L.N. 228 of 2003

OCCUPATIONAL HEALTH AND SAFETY AUTHORITY ACT (CAP. 424)

Protection of Workers from Risks related to Exposure to Biological Agents at Work Regulations, 2003

IN EXERCISE of the powers conferred by article 12 of the Occupational Health and Safety Authority Act, the Deputy Prime Minister and Minister of Social Policy, in consultation with the Occupational Health and Safety Authority, has made the following regulations:-

Citation and scope.

1. (1) The title of these regulations is the Protection of Workers from Risks related to Exposure to Biological Agents at Work Regulations, 2003.

(2) The scope of these regulations is to protect workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to biological agents at work.

(3) These regulations lay down particular minimum provisions in this area without prejudice to any laws, regulations or other legislative provisions stipulating general principles concerning the prevention of occupational risks, the protection of health and safety, the elimination of risk and accident factors, the information to, consultation, balanced participation and training of workers and their representatives.

(4) These regulations shall also be without prejudice to other regulations that may be issued on the contained use of genetically modified micro-organisms or on the deliberate release in the environment of genetically modified organisms.

2. In these regulations, unless the context otherwise requires: Interpretation

'Act' means the Occupational Health and Safety Authority Act; Cap. 424

"Authority" means the Occupational Health and Safety Authority established by section 8 of the Act;

'biological agents' means micro-organisms, including those which have been genetically modified, cell cultures and human endoparasites, which may be able to provoke any infection, allergy or toxicity, and which shall be classified into the following four risk groups, according to their level of risk of infection:

(i) group 1 biological agent means an agent that is unlikely to cause human disease;

(ii) group 2 biological agent means an agent that can cause human disease and might be a hazard to workers; it is unlikely to spread to the community; there is usually effective prophylaxis or treatment available;

(iii) group 3 biological agent means an agent that can cause severe human disease and present a serious hazard to workers; it may present a risk of spreading to the community, but there is usually effective prophylaxis or treatment available;

(iv) group 4 biological agent means an agent that causes severe human disease and is a serious hazard to workers; it may present a high risk of spreading to the community; there is usually no effective prophylaxis or treatment available.

'cell culture' means the in-vitro growth of cells derived from multicellular organisms;

'micro-organism' means a microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material.

Determination and assessment of risks

3. (1) These regulations shall apply to activities in which workers are, or are potentially exposed to biological agents as a result of their work.

(2) (a) In the case of any activity likely to involve a risk of exposure to biological agents, the nature, degree and duration of workers' exposure must be determined in order to make it possible to assess any risk to the workers' health or safety and to lay down the measures to be taken.

(b) In the case of activities involving exposure to several groups of biological agents, the risk shall be assessed on the basis of the danger presented by all hazardous biological agents present.

(c) The assessment must be renewed regularly and in any event when any change occurs in the conditions that may affect workers' exposure to biological agents.

(d) The employer must supply the Authority, at its request, with the information used for making the assessment.

(3) The assessment referred to in sub-regulation (2) shall be conducted on the basis of all available information including:

(a) the classification of biological agents which are, or which may be a hazard to human health, as referred to in regulations 17 and 18 ;

(b) any recommendations from the Authority which indicate that the biological agent should be controlled in order to protect workers' health when workers are or may be exposed to such a biological agent as a result of their work;

(c) information on diseases which may be contracted as a result of the work of the workers;

(d) potential allergenic or toxigenic effects as a result of the work of the workers;

(e) knowledge of a disease from which a worker is found to be suffering

and which has a direct connection with his work.

Application of various regulations in relation to assessment of risks

4. (1) If the results of the assessment referred to in regulation 3 show that the exposure and, or potential exposure is to a group 1 biological agent, with no identifiable health risk to workers, regulations 5 to 16 and regulation 17 shall not apply. However, point 1 of Schedule VI should be observed.

(2) If the results of the assessment referred to in regulation 3 show that the activity does not involve a deliberate intention to work with or use a biological agent but may result in the workers being exposed to a biological agent, as in the course of the activities for which an indicative list is given in Schedule I, regulations 5, 7, 8, 10, 11, 12, 13 and 14 shall apply unless the results of the assessment referred to in regulation 3 show them to be unnecessary.

Avoiding the use of harmful biological agents

5. The employer shall avoid the use of a harmful biological agent if the nature of the activity so permits, by replacing it with a biological agent that, under its conditions of use, is not dangerous or is less dangerous to workers' health, as the case may be, in the present state of knowledge.

Reduction of risks

6. (1) Where the results of the assessment referred to in regulation 3 reveal a risk to workers' health or safety, workers' exposure must be prevented.

