

## SUBSIDIARY LEGISLATION 424.25

### PROTECTION OF WORKERS FROM RISKS RELATED TO EXPOSURE TO BIOLOGICAL AGENTS AT WORK REGULATIONS\*

5th September, 2003

*LEGAL NOTICE 228 of 2003, as amended by Legal Notices 442 of 2020 and 4 of 2022 and Act XXXIII of 2024.*

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

Citation and scope.  
Amended by:  
L.N. 442 of 2020;  
L.N. 4 of 2022.

(2) The scope of these regulations is to:

- (a) 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;
- (b) transpose Commission Directive (EU) 2020/739 of 3 June 2020 amending Annex III to Directive 2000/54/EC of the European Parliament and of the Council as regards the inclusion of SARS-CoV-2 in the list of biological agents known to infect humans and amending Commission Directive (EU) 2019/1833;
- (c) transpose Commission Directive (EU) 2019/1833 of 24 October 2019 amending Annexes I, III, V and VI to Directive 2000/54/EC of the European Parliament and of the Council as regards purely technical adjustments.

(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.  
Amended by:  
XXXIII.2024.  
First Schedule.

"Act" means the Health and Safety at Work Act;

Cap. 646.

"Authority" means the Occupational Health and Safety Authority established by virtue of article 4 of the Act;

\*These regulations have been transferred to Cap. 646. Vide S.L. 646.17 and Act XXXIII of 2024.

"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:

- (a) group 1 biological agent means an agent that is unlikely to cause human disease;
- (b) 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;
- (c) 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;
- (d) 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 regulation 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.

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 shall not apply. However, point 1 of Schedule VI should be observed.

Application of various regulations in relation to assessment of risks.

(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 to 16 shall apply unless the results of the assessment referred to in regulation 3 show them to be unnecessary.

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.

Avoiding the use of harmful biological agents.

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.

Reduction of risks.

(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 a 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 records 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) 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 paragraph (b), 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.

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:

Information and training of workers.

- (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.

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:

Worker information in particular cases.

- (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 sub-regulation (1) shall be kept for at least ten 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 forty 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).

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:

Consultation and participation of workers.

- 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, and 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 subparagraphs (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 subparagraphs (v) and (vi);
  - the list and reports referred to in subparagraphs (iii) and (iv);
  - 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 sub-regulation (2) and the workers' representatives referred to in sub-regulation (2) and (3) may not be placed at a disadvantage because of their respective activities referred to in sub-regulations (2) and (3).

(5) Employers must allow workers' representatives with specific responsibility for the health and safety of workers adequate time during work hours, 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 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.

- (i) group 2 biological agents;
    - (ii) group 3 biological agents;
    - (iii) group 4 biological agents.
  - (b) The notification shall be made at least thirty days before the commencement of the work.
  - (c) Subject to sub-regulation (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) Re-notification 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; and
  - (e) the protection and preventive measures that are envisaged.
- 14.(1)(a) 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 re-assessment 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 ten years following the end of exposure.
- (b) In the special cases referred to in regulation 11(2)(a) to (e), an individual medical record shall be kept for an appropriately longer time up to forty 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 taken 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.

**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:

Special measures  
for industrial  
processes, etc.

- (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 paragraph of sub-regulation (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 sub-regulations (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.

Use of data.

**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).

Classification of  
biological agents.

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

(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.

Onus of proof.

**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.

Offences.

**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.

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*Substituted by:  
L.N. 4 of 2022.*

## SCHEDULE I

### INDICATIVE LIST OF ACTIVITIES (Regulation 4(2))

#### *Preliminary note*

Where the result of the risk assessment carried out in accordance with Regulation 3 and Regulation 4(2) of these Regulations, shows an unintentional exposure to biological agents, there may be other work activities, not included in this Schedule, which should be considered.

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.

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## SCHEDULE II BIOHAZARD SIGN (Regulation 6)



Biological risk

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*Substituted by:  
L.N. 4 of 2022.*

### SCHEDULE III

#### COMMUNITY 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 16.

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 genera where more than one species is known to be pathogenic to man, the list will include those species which are known to be the most frequently responsible for diseases, together with a more general 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 known 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 are classified in 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 ten 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 ten years after the end of last known exposure
- T: Toxin production
- V: Effective vaccine available and registered within the EU

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, the entry of the whole genus with the addition of 'spp.' refers to other species belonging to this genus that have not specifically been included in the list, but which are known pathogens in humans. See

introductory note 3 for further details.

