infected material should not be left in corridors or suchlike spaces but moved to the autoclave as soon as it leaves the work area.

13. Biosafety level 2
If equipment is pooled between activities at different biosafety levels, a risk assessment must be carried out to ascertain what is needed in order for this to be done safely.

14. Safety levels 1-4
If a microbiological safety cabinet is needed, it must be functionally tested so as not to give a false sense of security. The standard SS-EN 12469 "Biotechnology – Performance criteria for microbiological safety cabinets" describes type tests, installation tests and tests for annual operational control. AFS 2000:42 lays down that newly installed safety equipment shall be inspected to make sure that it is in working order before being taken into service. The various conditions prevailing on premises where a safety cabinet is installed can affect the way in which it works. In order, therefore, for an installation test to meet the stipulation, a protection factor test needs to be included. When a safety cabinet is moved or other conditions are altered, the installation tests may need to be repeated.

17. Biosafety level 2
Ordinary laboratory standard normally affords adequate protection against pests. If pests do occur, this is a sign that the protection is inadequate, in which case measures need to be taken to rectify the situation.

18. Biosafety levels 2-4
See also the guidance on Section 18, Additional information on signage.

19 and 20.
Protective clothing needs to be stored in a separate space. See also the guidance on Section 13.

21. Biosafety level 2
It is important that risk group 2 infectious agents be kept quite separate from other material and that they be clearly marked as provided in Section 11.

21. Biosafety levels 3-4
The permit application procedure includes a check to see that infectious agents are stored safely. Normally safe storage at biosafety level 3 means that the organism is kept inside the controlled area. Storage elsewhere is possible in special circumstances, provided adequate safety can be guaranteed. If, for example, a special low temperature freezer is used which is also used for storing biological agents for other projects or suchlike, special safety measures are needed. Safety can, for example, be maintained with locks, user restrictions for the freezer and placement of the material in a special freezer compartment. It is important to mark the freezer or the compartment in which the material is placed, to have routines for maintaining

good order and to mark the storage vessels used for the organisms according to a clear system known to everyone having access to the freezer.

22. Biosafety levels 1-4
Routines need to be adapted to assessed risks. See, e.g., Section 10 on decontamination, Sections 14-15 on information and instructions and Section 16 on unwanted events and contingency planning. See also the guidance on these various sections.

23. Biosafety level 1
Aerosols of biological agents can often pose a risk of hypersensitivity etc. Fungal spores, for example, are easily spread by air currents.

23. Biosafety level 2
Aerosol spread can be minimised by a working procedure which counteracts the formation of aerosols. In case where aerosol formation is unavoidable, it is important to decide what measures are needed to prevent aerosols from spreading. This can, for example, be achieved by using a safety cabinet and by using safety cups when centrifuging. See also Section 6, points 3 and 4.

24. Biosafety levels 1-4
See also Sections 10 and 11.

25. Biosafety levels 2-3
Solitary work, according to AFS 1982:3 Solitary Work, means that the person doing the work cannot contact other people in the workplace without using a technical means of communication, or otherwise cannot count on their help in a critical situation.

Solitary work ought not normally to occur at biosafety level 3. Routines which may be needed in order for solitary work to be permissible may be special instructions and skills for the person working alone, routines for informing someone outside the controlled area when solitary work begins and ends, an alarm installation, telephone contact and CCTV monitoring.

28. Biosafety levels 1-4
The measures needed can vary according to the type of animal used.

31. Biosafety levels 1-4
It is important that carcases should be incinerated in a facility with a high enough incineration temperature. Facilities for the incineration of conventional waste are not normally suitable. In cases where infected animals are to be incinerated elsewhere, they normally need to be decontaminated before transportation. Binding rules on the disposal of carcases are contained in Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption.

Guidance on App. 3 C, table 2, Protective measures when using biological agents in large-scale processes

This table is geared to large-scale processes, e.g. processes in which fermentors or other large cultivation vessels are used, but it may also need to be applied to medium-sized processes. Note that large-scale activities normally also include laboratory activity, e.g. for the upgrading of inoculation material, extraction of specimens for analysis etc. If so, protective measures as per table 1 apply to the laboratory part.

At biosafety level 2, where more than 500 litres culture medium is used simultaneously, the protective measures to be applied are decided following a permit application procedure. For volumes of less than 500 litres the employer, on the basis of the risk assessment, judges the protective measures needing to be applied as per App. 3 C. A combination of measures as per tables 1 and 2 can be appropriate in certain cases. The Work Environment Authority has to be notified if the activity is new or if an alteration has been made to an activity notified previously.