(2) Where this is not technically practicable, having regard to the activity and the risk assessment referred to in regulation 3, the risk of exposure must be reduced to as low a level as necessary in order to protect adequately the health and safety of the workers concerned, in particular by the following measures which are to be applied in the light of the results of the assessment referred to in regulation 3:

(a) keeping as low as possible the number of workers exposed or likely to be exposed;

(b) by the design of work processes and engineering control measures so as to avoid or minimise the release of biological agents into the place of work;

(c) taking of collective protection measures and, or, where exposure cannot be avoided by other means, individual protection measures;

(d) adopting hygiene measures compatible with the aim of the prevention or

reduction of the accidental transfer or release of a biological agent from the workplace;

(e) by the use of the biohazard sign depicted in Schedule II and other relevant warning signs;

(f) the drawing up of plans to deal with accidents involving biological agents;

(g) testing, where it is necessary and technically possible, for the presence, outside the primary physical confinement, of biological agents used at work;

(h) providing means for safe collection, storage and disposal of waste by workers including the use of secure and identifiable containers, after suitable treatment where appropriate;

(i) making arrangements for the safe handling and transport of biological agents within the workplace.

Information for the Authority

7. (1) Where the results of the assessment referred to in regulation 3 reveal risk to workers' health or safety, employers shall, when requested, give to the Authority appropriate information on:

(a) the results of the assessment;

(b) the activities in which workers have been exposed or may have been exposed to biological agents;

(c) the number of workers exposed;

(d) the name and capabilities of the person responsible for health and safety at work;

(e) the protective and preventive measures taken, including working procedures and methods;

(f) an emergency plan for the protection of workers from exposure to group 3 or a group 4 biological agent which might result from a loss of physical containment.

(2) Employers shall inform forthwith the Authority of any accident or incident which may have resulted in the release of a biological agent and which could cause severe human infection and, or illness.

(3) The list referred to in regulation 11 and the medical record referred to in regulation 14 shall be made available to the Authority in cases where the undertaking ceases activity.

Personal hygiene and individual protection

8. (1) Employers shall be obliged, in the case of all activities for which there is a risk to the health or safety of workers due to work with biological agents, to take appropriate measures to ensure that:

(a) workers do not eat or drink in working areas where there is a risk of contamination by biological agents;

(b) workers are provided with appropriate protective clothing or other appropriate special clothing;

(c) workers are provided with appropriate and adequate washing and toilet facilities, which may include eye washes and, or skin antiseptics;

(d) any necessary protective equipment is:

i) properly stored in a well-defined place,

ii) checked and cleaned if possible before,and in any case after, each use,

iii) is repaired, where defective, or is replaced before further use;

(e) procedures are specified for taking, handling and processing samples of human or animal origin.

(2) (a) Working clothes and protective equipment, including protective clothing referred to in sub-regulation (1), which may be contaminated by biological agents, must be removed on leaving the working area and, before taking the measures referred to in the second subparagraph, kept separately from other clothing.

(b) The employer must ensure that such clothing and protective equipment is decontaminated and cleaned or, if necessary, destroyed.

(3) Workers may not be charged for the cost of any of the measures referred to in these regulations.

Information and training of workers

9. (1) Appropriate measures shall be taken by the employer to ensure that workers and, or any workers' representatives in the undertaking or establishment receive sufficient and appropriate training, on the basis of all available information, in particular in the form of information and

instructions, concerning:

(a) potential risks to health;
(b) precautions to be taken to prevent exposure;
(c) hygiene requirements;
(d) wearing and use of protective equipment and clothing;
(e) steps to be taken by workers in the case of incidents and to prevent incidents.

(2) The training shall be:
(a) given at the beginning of work involving contact with biological agents,
(b) adapted to take account of new or changed risks, and
(c) repeated periodically if necessary.

Worker information in particular cases

10. (1) Employers shall provide written instructions at the workplace and, if appropriate, display notices which shall, as a minimum, include the procedure to be followed in the case of:

(a) a serious accident or incident involving the handling of a biological agent;
(b) handling a group 4 biological agent.

(2) Workers shall immediately report any accident or incident involving the handling of a biological agent to the person in charge, or to the person responsible for health and safety at work.

(3) (a) Employers shall inform forthwith the workers and, or any workers' representatives of any accident or incident which may have resulted in the release of a biological agent and which could cause severe human infection and, or illness.

(b) In addition, employers shall inform the workers and, or any workers' representatives in the undertaking or establishment as quickly as possible when a serious accident or incident occurs, of the causes thereof and of the measures taken or to be taken to rectify the situation.

(4) Each worker shall have access to the information on the list referred to

in regulation 11 that relates to him personally.

(5) Workers and, or any workers' representatives in the undertaking or establishment shall have access to anonymous collective information.

(6) Employers shall provide workers and, or their representatives, at their request, with the information provided for in regulation 7(1).

List of exposed workers

11. (1) Employers shall keep a list of workers exposed to group 3 and, or group 4 biological agents, indicating the type of work done and, whenever possible, the biological agent to which they have been exposed, as well as records of exposures, accidents and incidents, as appropriate.

(2) (a) The list referred to in paragraph 1 shall be kept for at least 10 years following the end of exposure.

(b) In the case of those exposures which may result in infections:

(i) with biological agents known to be capable of establishing persistent or latent infections;
(ii) that, in the light of present knowledge, are undiagnosable until illness develops many years later;
(iii) that have particularly long incubation periods before illness develops;
(iv) that result in illnesses which recrudesce at times over a long period despite treatment, or
(v) that may have serious long-term sequelae,

the list shall be kept for an appropriately longer time up to 40 years following the last known exposure.

(3) The doctor referred to in regulation 14 and, or the Authority and any other person responsible for health and safety at that particular place of work, shall have access to the list referred to in sub-regulation (1).