| Biological Agent                                                                                | Classification | Notes |
|-------------------------------------------------------------------------------------------------|----------------|-------|
| <i>Actinomadura madurae</i>                                                                     | 2              |       |
| <i>Actinomadura pelletieri</i>                                                                  | 2              |       |
| <i>Actinomyces gerencseriae</i>                                                                 | 2              |       |
| <i>Actinomyces israelii</i>                                                                     | 2              |       |
| <i>Actinomyces</i> spp.                                                                         | 2              |       |
| <i>Aggregatibacter actinomycetemcomitans</i><br>( <i>Actinobacillus actinomycetemcomitans</i> ) | 2              |       |
| <i>Anaplasma</i> spp.                                                                           | 2              |       |
| <i>Arcanobacterium haemolyticum</i> ( <i>Corynebacterium haemolyticum</i> )                     | 2              |       |
| <i>Arcobacter butzleri</i>                                                                      | 2              |       |
| <i>Bacillus anthracis</i>                                                                       | 3              | T     |
| <i>Bacteroides fragilis</i>                                                                     | 2              |       |
| <i>Bacteroides</i> spp.                                                                         | 2              |       |
| <i>Bartonella bacilliformis</i>                                                                 | 2              |       |
| <i>Bartonella quintana</i> ( <i>Rochalimaea quintana</i> )                                      | 2              |       |
| <i>Bartonella</i> ( <i>Rochalimea</i> ) spp.                                                    | 2              |       |
| <i>Bordetella bronchiseptica</i>                                                                | 2              |       |
| <i>Bordetella parapertussis</i>                                                                 | 2              |       |
| <i>Bordetella pertussis</i>                                                                     | 2              | T, V  |
| <i>Bordetella</i> spp.                                                                          | 2              |       |
| <i>Borrelia burgdorferi</i>                                                                     | 2              |       |
| <i>Borrelia duttonii</i>                                                                        | 2              |       |
| <i>Borrelia recurrentis</i>                                                                     | 2              |       |
| <i>Borrelia</i> spp.                                                                            | 2              |       |
| <i>Brachyspira</i> spp.                                                                         | 2              |       |
| <i>Brucella abortus</i>                                                                         | 3              |       |
| <i>Brucella canis</i>                                                                           | 3              |       |
| <i>Brucella inopinata</i>                                                                       | 3              |       |
| <i>Brucella melitensis</i>                                                                      | 3              |       |
| <i>Brucella suis</i>                                                                            | 3              |       |
| <i>Burkholderia cepacia</i>                                                                     | 2              |       |
| <i>Burkholderia mallei</i> ( <i>Pseudomonas mallei</i> )                                        | 3              |       |
| <i>Burkholderia pseudomallei</i> ( <i>Pseudomonas pseudomallei</i> )                            | 3              | D     |
| <i>Campylobacter fetus</i> subsp. <i>fetus</i>                                                  | 2              |       |
| <i>Campylobacter fetus</i> subsp. <i>venerealis</i>                                             | 2              |       |

|                                                                    |       |      |
|--------------------------------------------------------------------|-------|------|
| Campylobacter jejuni subsp. doylei                                 | 2     |      |
| Campylobacter jejuni subsp. jejuni                                 | 2     |      |
| Campylobacter spp.                                                 | 2     |      |
| Cardiobacterium hominis                                            | 2     |      |
| Cardiobacterium valvarum                                           | 2     |      |
| Chlamydia abortus (Chlamydophila abortus)                          | 2     |      |
| Chlamydia caviae (Chlamydophila caviae)                            | 2     |      |
| Chlamydia felis (Chlamydophila felis)                              | 2     |      |
| Chlamydia pneumoniae (Chlamydophila pneumoniae)                    | 2     |      |
| Chlamydia psittaci (Chlamydophila psittaci) (avian strains)        | 3     |      |
| Chlamydia psittaci (Chlamydophila psittaci) (other strains)        | 2     |      |
| Chlamydia trachomatis (Chlamydophila trachomatis)                  | 2     |      |
| Clostridium botulinum                                              | 2     | T    |
| Clostridium difficile                                              | 2     | T    |
| Clostridium perfringens                                            | 2     | T    |
| Clostridium tetani                                                 | 2     | T, V |
| Clostridium spp.                                                   | 2     |      |
| Corynebacterium diphtheriae                                        | 2     | T, V |
| Corynebacterium minutissimum                                       | 2     |      |
| Corynebacterium pseudotuberculosis                                 | 2     | T    |
| Corynebacterium ulcerans                                           | 2     | T    |
| Corynebacterium spp.                                               | 2     |      |
| Coxiella burnetii                                                  | 3     |      |
| Edwardsiella tarda                                                 | 2     |      |
| Ehrlichia spp.                                                     | 2     |      |
| Eikenella corrodens                                                | 2     |      |
| Elizabethkingia meningoseptica (Flavobacterium meningosepticum)    | 2     |      |
| Enterobacter aerogenes (Klebsiella mobilis)                        | 2     |      |
| Enterobacter cloacae subsp. cloacae (Enterobacter 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 (*) | T    |