34. Biosafety levels 1-4
A closed system segregates the process from the surroundings. This can, for example, take the form of a fermentor or separation equipment. The degree of containment is determined according to the risk assessment. The stipulations concerning design of gaskets, valves, evacuation etc. rise with the biosafety level and are decided in connection with the permit application procedure for the use of biological agents in risk group 2 and above.

36 and 37.
See the guidance on Table 1, point 4.

40. Biosafety levels 1-4
A bench is the worktop where work is usually done, e.g. a laboratory bench or a safety cabinet.

45. Biosafety level 3
When presenting the contingency plan and measures for the prevention of unwanted events, the employer may need to indicate whether there are special reasons why an emergency power supply should not be needed.

47.
Cf. the guidance on table 1, point 7.

48. Biosafety levels 3-4
This is not to be regarded as an emergency shower, since in these instances a shower is taken as a preventive measure, and accordingly does not presuppose any unwanted event.

54. Biosafety levels 1-4

The reference here is to downstream processing, i.e. upgrading and purification of substances for as long as biological agents can remain, and to the extent to which the entire chain of handling operations is confined to a closed system.

56. Biosafety levels 2-3
Solitary work, according to AFS 1982:3 Solitary Work, means that the person doing the work cannot contact other people in the workplace without using a technical means of communication, or otherwise cannot count on their help in a critical situation.

Solitary work ought not normally to occur at biosafety level 2 large scale. Routines which may be needed in order for solitary work to be permissible may be special instructions and skills for the person working alone, routines for informing someone outside the controlled area when solitary work begins and ends, an alarm installation, telephone contact and CCTV monitoring.

Guidance on App. 4, Particulars furnished in notification

The particulars furnished in the notification are very similar to those in the permit application but do not generally need to be as detailed. See relevant parts of the guidance on Section 29 and App. 5 concerning particulars furnished in permit applications.

Guidance on App. 5, Particulars furnished in permit applications

Further guidance on permit applications is obtainable from www.av.se, subject field *Mikrobiologiska arbetsmiljörisker*, under the heading *Anmälan och tillstånd* (in swedish).

Guidance on the various points in App. 5:

1. The employer is the party ultimately responsible, which also includes legal persons, e.g. universities or companies.

2. Here the street address is given of the part of the worksite where the activity subject to a permit is carried on.

3. Section 6 of AFS 2001:1 Systematic Work Environment Management requires the employer to allot tasks to managers, supervisory staff or other employees tasked with preventing risks and achieving a satisfactory work environment. Where there are several such persons, it is important to make clear the duties of each and every one of them. In larger organisations it may be appropriate to appoint someone with general duties of co-ordinating biosafety issues and giving support to other associates.

4. A description of the nature of the activity can include particulars of its purpose, e.g. diagnosis, production or research. Research projects and

production activities can be further specified, as can diagnosis where particular biological agents are involved.

5. See the guidance on Sections 4-5.

6. The handling and safety instructions are to be addressed to the employees concerned. See the guidance on Section 15 and App. 3 concerning protective measures.

7. The description of facilities and technical devices can, for example, include process equipment, ventilation system, surfacing, devices for preventing the spread of aerosols and spillage and devices for personal hygiene. To facilitate assessment of whether facilities and equipment can afford adequate protection against the risks liable to occur, the description can very well comprise drawings and flow charts as well as descriptive text. The process equipment may, for example, take the form of cultivation vessels, disintegrators, centrifuges and autoclaves. Devices for personal hygiene comprise changing rooms, showers, hand-wash facilities and suchlike. See also App. 3 C.

8. Technical controls can, for example, mean the inspection of ventilation systems, microbiological safety cabinets and autoclaves.

9. See the guidance on Section 17.

10. An approximate number, e.g. fewer than 5, may suffice.

11. Permits are normally granted for a period of 3 or at most 5 years. First-time permits, or permits relating to special conditions, may be issued for shorter periods.

12. The provisions of App. 5, point 12, mean that if there is no safety delegate in the workplace, a statement is to be appended from a regional safety delegate, if one exists. The statement should make clear whether the safety delegate seconds a permit as per the application papers. If the permit is not seconded, the reasons for this should be given in the statement.

The Work Environment Authority may require further particulars if needed in order to decide the matter.

Information from the Work Environment Authority

Current rules

Acts, Ordinances and Provisions being subject to revision or replacement by other statutes, it is important to keep oneself updated concerning the instruments in force. When revised, Acts and Ordinances often retain their reference number in the Swedish Statue Code (SFS). The Work Environment Act, for example, is assigned SFS number 1977:1160, despite having been revised many times since 1977.