Consultation and participation of workers

12. (1) Employers shall consult workers and, or their representatives and allow them to take part in discussions on all questions relating to health and safety at work. This presupposes:

- the consultation of workers,

- the right of workers and, or their representatives to make proposals, and to balanced participation in accordance with applicable laws and, or practices.

(2) Workers or workers' representatives with specific responsibility for the health and safety of workers shall take part in a balanced way, in accordance with applicable laws and, or practices, or shall be consulted in advance and in good time by the employer with regard to:

(a) any measure which may substantially affect health and safety;

(b) the designation of worker or workers which the employer is obliged to designate to carry out activities related to the protection and prevention of occupational risks for the undertaking and, or establishment and the workers which the employer is obliged to designate to implement measures inter alia, for first aid, fire-fighting and the evacuation of workers, and the activities related to the protection and prevention of occupational risks;

(c) the following information:

(i) an assessment of the risks to health and safety at work, including those facing groups of workers exposed to particular risks;

(ii) the protective measures to be taken and, if necessary, the protective equipment to be used;

(iii) a list of occupational accidents resulting in a worker being unfit for work for more than three working days;

(iv) reports on occupational accidents suffered by his workers;

(v) the health and safety risks and protective and preventive measures and activities in respect of both the undertaking and, or establishment in general and each type of workstation and, or job;

(vi) the measures taken in relation to first aid, fire-fighting and the evacuation of workers;

(vii) the appropriate measures taken so that employers of workers

from any outside undertakings and, or establishments engaged in work in his undertaking and, or establishment receive adequate information concerning the points referred to in sub-paragraphs (v) and (vi);

(viii) the appropriate measures taken so that workers with specific functions in protecting the health and safety of workers, or workers' representatives with specific responsibility for the health and safety of workers may be able to have access, to carry out their functions and to:

- the risk assessment and protective measures referred to in sub-paragraphs (v) and (vi) above;
- the list and reports referred to in sub-paragraphs (iii) and (iv) above;
- the information yielded by protective and preventive measures, inspection agencies and bodies responsible for health and safety;

(d) the enlistment, where appropriate, of the competent services or persons outside the undertaking and, or establishment, where such protective and preventive measures cannot be organized for lack of competent personnel in the undertaking and, or establishment;

(e) the planning and organization of the training to each worker regarding adequate health and safety training, in particular in the form of information and instructions specific to his workstation or job:

- on recruitment,

- in the event of a transfer or a change of job,

- in the event of the introduction of new work equipment or a change in equipment,

- in the event of the introduction of any new technology.

(3) Workers' representatives with specific responsibility for the health and safety of workers shall have the right to ask the employer to take appropriate measures and to submit proposals to him to that end to mitigate hazards for workers and, or to remove sources of danger.

(4) The workers referred to in subregulation (2) and the workers' representatives referred to in subregulation (2) and (3) may not be placed at

a disadvantage because of their respective activities referred to in subregulations (2) and (3).

(5) Employers must allow workers' representatives with specific responsibility for the health and safety of workers adequate time off work, without loss of pay, and provide them with the necessary means to enable such representatives to exercise their rights and functions.

(6) Workers and, or their representatives are entitled to appeal, in accordance with relevant legislation law and, or practice, to the Authority if they consider that the measures taken and the means employed by the employer are inadequate for the purposes of ensuring health and safety at work. Workers' representatives must be given the opportunity to submit their observations during inspection visits by the Authority.

Prior notification to the Authority

13. (1) (a) Prior notification shall be made to the Authority of the use for the first time of:

(i) group 2 biological agents;

(ii) group 3 biological agents;

(iii) group 4 biological agents.

(b) The notification shall be made at least 30 days before the commencement of the work.

(c) Subject to subregulation (2), prior notification shall also be made of the use for the first time of each subsequent group 4 biological agent and of any subsequent new group 3 biological agent where the employer himself provisionally classifies that biological agent.

(2) Laboratories providing a diagnostic service in relation to group 4 biological agents shall be required only to make an initial notification of their intention.

(3) Renotification must take place in any case where there are substantial changes of importance to safety or health at work to processes and, or procedures which render the notification out of date.

(4) The notification referred to in sub-regulations (1), (2) and (3) shall include:

(a) the name and address of the undertaking and, or establishment;
(b) the name and capabilities of the person responsible for health and safety at work;
(c) the results of the assessment referred to in regulation 3;
(d) the species of the biological agent;
(e) the protection and preventive measures that are envisaged.

Health surveillance

14. (1) Where the results of the assessment referred to in regulation 3 reveal a risk to health or safety, an employer shall make arrangements so that each of the workers involved shall be able to undergo relevant health surveillance:

(i) prior to exposure;
(ii) at regular intervals thereafter.

(b) Those arrangements shall be such that it is directly possible to implement individual and occupational hygiene measures.

(2) (a) The assessment referred to in regulation 3 should identify those workers for whom special protective measures may be required.

(b)When necessary, effective vaccines should be made available for those workers who are not already immune to the biological agent to which they are exposed or are likely to be exposed.

(c) When employers make vaccines available, they should take account of the recommended code of practice set out in Schedule VII.