|                                                                              |   |   |
|------------------------------------------------------------------------------|---|---|
| Fluoribacter bozemanæ (Legionella)                                           | 2 |   |
| Francisella hispaniensis                                                     | 2 |   |
| Francisella tularensis subsp. holarctica                                     | 2 |   |
| Francisella tularensis subsp. mediasiatica                                   | 2 |   |
| Francisella tularensis subsp. novicida                                       | 2 |   |
| Francisella tularensis subsp. tularensis                                     | 3 |   |
| Fusobacterium necrophorum subsp. funduliforme                                | 2 |   |
| Fusobacterium necrophorum subsp. necrophorum                                 | 2 |   |
| Gardnerella vaginalis                                                        | 2 |   |
| Haemophilus ducreyi                                                          | 2 |   |
| Haemophilus influenzae                                                       | 2 | V |
| Haemophilus spp.                                                             | 2 |   |
| Helicobacter pylori                                                          | 2 |   |
| Helicobacter spp.                                                            | 2 |   |
| Klebsiella oxytoca                                                           | 2 |   |
| Klebsiella pneumoniae subsp. ozaenae                                         | 2 |   |
| Klebsiella pneumoniae subsp. pneumoniae                                      | 2 |   |
| Klebsiella pneumoniae subsp. rhinoscleromatis                                | 2 |   |
| Klebsiella spp.                                                              | 2 |   |
| Legionella pneumophila subsp. fraseri                                        | 2 |   |
| Legionella pneumophila subsp. pascullei                                      | 2 |   |
| Legionella pneumophila subsp. pneumophila                                    | 2 |   |
| Legionella spp.                                                              | 2 |   |
| Leptospira interrogans (all serovars)                                        | 2 |   |
| Leptospira interrogans spp.                                                  | 2 |   |
| Listeria monocytogenes                                                       | 2 |   |
| Listeria ivanovii subsp. ivanovii                                            | 2 |   |
| Listeria ivanovii subsp. londoniensis                                        | 2 |   |
| Morganella morganii subsp. morganii (Proteus morganii)                       | 2 |   |
| Morganella morganii subsp. sibonii                                           | 2 |   |
| Mycobacterium abscessus subsp. abscessus                                     | 2 |   |
| Mycobacterium africanum                                                      | 3 | V |
| Mycobacterium avium subsp. avium (Mycobacterium avium)                       | 2 |   |
| Mycobacterium avium subsp. paratuberculosis (Mycobacterium paratuberculosis) | 2 |   |
| Mycobacterium avium subsp. silvaticum                                        | 2 |   |
| Mycobacterium bovis                                                          | 3 | V |

|                                                                  |       |   |
|------------------------------------------------------------------|-------|---|
| Mycobacterium caprae (Mycobacterium tuberculosis subsp. caprae)  | 3     |   |
| Mycobacterium chelonae                                           | 2     |   |
| Mycobacterium chimaera                                           | 2     |   |
| Mycobacterium fortuitum                                          | 2     |   |
| Mycobacterium intracellulare                                     | 2     |   |
| Mycobacterium kansasii                                           | 2     |   |
| Mycobacterium leprae                                             | 3     |   |
| Mycobacterium malmoense                                          | 2     |   |
| Mycobacterium marinum                                            | 2     |   |
| Mycobacterium microti                                            | 3 (*) |   |
| Mycobacterium pinnipedii                                         | 3     |   |
| Mycobacterium scrofulaceum                                       | 2     |   |
| Mycobacterium simiae                                             | 2     |   |
| Mycobacterium szulgai                                            | 2     |   |
| Mycobacterium tuberculosis                                       | 3     | V |
| Mycobacterium ulcerans                                           | 3 (*) |   |
| Mycobacterium xenopi                                             | 2     |   |
| Mycoplasma hominis                                               | 2     |   |
| Mycoplasma pneumoniae                                            | 2     |   |
| Mycoplasma spp.                                                  | 2     |   |
| Neisseria gonorrhoeae                                            | 2     |   |
| Neisseria meningitidis                                           | 2     | V |
| Neorickettsia sennetsu (Rickettsia sennetsu, Ehrlichia sennetsu) | 2     |   |
| Nocardia asteroides                                              | 2     |   |
| Nocardia brasiliensis                                            | 2     |   |
| Nocardia farcinica                                               | 2     |   |
| Nocardia nova                                                    | 2     |   |
| Nocardia otitidiscaviarum                                        | 2     |   |
| Nocardia spp.                                                    | 2     |   |
| Orientia tsutsugamushi (Rickettsia tsutsugamushi)                | 3     |   |
| Pasteurella multocida subsp. gallicida (Pasteurella gallicida)   | 2     |   |
| Pasteurella multocida subsp. multocida                           | 2     |   |
| Pasteurella multocida subsp. septica                             | 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 (Proteus inconstans)     | 2     |      |
| Providencia rettgeri (Proteus rettgeri)            | 2     |      |
| Providencia spp.                                   | 2     |      |
| Pseudomonas aeruginosa                             | 2     | T    |
| Rhodococcus hoagii (Corynebacterium equii)         | 2     |      |
| Rickettsia africae                                 | 3     |      |
| Rickettsia akari                                   | 3 (*) |      |
| Rickettsia australis                               | 3     |      |
| Rickettsia canadensis                              | 2     |      |
| Rickettsia conorii                                 | 3     |      |
| Rickettsia heilongjiangensis                       | 3(*)  |      |
| Rickettsia japonica                                | 3     |      |
| Rickettsia montanensis                             | 2     |      |
| Rickettsia typhi                                   | 3     |      |
| Rickettsia prowazekii                              | 3     |      |
| Rickettsia rickettsii                              | 3     |      |
| Rickettsia sibirica                                | 3     |      |
| Rickettsia spp.                                    | 2     |      |
| Salmonella enterica (choleraesuis) subsp. arizonae | 2     |      |
| Salmonella Enteritidis                             | 2     |      |
| Salmonella Paratyphi A, B, C                       | 2     | V    |
| Salmonella Typhi                                   | 3 (*) | V    |
| Salmonella Typhimurium                             | 2     |      |
| Salmonella (serotipi ohrajn)                       | 2     |      |
| Shigella boydii                                    | 2     |      |
| Shigella dysenteriae (tat-Tip 1)                   | 3 (*) | T    |
| Shigella dysenteriae, ghajr tat-Tip 1              | 2     |      |
| Shigella flexneri                                  | 2     |      |
| Shigella sonnei                                    | 2     |      |
| Staphylococcus aureus                              | 2     | T    |
| Streptobacillus moniliformis                       | 2     |      |
| Streptococcus agalactiae                           | 2     |      |
| Streptococcus dysgalactiae subsp. equisimilis      | 2     |      |
| Streptococcus pneumoniae                           | 2     | T, V |
| Streptococcus pyogenes                             | 2     | T    |