To find the text of the current (consolidated) Act or Ordinance, one can, for example, visit www.lagrummet.gov se and look up the full text of the latest version of the Acts or Ordinances concerned.

One good way of keeping abreast of the rules issued by the Swedish Work Environment Authority is by regularly visiting its website (www.av.se) and checking, under “Legislation” or “Regler”, which rules apply to the activity concerned. Particulars of the relevant rules are also obtainable from the publication service and can be ordered from Arbetsmiljöverket., Publikationsservice, Box 1300, SE-171 25 SOLNA, fax +46(0)8-735 85 55, tel. +46-(0)8-730 97 00. Publications can also be ordered from www.av.se under the heading “Publications”.

Please note that documents on the Internet are liable to contain inaccuracies and that only the printed text is legally valid.

Acts and Ordinances

The Work Environment Act, with amendments (SFS 1977:1160)
(The Work Environment Act, in consolidated form and with guidance commentaries, is published regularly by the Swedish Work Environment Authority.)
The Work Environment Ordinance, with amendments (SFS 1977:1166)
The Waste Ordinance, with amendments (SFS 2001:1063)
Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption
The Accidents (Protection) Act (SFS 2003:778)
The Infectious Diseases (Protection) Act (SFS 2004:168)
he Infectious Diseases (Protection) Ordinance (SFS 2004:255)

Provisions (AFS) issued by the Swedish Work Environment Authority (formerly the Swedish National Board of Occupational Safety and Health)

Use of Personal Protective Equipment (AFS 2001:3)
Work in Confined Spaces (AFS 1993:3)
Work with Laboratory Animals (AFS 1990:11)

Design of the Workplace (AFS 2000:42)
Sewer Systems (AFS 1984:15)
Ergonomics for the Prevention of Musculoskeletal Disorders (AFS 1998:1)
Solitary Work (AFS 1982:3)
First Aid and Crisis Support (AFS 1999:7)
Gas Cylinders (AFS 2001:4)
Pregnant and Breast-Feeding Employees (AFS 1994:32)
Contained Use of Genetically Modified Micro-Organisms (AFS 2000:5)
Chemical Hazards in the Working Environment (AFS 2000:4)
Chemical Laboratory Work (AFS 1997:10)
Minors at Work (AFS 1996:1)
Organic Dust in Agriculture (AFS 1994:11)
Protection against Bloodborne Infections (AFS 1986:23)
Systematic Work Environment Management (AFS 2001:1)
Pressure-Retaining Devices (AFS 1999:4)
Pressure Vessels (AFS 1999:6)
Wood Mould (AFS 1988:6)
Safety Signs and Warning Signals at Workplaces (AFS 1997:11)

Examples of rules from the statute books of other national authorities

The National Board of Health and Welfare

SOSFS 1999:27 om hantering av smittförande avfall från hälso- och sjukvården.

SOSFS 2001:8 om försiktighetsmått vid hantering och märkning av sådant biologiskt avfall som kan medföra olägenhet för människors hälsa enligt miljöbalken.

The Swedish Rescue Services Agency

SRVFS 2002:1 om transport av farligt gods på väg och i terräng. (Updated regularly.)

The Swedish Board of Agriculture

SJVFS 2003:71 om förebyggande åtgärder avseende zoonoser

Current literature, guides etc.

(H-numbered publications can be ordered from Arbetsmiljöverkets publikationsservice. See further www.av.se Publikationer/Publications)
Arbetsmiljöansvar och straffansvar – två helt olika saker, Arbetsmiljöverket 2003, H302
Desinfektion på arbetsplatsen, Arbetsmiljöverket 1999, H338
Din personliga skyddsutrustning, Arbetsmiljöverket 2003, H349
Laboratory Biosafety Manual, second edition, World Health Organization, Geneva 1993 ISBN 92 4 154450 3

AFS2005:1

Mikroorganismer i arbetsmiljön, www.prevent.se
Smittskyddsboken, Studentlitteratur, 2003 H376
Socialstyrelsens rapport 1998:12 med kunskapsunderlag om att förebygga infektioner i vården

On www.av.se under ”ämnesområden” there is a subject page (in Swedish) on microbiological work environment risks giving additional guidance material and links to other authorities. Another subject page deals with sick buildings.

Standards

If a procedure according to a standard fails to comply with the rules of Swedish legislation, the national rules apply.
Examples of standards:
SS-EN 12469, “Biotechnology – Performance criteria for microbiological safety cabinets”.
SS-EN 13098, “Workplace atmosphere – Guidelines for measurement of airborne micro-organisms and endotoxin”.
SS-EN 14031, “Workplace atmospheres - Determination of airborne endotoxins”.