(d) If a worker is found to be suffering from an infection and, or illness which is suspected to be the result of exposure, the doctor or the employer shall offer such surveillance to other workers who have been similarly exposed.

(e) In that event, a reassessment of the risk of exposure shall be carried out in accordance with regulation 3.

(3) (a) In cases where health surveillance is carried out, an individual medical record shall be kept for at least 10 years following the end of exposure.

(b) In the special cases referred to in paragraphs (a) to (e) of regulation 11(2), an individual medical record shall be kept for an appropriately longer time up to 40 years following the last known exposure.

(4) The doctor or the Authority may propose any protective or preventive measures to be taken in respect of any individual worker.

(5) Information and advice must be given to workers regarding any health surveillance, which they may undergo following the end of exposure.

(6) Saving any other applicable laws and, or regulations:

(a) workers shall have access to the results of the health surveillance which concern them, and
(b) the workers concerned or the employer may request a review of the results of the health surveillance.

(7) Practical recommendations for the health surveillance of workers are given in Schedule IV.

(8) All cases of diseases or death identified in accordance with applicable laws and, or regulations as resulting from occupational exposure to biological agents shall be notified to the Authority.

Health and veterinary care facilities other than diagnostic laboratories

15. (1) For the purpose of the assessment referred to in regulation 3, particular attention should be paid to:

(a) uncertainties about the presence of biological agents in human patients or animals and the materials and specimens take from them;

(b) the hazard represented by biological agents known or suspected to be present in human patients or animals and materials and specimens taken from them;

(c) the risks posed by the nature of the work.

(2) (a) Appropriate measures shall be taken in health and veterinary care facilities in order to protect the health and safety of the workers concerned.

(b) The measures to be taken shall include in particular:

(i) specifying appropriate decontamination and disinfection procedures, and

(ii) implementing procedures enabling contaminated waste to be handled and disposed of without risk.

(3) In isolation facilities where there are human patients or animals who are, or who are suspected of being, infected with group 3 or group 4 biological agents, containment measures shall be selected from those in Schedule V column A, in order to minimise the risk of infection.

Special measures for industrial processes, etc

16. (1) The following measures must be taken in laboratories, including diagnostic laboratories, and in rooms for laboratory animals which have been deliberately infected with group 2, 3 or 4 biological agents or which are or are suspected to be carriers of such agents:-

(a) Laboratories carrying out work which involves the handling of group 2, 3 or 4 biological agents for research, development, teaching or diagnostic purposes shall determine the containment measures in accordance with Schedule V, in order to minimise the risk of infection.

(b) Following the assessment referred to in regulation 3, measures shall be determined in accordance with Schedule V, after fixing the physical containment level required for the biological agents according to the degree of risk.

Activities involving the handling of a biological agent must be carried out only:

(i) in working areas corresponding to at least containment level 2, for a group 2 biological agent,

(ii) in working areas corresponding to at least containment level 3, for a group 3 biological agent,

(iii) in working areas corresponding to at least containment level 4, for a group 4 biological agent.

(c) Laboratories handling materials in respect of which there exist uncertainties about the presence of biological agents which may cause human disease but which do not have as their aim working with biological agents as such (i.e. cultivating or concentrating them) should adopt containment level 2 at least. Containment levels 3 or 4 must be used, when appropriate, where it is known or it is suspected that they are necessary, except where guidelines that may be issued from time to time by the Authority show that, in certain cases, a lower containment level is appropriate.

(2) The following measures concerning industrial processes using group 2, 3 or 4 biological agents must be taken:

(a) The containment principles set out in the second subparagraph of paragraph 1(b) should also apply to industrial processes on the basis of the practical measures and appropriate procedures given in Schedule VI.

(b) In accordance with the assessment of the risk linked to the use of group 2, 3 or 4 biological agents, the Authority may decide on appropriate measures which must be applied to the industrial use of such biological agents.

(3) For all activities covered by paragraphs 1 and 2 where it has not been possible to carry out a conclusive assessment of a biological agent but concerning which it appears that the use envisaged might involve a serious health risk for workers, activities may only be carried out in workplaces where the containment level corresponds at least to level 3.

17. The Minister may by order authorise the Authority to give access to the Commission of the European Communities of the use made by it of the information referred to in regulation 14(8). Use of data

18. (1) Biological agents shall be classified in accordance with the relative Community classification. Classification of biological agents

(2) In the absence of Community classification the Authority shall classify biological agents that are or may be a hazard to human health on the basis of the definition of biological agents in regulation 2, points 2 to 4 (groups 2 to 4).

(3) If the biological agent to be assessed cannot be classified clearly in one of the groups referred to in sub-regulation (2), it must be classified in the highest risk group among the alternatives.