|                                                   |   |      |
|---------------------------------------------------|---|------|
| Streptococcus suis                                | 2 |      |
| Streptococcus spp.                                | 2 |      |
| Treponema carateum                                | 2 |      |
| Treponema pallidum                                | 2 |      |
| Treponema pertenu                                 | 2 |      |
| Treponema spp.                                    | 2 |      |
| Trueperella pyogenes                              | 2 |      |
| Ureaplasma parvum                                 | 2 |      |
| Ureaplasma urealyticum                            | 2 |      |
| Vibrio cholerae (including E1 Tor)                | 2 | T, V |
| Vibrio parahaemolyticus (Benecka parahaemolytica) | 2 |      |
| Vibrio spp.                                       | 2 |      |
| Yersinia enterocolitica subsp. enterolitica       | 2 |      |
| Yersinia enterocolitica subsp. palearctica        | 2 |      |
| Yersinia pestis                                   | 3 |      |
| Yersinia pseudotuberculosis                       | 2 |      |
| Yersinia spp.                                     | 2 |      |

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

### VIRUSES (\*)

NB: Viruses have been listed according to their order (O), family (F) and genus (G).

| Biological Agent<br>(virus species or indicated taxonomy order)                                             | Classification | Notes |
|-------------------------------------------------------------------------------------------------------------|----------------|-------|
| Bunyavirales (O)                                                                                            |                |       |
| Hantaviridae (F)                                                                                            |                |       |
| Orthohantavirus (G)                                                                                         |                |       |
| Andes orthohantavirus (Hantavirus species causing Hantavirus Pulmonary Syndrome [HPS])                      | 3              |       |
| Bayou orthohantavirus                                                                                       | 3              |       |
| Black Creek Canal orthohantavirus                                                                           | 3              |       |
| Cano Delgadito orthohantavirus                                                                              | 3              |       |
| Choclo orthohantavirus                                                                                      | 3              |       |
| Dobrava-Belgrade orthohantavirus (Hantavirus species causing Haemorrhagic Fever with Renal Syndrome [HFRS]) | 3              |       |
| El Moro Canyon orthohantavirus                                                                              | 3              |       |

\* See paragraph 7 of the introductory notes.

|                                                                                                    |   |  |
|----------------------------------------------------------------------------------------------------|---|--|
| Hantaan orthohantavirus (Hantavirus species causing Haemorrhagic Fever with Renal Syndrome [HFRS]) | 3 |  |
| Laguna Negra orthohantavirus                                                                       | 3 |  |
| Prospect Hill orthohantavirus                                                                      | 2 |  |
| Puumala orthohantavirus (Hantavirus species causing Nephropathia Epidemica [NE])                   | 2 |  |
| Seoul orthohantavirus (Hantavirus species causing Haemorrhagic Fever with Renal Syndrome [HFRS])   | 3 |  |
| Sin Nombre orthohantavirus (Hantavirus species causing Hantavirus Pulmonary Syndrome [HPS])        | 3 |  |
| Other hantaviruses known to be pathogenic                                                          | 2 |  |
| <i>Nairoviridae</i> (F)                                                                            |   |  |
| Orthonairovirus (G)                                                                                |   |  |
| Crimean-Congo haemorrhagic fever orthonairovirus                                                   | 4 |  |
| Dugbe orthonairovirus                                                                              | 2 |  |
| Hazara orthonairovirus                                                                             | 2 |  |
| Nairobi sheep disease orthonairovirus                                                              | 2 |  |
| Other nairoviruses known to be pathogenic                                                          | 2 |  |
| <i>Peribunyaviridae</i> (F)                                                                        |   |  |
| Orthobunyavirus (G)                                                                                |   |  |
| Bunyamwera orthobunyavirus (Germiston virus)                                                       | 2 |  |
| California encephalitis orthobunyavirus                                                            | 2 |  |
| Oropouche orthobunyavirus                                                                          | 3 |  |
| Other orthobunyaviruses known to be pathogenic                                                     | 2 |  |
| <i>Phenuiviridae</i> (F)                                                                           |   |  |
| Phlebovirus (G)                                                                                    |   |  |
| Bhanja phlebovirus                                                                                 | 2 |  |
| Punta Toro phlebovirus                                                                             | 2 |  |
| Rift Valley fever phlebovirus                                                                      | 3 |  |
| Sandfly fever Naples phlebovirus (Toscana Virus)                                                   | 2 |  |
| SFTS phlebovirus (Severe Fever with Thrombocytopenia Syndrome-Virus)                               | 3 |  |
| Other phleboviruses known to be pathogenic                                                         | 2 |  |
| Herpesvirales (O)                                                                                  |   |  |
| <i>Herpesviridae</i> (F)                                                                           |   |  |
| Cytomegalovirus (G)                                                                                |   |  |
| Human betaherpesvirus 5 (Cytomegalovirus)                                                          | 2 |  |
| Lymphocryptovirus (G)                                                                              |   |  |
| Human gammaherpesvirus 4 (Epstein-Barr virus)                                                      | 2 |  |
| Rhadinoovirus (G)                                                                                  |   |  |