19. In any proceedings for an offence under these regulations consisting of a failure to comply with a duty or requirement to do something, or to do something so far as is reasonably practicable, it shall be for the accused to prove (as the case may be) that it was not practicable or not reasonably practicable to do more than was in fact done to satisfy the duty or requirement, or that there was no better practicable means than was in fact used to satisfy the duty or requirement. Onus of proof

20. Any person who knowingly or recklessly interferes with the process of providing a safe and healthy place of work, shall be guilty of an offence. Offences

SCHEDULE I
INDICATIVE LIST OF ACTIVITIES
(Regulation 4)

1. Work in food production plants.
2. Work in agriculture.
3. Work activities where there is contact with animals and, or products of animal origin.
4. Work in healthcare, including isolation and post-mortem units.
5. Work in clinical, veterinary and diagnostic laboratories, excluding diagnostic microbiological laboratories.
6. Work in refuse disposal plants.
7. Work in sewage purification installations.

SCHEDULE II

BIOAZZARD SIGN

(Regulation 6)

Biological risk

SCHEDULE III
CLASSIFICATION
Regulation 2 (definition of biological agents) and Regulation 18

INTRODUCTORY NOTES

1. In line with the scope of these regulations, only agents which are known to infect humans are to be included in the classified list.

   Where appropriate, indicators are given of the toxic and allergic potential of these agents.

   Animal and plant pathogens which are known not to affect man are excluded.

   In drawing up this list of classified biological agents consideration has not been given to genetically modified micro-organisms.

2. The list of classified agents is based on the effect of those agents on healthy workers.

   No specific account is taken of particular effects on those whose susceptibility may be affected for one or other reason such as pre-existing disease, medication, compromised immunity, pregnancy or breast feeding.

   Additional risk to such workers should be considered as part of the risk assessment required by these regulations.

   In certain industrial processes, certain laboratory work or certain work with animals involving actual or potential exposure to biological agents of groups 3 or 4, any technical precautions taken must comply with regulation 15 of these regulations.

3. Biological agents which have not been classified for inclusion in groups 2 to 4 of the list are not implicitly classified in group 1.

   For agents where more than one species is know to be pathogenic to man, the list will include those species which are know to be the most frequently responsible for diseases, together with a more generic reference to the fact that other species of the same genus may affect health.

   When a whole genus is mentioned in the classified list of biological agents, it is implicit that the species and strains know to be non-pathogenic are excluded.

4. Where a strain is attenuated or has lost known virulence genes, then the containment required by the classification of its parent strain need not necessarily apply, subject to assessment appropriate for risk in the workplace.

   This is the case, for example, when such a strain is to be used as a product or part of a product for prophylactic or therapeutic purposes.

5. The nomenclature of classified agents used to establish this list reflects and is in conformity with the latest international agreements of the taxonomy and nomenclature of agents at the time the list was prepared.

6. The list of classified biological agents reflects the state of knowledge at the time that it was devised.

   It will be updated as soon as it no longer reflects the latest state of knowledge.

7. All viruses which have already been isolated in humans and which have not been assessed and allocated in this Schedule shall be deemed to fall within group 2 as a minimum, except in those cases where there is sufficient proof that they are unlikely to cause disease in humans.

8. Certain biological agents classified in group 3 which are indicated in the appended list by *two asterisks (**)*, may present a limited risk of infection for workers because they are not normally infectious by the airborne route.

   The Authority shall assess the containment measures to be applied to such agents, taking account of the nature of specific activities in question and of the quantity of the agent involved, with a view to determining whether, in particular circumstances, some of these measures may be dispensed with.

9. The requirements as to containment consequent on the classification of parasites apply only to stages in the life cycle of the parasite in which it is liable to be infectious to humans at the workplace.

10. This list also gives a separate indication in cases where the biological agents are likely to cause allergic or toxic reactions, where an effective vaccine is available, or where it is advisable to keep a list of exposed workers for more than 10 years.

    These indications are shown by the following letters:

    A: Possible allergic effects

    D: List of workers exposed to this biological agent to be kept for more than 10 years after the end of last known exposure

    T: Toxin production

    V: Effective vaccine available

    The application of preventive vaccination should take account of the code of practice given in Schedule VII.

BACTERIA
and similar organisms

NB: For biological agents appearing on this list, 'spp.' refers to other species which are know pathogens in humans.

Biological agent	Classification	Notes
Actinobacillus actinomycetemcomitans	2	
Actinomadura madurae	2	
Actinomadura pelletieri	2	
Actinomyces gerencseriae	2	
Actinomyces israelii	2	
Actino myces pyogenes	2	
Actinomyces spp.	2	
Arcanobacterium haemolyticum (Corynebacterium haenolyticum)	2	
Bacillus anthracic	3	
Bacteroides fragilis	2	
Bartonella bacillifonnis	2	
Bartonella quintana (Rochalimaea quintana)	2	
Bartonella (Rochalinea) 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 (Pseudomonas 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 diphtheriae	2	T, V

Corynebacterium minutissimum	2	
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	
Enterobacter 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 (**)	
Flavobacterium meningosepticum	2	
Fluoribacter bozemanae (Legionella)	2	
Francisella tularensis (Type A)	3	
Francisella tularensis (Type B)	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	
Listeria monocytogenes	2	
Listeria ivanovii	2	
Morganella morganii	2	
Mycobacterium africanum	3	V
Mycobacterium avium/intracellulare	2	
Mycobacterium bovis (except BCG strain)	3	V
Mycobacterium chelonae	2	
Mycobacterium fortuitum	2	
Mycobacterium kansasii	2	
Mycobacterium leprae	3	
Mycobacterium malmoense	2	
Mycobacterium marinum	2	
Mycobacterium microti	3 (**)	
Mycobacterium paratuberculosis	2	
Mycobacterium scrofulaceum	2	
Mycobacterium simiae	2	
Mycobacterium szulgai	2	
Mycobacterium tuberculsis	3	V

Mycobacterium ulcerans	3 (**)	
Mycobacterium xenopi	2	
Mycoplasma caviae	2	
Mycoplasma hominis	2	
Mycoplasma pneumoniae	2	
Neisseria gonorrhoeae	2	
Neisseria meningitidis	2	V
Nocardia asteroides	2	
Nocardia brasiliensis	2	
Nocardia farcinica	2	
Nocardia nova	2	
Nocardia otitidiscaviarum	2	
Pasteurella multocida	2	
Pasteurella spp.	2	
Peptostreptococcus anaerobius	2	
Plesiomonas shigelloides	2	
Porphyromonas spp.	2	
Prevotella spp.	2	
Proteus mirabilis	2	
Proteus penneri	2	
Proteus vulgaris	2	
Providencia alcalifaciens	2	
Providencia rettgeri	2	
Providencia spp.	2	
Pseudomonas aeruginosa	2	
Rhodococcus equi	2	
Rickettsia akari	3 (**)	
Rickettsia canada	3 (**)	
Rickettsia conorii	3	
Rickettsia montana	3 (**)	
Rickettsia typhi (Rickettsia mooseri)	3	
Rickettsia prowazekii	3	
Rickettsia rickettsii	3	
Rickettsia tsutsugamushi	3	
Rickettsia spp.	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 boydii	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	
Yersinia pestis	3	V
Yersinia pseudotuberculosis	2	
Yersinia spp.	2	
(**)See paragraph 8 of the introductory notes.		

VIRUSES (*)

Biological Agent	Classification	Notes
Adenoviridae	2	
Arenaviridae		
LCM-Lassa-virus complex (old world arena viruses):		
Lassa virus	4	
Lymphocytic (strains)	3	
Lymphocytic choriomeningitis virus (other strains)	2	
Mopeia virus	2	
Other LCM-Lassa complex viruses	2	
Tacaribe-Virus-complex (new world arena viruses):		
Guanarito virus	4	
Junin virus	4	
Sabia virus	4	
Machupo virus	4	
Flexal virus	3	
Other Tacaribe complex viruses	2	
Astroviridae	2	
Bunyaviridae		
Belgrade (also known as Dobrava)	3	
Bhanja	2	
Bunyamwera virus	2	
Germiston	2	
Oropouche virus	3	
Sin Nombre (formerly Muerto Canyon)	3	
California encephalitis virus	2	
Hantaviruses:		

Hantaan (Korean haemorrhagic fever)	3	
Seoul virus	3	
Puumala virus	2	
Prospect Hill virus	2	
Other hantaviruses	2	
Nairoviruses:		
Crimean-Congo haemorrhagic fever	4	
Hazara virus	2	
Phleboviruses:		
Rift Valley fever	3	V
Sandfly fever	2	
Toscana virus	2	
Other bunyaviridae known to be pathogenic	2	
Caliciviridae		
Hepatitis E virus	3 (**)	
Norwalk virus	2	
Other Caliciviridae	2	
Coronaviridae	2	
Filoviridae		
Ebola virus	4	
Marburg virus	4	
Flaviviridae		
Australia encephalitis (Murray Valley encephalitis)	3	
Central European tick-borne encephalitis virus	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	V
Louping ill	3 (**)	
Omsk (a)	3	V
Powassan	3	
Rocio	3	
Russian spring-summer encephalitis (TBE)(a)	3	V
St Louis encephalitis	3	
Wesselsbron virus	3 (**)	
West Nile fever virus	3	
Yellow fever	3	V
Other flaviviruses known to be pathogenic	2	
Hepadnaviridae		
Hepatitis B virus	3 (**)	V,D
Hepatitis D virus (Delta)(b)	3 (**)	V,D
Herpesviridae		

Cytomegalovirus	2	
Epstein-Barr virus	2	
Herpesvirus simiae (B virus)	3	
Herpes simplex virus types 1 and 2	2	
Herpesvirus varicella-zoster	2	
Human B-lymphotropic virus (HBLV-HHV6)	2	
Human herpes virus 7	2	
Human herpes virus 8	2	D
Orthomyxoviridae		
Influenza viruses types A,B and C	2	V (c)
Tick-borne orthomyxoviridae :Dhori and Thogoto	2	
Papovaviridae		
BK and JC viruses	2	D (d)
Human papillomaviruses	2	D (d)
Paramyxoviridae		
Measles virus	2	V
Mumps virus	2	V
Newcastle disease virus	2	
Parainfluenza viruses types 1 to 4	2	
Respiratory syncytial virus	2	
Parvoviridae		
Human parvovirus (B 19)	2	
Picomaviridae		
Acute haemorrhagic conjunctivitis virus (AHC)	2	
Coxsackie viruses	2	
Echo viruses	2	
Hepatitis 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	
Molluscum contagiosum virus	2	
Monkeypox virus	3	V
Orf virus	2	
Rabbitpox virus (g)	2	
Vaccinia virus	2	
Variola (major and minor)virus	4	V
Whitepox virus (‘*Vari la* virus’)	4	V
Yatapox virus (Ta a & Yaba)	2	
Re viridae		
Coltivirus	2	
Human rotaviruses	2	
Orbiviruses	2	
Reuviruses	2	
Retroviridae		
Human immunodeficiency viruses	3 (**)	D
Human T-cell lymphotropic viruses (HTLV), types 1 and 2	3 (**)	D
SIV (h)	3 (**)	