|                                                                             |   |   |
|-----------------------------------------------------------------------------|---|---|
| Human gammaherpesvirus 8                                                    | 2 | D |
| Roseolovirus (G)                                                            |   |   |
| Human betaherpesvirus 6A (Human B- lymphotropic virus)                      | 2 |   |
| Human betaherpesvirus 6B                                                    | 2 |   |
| Human betaherpesvirus 7                                                     | 2 |   |
| Simplexvirus (G)                                                            |   |   |
| Macacine alphaherpesvirus 1 (Herpesvirus simiae, Herpes B virus)            | 3 |   |
| Human alphaherpesvirus 1 (Human herpesvirus 1, Herpes simplex virus type 1) | 2 |   |
| Human alphaherpesvirus 2 (Human herpesvirus 2, Herpes simplex virus type 2) | 2 |   |
| Varicellovirus (G)                                                          |   |   |
| Human alphaherpesvirus 3 (Herpesvirus varicella-zoster)                     | 2 | V |
| Mononegavirales (O)                                                         |   |   |
| <i>Filoviridae</i> (F)                                                      |   |   |
| Ebolavirus (G)                                                              | 4 |   |
| Marburgvirus (G)                                                            |   |   |
| Marburg marburgvirus                                                        | 4 |   |
| <i>Paramyxoviridae</i> (F)                                                  |   |   |
| Avulavirus (G)                                                              |   |   |
| Newcastle disease virus                                                     | 2 |   |
| Henipavirus (G)                                                             |   |   |
| Hendra henipavirus                                                          | 4 |   |
| Nipah henipavirus                                                           | 4 |   |
| Morbillivirus (G)                                                           |   |   |
| Measles morbillivirus                                                       | 2 | V |
| Respirovirus (G)                                                            |   |   |
| Human respirovirus 1 (Parainfluenza virus 1)                                | 2 |   |
| Human respirovirus 3 (Parainfluenza virus 3)                                | 2 |   |
| Rubulavirus (G)                                                             |   |   |
| Mumps rubulavirus                                                           | 2 | V |
| Human rubulavirus 2 (Parainfluenza virus 2)                                 | 2 |   |
| Human rubulavirus 4 (Parainfluenza virus 4)                                 | 2 |   |
| <i>Pneumoviridae</i> (F)                                                    |   |   |
| Metapneumovirus (G)                                                         |   |   |
| Orthopneumovirus (G)                                                        |   |   |
| Human orthopneumovirus (Respiratory syncytial virus)                        | 2 |   |
| <i>Rhabdoviridae</i> (F)                                                    |   |   |

|                                                                                      |        |   |
|--------------------------------------------------------------------------------------|--------|---|
| Lyssavirus (G)                                                                       |        |   |
| Australian bat lyssavirus                                                            | 3 (**) | V |
| Duvenhage lyssavirus                                                                 | 3 (**) | V |
| European bat lyssavirus 1                                                            | 3 (**) | V |
| European bat lyssavirus 2                                                            | 3 (**) | V |
| Lagos bat lyssavirus                                                                 | 3 (**) |   |
| Mokola lyssavirus                                                                    | 3      |   |
| Rabies lyssavirus                                                                    | 3 (**) | V |
| Vesiculovirus (G)                                                                    |        |   |
| Vesicular stomatitis virus, Alagoas vesiculovirus                                    | 2      |   |
| Vesicular stomatitis virus, Indiana vesiculovirus                                    | 2      |   |
| Vesicular stomatitis virus, New Jersey vesiculovirus                                 | 2      |   |
| Piry vesiculovirus (Piry virus)                                                      | 2      |   |
| Nidovirales (O)                                                                      |        |   |
| <i>Coronaviridae</i> (F)                                                             |        |   |
| Betacoronavirus (G)                                                                  |        |   |
| Severe acute respiratory syndrome-related coronavirus (SARS-virus)                   | 3      |   |
| Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (***)                   | 3      |   |
| Middle East respiratory syndrome coronavirus (MERS-virus)                            | 3      |   |
| Other <i>Coronaviridae</i> known to be pathogenic                                    | 2      |   |
| Picornavirales (O)                                                                   |        |   |
| <i>Picornaviridae</i> (F)                                                            |        |   |
| Cardiovirus (G)                                                                      |        |   |
| Saffold virus                                                                        | 2      |   |
| Cosavirus (G)                                                                        |        |   |
| Cosavirus A                                                                          | 2      |   |
| Enterovirus (G)                                                                      |        |   |
| Enterovirus (A)                                                                      | 2      |   |
| Enterovirus (B)                                                                      | 2      |   |
| Enterovirus (C)                                                                      | 2      |   |
| Enterovirus (D), Human Enterovirus type 70 (Acute haemorrhagic conjunctivitis virus) | 2      |   |
| Rhinoviruses                                                                         | 2      |   |
| Poliovirus, type 1 and 3                                                             | 2      | V |
| Poliovirus, type 2 ( <sup>1</sup> )                                                  | 3      | V |
| Hepatovirus (G)                                                                      |        |   |