Rhabdoviridae		
rabies virus	3 (**)	V
Vesicular stomatitis virus	2	
Togaviridae		
Alphaviruses		
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 (**)	
Western equine encephalomyelitis	3	V
Other know alphaviruses	2	
Rubivirus (rubella)	2	V
Toroviridae	2	
Unclassified viruses		
Equine morbillivirus 4		
Hepatitis viruses not yet identified	3 (**)	D
Unconventional agents associated with the transmissible spongiform encephalopathies (TSEs)		
Creutzfeldt-Jakob disease	3 (**)	D (d)
Variant Creutzfeldt-Jakob disease	3 (**)	D (d)
Bovine spongiform encephalopathy (BSE) and other related animal TSEs (i)	3 (**)	D (d)
Gerstma -Sträussler-Scheinker syndrome	3 (**)	D (d)
Kuru	3 (**)	D (d)

(*) See paragraph 7 of the introductory notes.
(**) See paragraph 8 of the introductory notes.
(a) Tick-borne encephalitis.
(b) Hepatitis D virus is pathogenic in workers only in the presence of simultaneous or secondary infection caused by hepatitis B virus.
Vaccination against hepatitis B virus will therefore protect workers who are not affected by hepatitis B virus against hepatitis D virus (Delta).
(c) Only for types A and B.
(d) Recommended for work involving direct contact with these agents.
(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.
(h) At present there is no evidence of disease in humans caused by the other retroviruses of simian origin. As a precaution containment level 3 is recommended for work with them.
(i) There is no evidence in humans of infections caused by the agents responsible for other animal TSEs. Nevertheless, the containment measures for agents categorised in risk group 3 (**) are recommended as a precaution for laboratory work, except for laboratory work relating to an identified agent of scrapie where containment level 2 is sufficient.

PARASITES

Biological agent	Classification	Notes
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	
Clonorchisviverrini	2	
Cryptosporidium parvum	2	
Cryptosporidium spp.	2	
Cyclospora cayetanensis	2	
Dipetalonema streptocerca	2	
Diphyllobothrium latum	2	
Dracunculusmedinensis	2	
Echinococcusgranulosus	3 (**)	
Echinococcusmultilocularis	3 (**)	
Echinococcusvogeli	3 (**)	
Entamoeba histolytica	2	
Fasciola gigantica	2	
Fasciola hepatica	2	
Fasciolopsis buski	2	
Giardia lamblia (Giardia intestinalis)	2	
Hymenolepisdiminuta	2	
Hymenolepisnana	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	
Mansonella perstans	2	
Naegleria fowleri	3	
Necator americanus	2	
Onchocerca volvulus	2	
Opisthorchis felineus	2	
Opisthorchis spp.	2	
Paragonimuswestermani	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	

PARASITES (cont'd)

Biological agent	Classification	Notes
strongyloidesstercoralis	2	
Strongyloides spp.	2	
Taenia saginata	2	
Taenia solium	3 (**)	
Toxocara canis	2	
Toxoplasma gondii	2	
Trichinella spiralis	2	
Trichuristrichiura	2	
Trypanosoma brucei brucei	2	
Trypanosoma brucei gambiense	2	
Trypanosoma brucei rhodesiense	3 (**)	
Trypanosoma cruzi	3	
Wuchereria bancrofti	2	

(**)See paragraph 8 of the introductory notes.

FUNGI

Biological agent	Classification	Notes
Aspergillus fumigatus	2	A
Blastomycesdermatitidis(Ajellomyc esdermatitidis)	3	
Candida albicans	2	A
Candida tropicalis	2	
Cladophialophora bantiana (formerly:Xylohypha bantiana,Cladosporium bantianum or trichoides)	3	
Coccidioidesinunitis	3	A
Cryptococcusneoformans var.neofonnans(Filobasidiellaneofo nnans var.neofonnans)	2	A
Cryptococcusneoformans var.gattii (Filobasidiella bacillispora)	2	A
Emmonsia parva var.parva	2	
Emmonsiaparva var.crescens	2	
Epidermophyton floccosum	2	A
Fonsecaea compacta	2	
Fonsecaea pedrosoi	2	
Histoplasma capsulatum var.capsulatum (Ajellomyces capsulatus)	3	
Histoplasmacapsulatum duboisii	3	
Madurella grisea	2	
Madurella mycetomatis	2	
Microsporum spp.	2	A
Neotestudina rosatii	2	
Paracoccidioides brasiliensis	3	
Penicillium marneffei	2	A
Scedosporium apiospermum (Pseudallescheria boydii)	2	
Scedosporium prolificans (inflatum)	2	
Sporothrix schenckii	2	
Trichophyton rubrum	2	
Trichophyton spp.	2	

SCHEDULE IV

PRACTICAL RECOMMENDATIONS FOR THE HEALTH SURVEILLANCE OF WORKERS

(Regulation 14)

1. The doctor and, or the employer must be familiar with the exposure conditions or circumstances of each worker.

2. Health surveillance of workers must be carried out in accordance with the principles and practices of occupational medicine: it must include at least the following measures:
    - keeping records of a worker's medical and occupational history,
    - a personalised assessment of the worker's state of health.
    - where appropriate, biological monitoring as well as detection of early and reversible effects.