|                                                                  |        |      |
|------------------------------------------------------------------|--------|------|
| Hepatovirus A (Hepatitis A virus, Human Enterovirus type 72)     | 2      | V    |
| Kobuvirus (G)                                                    |        |      |
| Aichivirus A (Aichi virus 1)                                     | 2      |      |
| Parechovirus (G)                                                 |        |      |
| Parechoviruses A                                                 | 2      |      |
| Parechoviruses B (Ljungan virus)                                 | 2      |      |
| Other <i>Picornaviridae</i> known to be pathogenic               | 2      |      |
| Unassigned (O)                                                   |        |      |
| <i>Adenoviridae</i> (F)                                          | 2      |      |
| <i>Astroviridae</i> (F)                                          | 2      |      |
| <i>Arenaviridae</i> (F)                                          |        |      |
| Mammarenavirus (G)                                               |        |      |
| Brazilian mammarenavirus                                         | 4      |      |
| Chapare mammarenavirus                                           | 4      |      |
| Flexal mammarenavirus                                            | 3      |      |
| Guanarito mammarenavirus                                         | 4      |      |
| Junín mammarenavirus                                             | 4      |      |
| Lassa mammarenavirus                                             | 4      |      |
| Lujo mammarenavirus                                              | 4      |      |
| Lymphocytic choriomeningitis mammarenavirus, neurotropic strains | 2      |      |
| Lymphocytic choriomeningitis mammarenavirus (other strains)      | 2      |      |
| Machupo mammarenavirus                                           | 4      |      |
| Mobala mammarenavirus                                            | 2      |      |
| Mopeia mammarenavirus                                            | 2      |      |
| Tacaribe mammarenavirus                                          | 2      |      |
| Whitewater Arroyo mammarenavirus                                 | 3      |      |
| <i>Caliciviridae</i> (F)                                         |        |      |
| Norovirus (G)                                                    |        |      |
| Norovirus (Norwalk virus)                                        | 2      |      |
| Other <i>Caliciviridae</i> known to be pathogenic                | 2      |      |
| <i>Hepadnaviridae</i> (F)                                        |        |      |
| Orthohepadnavirus (G)                                            |        |      |
| Hepatitis B virus                                                | 3 (**) | V, D |
| <i>Hepeviridae</i> (F)                                           |        |      |
| Orthohepevirus (G)                                               |        |      |
| Orthohepevirus A (Hepatitis E virus)                             | 2      |      |
| <i>Flaviviridae</i> (F)                                          |        |      |

|                                                                       |        |       |
|-----------------------------------------------------------------------|--------|-------|
| Flavivirus (G)                                                        |        |       |
| Dengue virus                                                          | 3      |       |
| Japanese encephalitis virus                                           | 3      | V     |
| Kyasanur Forest disease virus                                         | 3      | V     |
| Louping ill virus                                                     | 3 (**) |       |
| Murray Valley encephalitis virus (Australia encephalitis virus)       | 3      |       |
| Omsk haemorrhagic fever virus                                         | 3      |       |
| Powassan virus                                                        | 3      |       |
| Rocio virus                                                           | 3      |       |
| St. Louis encephalitis virus                                          | 3      |       |
| Tick-borne encephalitis virus                                         |        |       |
| Absettarov virus                                                      | 3      |       |
| Hanzalova virus                                                       | 3      |       |
| Hypr virus                                                            | 3      |       |
| Kumlinge virus                                                        | 3      |       |
| Negishi virus                                                         | 3      |       |
| Russian spring-summer encephalitis <sup>(a)</sup>                     | 3      | V     |
| Tick-borne encephalitis virus Central European subtype                | 3 (**) | V     |
| Tick-borne encephalitis virus Far Eastern subtype                     | 3      |       |
| Tick-borne encephalitis virus Siberian subtype                        | 3      | V     |
| Wesselsbron virus                                                     | 3 (**) |       |
| West Nile fever virus                                                 | 3      |       |
| Yellow fever virus                                                    | 3      | V     |
| Zika virus                                                            | 2      |       |
| Other flaviviruses known to be pathogenic                             | 2      |       |
| Hepacivirus (G)                                                       |        |       |
| Hepacivirus C (Hepatitis C virus)                                     | 3 (**) | D     |
| <i>Orthomyxoviridae</i> (F)                                           |        |       |
| Gammainfluenzavirus (G)                                               |        |       |
| Influenza C virus                                                     | 2      | V (°) |
| Influenzavirus A (G)                                                  |        |       |
| Highly Pathogenic Avian Influenza Viruses HPAIV (H5), e.g. H5N1       | 3      |       |
| Highly Pathogenic Avian Influenza Viruses HPAIV (H7), e.g. H7N7, H7N9 | 3      |       |
| Influenza A virus                                                     | 2      | V (°) |
| Influenza A virus A/New York/1/18 (H1N1) (Spanish flu 1918)           | 3      |       |