    Further tests may be decided on for each worker when he is the subject of health surveillance, in the light of the most recent knowledge available to occupational medicine.

SCHEDULE V

INDICATIONS CONCERNING CONTAINMENT MEASURES AND CONTAINMENT LEVELS

(Regulations 15 and 16)

Preliminary note

The measures contained in this Schedule shall be applied according to the nature of the activities, the assessment of risk to workers, and the nature of the biological agent concerned.

A. Containment measures	B. Containment levels		
	2	3	4
1.The workplace is to be separated from any other activities in the same building	No	Recommended	Yes
2.Input air and extract air to the workplace are to be filtered using (HEPA)or likewise	No	Yes, on extract air	Yes, on input and extract air
3.Access is to be restricted to nominated workers only	Recommended	Yes	Yes, via airlock
4.The workplace is to be sealable to permit disinfection	No	Recommended	Yes
5.Specified disinfection procedures	Yes	Yes	Yes
6.The workplace is to be maintained at an air pressure negative to atmosphere	No	Recommended	Yes
7.Efficient vector control, for example rodents and insects	Recommended	Yes	Yes
8.Surfaces impervious to water and easy to clean	Yes, for bench	Yes, for bench and floor	Yes, for bench, walls, floor and ceiling
9.Surfaces resistant to acids, alkalis, solvents, disinfectants	Recommended	Yes	Yes
10.Safe storage of a biological agent	Yes	Yes	Yes, secure storage
11.An observation window, or, alternative, is to be present, so that occupants can be seen	Recommended	Recommended	Yes
12.A laboratory is to contain own equipment	No	Recommended	Yes
13.Infected material, including any animal, is to be handled in a safety cabinet or isolation or other suitable containment	Where appropriate	Yes, where infection is by airborne route	Yes
14.Incinerator for disposal of animal carcasses	Recommended	Yes (available)	Yes, on site

SCHEDULE VI

CONTAINMENT FOR INDUSTRIAL PROCESSES
(Regulation 4 and Regulation 16)

Group 1 biological agents

For work with group 1 biological agents including live attenuated vaccines, the principles of good occupational safety and hygiene should be observed.

Groups2, 3 and 4 biological agents

It may be appropriate to select and combine containment requirements from different categories below on the basis of a risk assessment related to any particular process or part of a process.

A. Containment measures	B. Containment levels		
	2	3	4
1.Viable organisms should be handled in a system which physically separates the process from the environment	Yes	Yes	Yes
2.Exhaust gases from the closed system should be treated so as to:	Minimise release	Prevent release	Prevent release
3.Sample collection, addition of materials to a closed system and transfer of viable organisms to another closed system, should be performed so as to:	Minimise release	Prevent release	Prevent release
4.Bulk culture fluids should not be removed from the closed system unless the viable organisms have been:	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means
5.Seals should be designed so as to:	Minimise release	Prevent release	Prevent release
6.Closed systems should be located within a controlled area	Optional	Optional	Yes, and purpose-built
(a)Biohazard signs should be posted	Optional	Yes	Yes
(b)Access should be restricted to nominated personnel only	Optional	Yes	Yes, via an airlock
(c)Personnel should wear protective clothing	Yes, work clothing	Yes	A complete change
(d)Decontamination and washing facilities should be provided for personnel	Yes	Yes	Yes
(e)Personnel should shower before leaving the controlled area	No	Optional	Yes
(f)Effluent from sinks and showers should be collected and inactivated before release	No	Optional	Yes
(g)The controlled area should be adequately ventilated to minimise air contamination	Optional	Optional	Yes
(h)The controlled area should be maintained at an air pressure negative to atmosphere	No	Optional	Yes
(i)Input air and extract air to the controlled area should be HEPA filtered	No	Optional	Yes
(j)The controlled area should be designed to contain spillage of the entire contents of the closed system	No	Optional	Yes
(k)The controlled area should be sealable to permit fumigation	No	Optional	Yes
(l)Effluent treatment before final discharge.	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means

SCHEDULE VII

RECOMMENDED CODE OF PRACTICE ON VACCINATION
(Regulation 14)

1. If the assessment referred to in regulation 3 reveals that there is a risk to the health and safety of workers due to their exposure to biological agents for which effective vaccines exist, their employers should offer them vaccination.

2. Vaccination should be carried out in accordance with the applicable legislative and or other administrative provisions.

   Workers should be informed of the benefits and drawbacks of both vaccination and non-vaccination.

3. Vaccination must be offered free of charge to workers.

4. A vaccination certificate may be drawn up which should be made available to the worker concerned and, on request, to the Authority.