|                                                                                                                                |   |                    |
|--------------------------------------------------------------------------------------------------------------------------------|---|--------------------|
| Influenza A virus A/Singapore/1/57 (H2N2)                                                                                      | 3 |                    |
| Low Pathogenic Avian Influenza Virus (LPAI) H7N9                                                                               | 3 |                    |
| Influenzavirus B (G)                                                                                                           |   |                    |
| Influenza B virus                                                                                                              | 2 | V ( <sup>c</sup> ) |
| Thogoto virus (G)                                                                                                              |   |                    |
| Dhori virus (Tick-borne orthomyxoviridae: Dhori)                                                                               | 2 |                    |
| Thogoto virus (Tick-borne orthomyxoviridae: Thogoto)                                                                           | 2 |                    |
| <i>Papillomaviridae</i> (F)                                                                                                    | 2 | D ( <sup>d</sup> ) |
| <i>Parvoviridae</i> (F)                                                                                                        |   |                    |
| Erythroparvovirus (G)                                                                                                          |   |                    |
| Primate erythroparvovirus 1 (Human parvovirus, B 19 virus)                                                                     | 2 |                    |
| <i>Polyomaviridae</i> (F)                                                                                                      |   |                    |
| Betapolyomavirus (G)                                                                                                           |   |                    |
| Human polyomavirus 1 (BK virus)                                                                                                | 2 | D ( <sup>d</sup> ) |
| Human polyomavirus 2 (JC virus)                                                                                                | 2 | D ( <sup>d</sup> ) |
| <i>Poxviridae</i> (F)                                                                                                          |   |                    |
| Molluscipoxvirus (G)                                                                                                           |   |                    |
| Molluscum contagiosum virus                                                                                                    | 2 |                    |
| Orthopoxvirus (G)                                                                                                              |   |                    |
| Cowpox virus                                                                                                                   | 2 |                    |
| Monkeypox virus                                                                                                                | 3 | V                  |
| Vaccinia virus (incl. Buffalopox virus ( <sup>e</sup> ), Elephantpox virus ( <sup>f</sup> ), Rabbitpox virus ( <sup>g</sup> )) | 2 |                    |
| Variola (major and minor) virus                                                                                                | 4 | V                  |
| Parapoxvirus (G)                                                                                                               |   |                    |
| Orf virus                                                                                                                      | 2 |                    |
| Pseudocowpox virus (Milkers' node virus, parapoxvirus bovis)                                                                   | 2 |                    |
| Yatapoxvirus (G)                                                                                                               |   |                    |
| Tanapox virus                                                                                                                  | 2 |                    |
| Yaba monkey tumor virus                                                                                                        | 2 |                    |
| <i>Reoviridae</i> (F)                                                                                                          |   |                    |
| Seadornavirus (G)                                                                                                              |   |                    |
| Banna virus                                                                                                                    | 2 |                    |
| Coltivirus (G)                                                                                                                 | 2 |                    |
| Rotaviruses (G)                                                                                                                | 2 |                    |
| Orbivirus (G)                                                                                                                  | 2 |                    |
| <i>Retroviridae</i> (F)                                                                                                        |   |                    |

|                                                                          |        |      |
|--------------------------------------------------------------------------|--------|------|
| Deltaretrovirus (G)                                                      |        |      |
| Primate T-lymphotropic virus 1 (Human T-cell lymphotropic virus, type 1) | 3 (**) | D    |
| Primate T-lymphotropic virus 2 (Human T-cell lymphotropic virus, type 2) | 3 (**) | D    |
| Lentivirus (G)                                                           |        |      |
| Human immunodeficiency virus 1                                           | 3 (**) | D    |
| Human immunodeficiency virus 2                                           | 3 (**) | D    |
| Simian Immunodeficiency Virus (SIV) <sup>(b)</sup>                       | 2      |      |
| <i>Togaviridae</i> (F)                                                   |        |      |
| Alphavirus (G)                                                           |        |      |
| Cabassouvirus                                                            | 3      |      |
| Eastern equine encephalomyelitis virus                                   | 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 virus                                | 3      | V    |
| Western equine encephalomyelitis virus                                   | 3      | V    |
| Other alphaviruses known to be pathogenic                                | 2      |      |
| Rubivirus (G)                                                            |        |      |
| Rubella virus                                                            | 2      | V    |
| <i>Unassigned</i> (F)                                                    |        |      |
| Deltavirus (G)                                                           |        |      |
| Hepatitis delta virus <sup>(b)</sup>                                     | 2      | V, D |

- (\*) See paragraph 7 of the introductory notes.
- (<sup>1</sup>) Classification according to WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use.
- (\*\*) See paragraph 8 of the introductory notes.
- (\*\*\*) In line with regulation 16(1)(c), non-propagative diagnostic laboratory work involving SARS-CoV-2 should be conducted at a facility using procedures equivalent to at least containment level 2. Propagative work involving SARS-CoV-2 should be conducted at a containment level 3 laboratory with air pressure negative to atmosphere.
- (<sup>a</sup>) Tick-borne encephalitis
- (<sup>b</sup>) Hepatitis delta 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 delta virus.
- (<sup>c</sup>) Only for types A and B.
- (<sup>d</sup>) Recommended for work involving direct contact with these agents.
- (<sup>e</sup>) Two viruses are identified: one a buffalopox type and the other a variant of the Vaccinia virus.
- (<sup>f</sup>) Variant of cowpox virus.
- (<sup>g</sup>) Variant of Vaccinia.
- (<sup>h</sup>) 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.

#### PRION DISEASE AGENTS

| Biological Agent                                                                                                                             | Classification | Notes              |
|----------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|
| Agent of Creutzfeldt-Jakob disease                                                                                                           | 3(*)           | D ( <sup>a</sup> ) |
| Variant Agent of Creutzfeldt-Jakob disease                                                                                                   | 3(*)           | D ( <sup>a</sup> ) |
| Agent of Bovine Spongiform Encephalopathy (BSE) and other related animal TSEs                                                                | 3(*)           | D ( <sup>a</sup> ) |
| Agent of Gerstmann-Sträussler-Scheinker syndrome                                                                                             | 3(*)           | D ( <sup>a</sup> ) |
| Agent of Kuru                                                                                                                                | 3(*)           | D ( <sup>a</sup> ) |
| Agent of Scrapie                                                                                                                             | 2              |                    |
| <p>(*) See paragraph 8 of the introductory notes.</p> <p>(<sup>a</sup>) Recommended for work involving direct contact with these agents.</p> |                |                    |

**PARASITES**

NB: For biological agents appearing on this list, the entry of the whole genus with the addition of 'spp.' refers to other species belonging to this genus that have not specifically been included in the list, but which are known pathogens in humans. See introductory note 3 for further details.

| <b>Biological Agent</b>                                       | <b>Classification</b> | <b>Notes</b> |
|---------------------------------------------------------------|-----------------------|--------------|
| <i>Acanthamoeba castellanii</i>                               | 2                     |              |
| <i>Ancylostoma duodenale</i>                                  | 2                     |              |
| <i>Angiostrongylus cantonensis</i>                            | 2                     |              |
| <i>Angiostrongylus costaricensis</i>                          | 2                     |              |
| <i>Anisakis simplex</i>                                       | 2                     | A            |
| <i>Ascaris lumbricoides</i>                                   | 2                     | A            |
| <i>Ascaris suum</i>                                           | 2                     | A            |
| <i>Babesia divergens</i>                                      | 2                     |              |
| <i>Babesia microti</i>                                        | 2                     |              |
| <i>Balamuthia mandrillaris</i>                                | 3                     |              |
| <i>Balantidium coli</i>                                       | 2                     |              |
| <i>Brugia malayi</i>                                          | 2                     |              |
| <i>Brugia pahangi</i>                                         | 2                     |              |
| <i>Brugia timori</i>                                          | 2                     |              |
| <i>Capillaria philippinensis</i>                              | 2                     |              |
| <i>Capillaria</i> spp.                                        | 2                     |              |
| <i>Clonorchis sinensis</i> ( <i>Opisthorchis sinensis</i> )   | 2                     |              |
| <i>Clonorchis viverrini</i> ( <i>Opisthorchis viverrini</i> ) | 2                     |              |
| <i>Cryptosporidium hominis</i>                                | 2                     |              |
| <i>Cryptosporidium parvum</i>                                 | 2                     |              |
| <i>Cyclospora cayetanensis</i>                                | 2                     |              |
| <i>Dicrocoelium dentriticum</i>                               | 2                     |              |
| <i>Dipetalonema streptocerca</i>                              | 2                     |              |
| <i>Diphyllbothrium latum</i>                                  | 2                     |              |
| <i>Dracunculus medinensis</i>                                 | 2                     |              |
| <i>Echinococcus granulosus</i>                                | 3 (*)                 |              |
| <i>Echinococcus multilocularis</i>                            | 3 (*)                 |              |
| <i>Echinococcus oligarthrus</i>                               | 3 (*)                 |              |
| <i>Echinococcus vogeli</i>                                    | 3 (*)                 |              |
| <i>Entamoeba histolytica</i>                                  | 2                     |              |
| <i>Enterobius vermicularis</i>                                | 2                     |              |

|                                                            |       |  |
|------------------------------------------------------------|-------|--|
| Enterocytozoon bienersi                                    | 2     |  |
| Fasciola gigantica                                         | 2     |  |
| Fasciola hepatica                                          | 2     |  |
| Fasciolopsis buski                                         | 2     |  |
| Giardia lamblia (Giardia duodenalis, Giardia intestinalis) | 2     |  |
| Heterophyes spp.                                           | 2     |  |
| Hymenolepis diminuta                                       | 2     |  |
| Hymenolepis nana                                           | 2     |  |
| Leishmania aethiopica                                      | 2     |  |
| Leishmania braziliensis                                    | 3 (*) |  |
| Leishmania donovani                                        | 3 (*) |  |
| Leishmania guyanensis (Viannia guyanensis)                 | 3 (*) |  |
| Leishmania infantum (Leishmania chagasi)                   | 3 (*) |  |
| Leishmania major                                           | 2     |  |
| Leishmania mexicana                                        | 2     |  |
| Leishmania panamensis (Viannia panamensis)                 | 3 (*) |  |
| Leishmania peruviana                                       | 2     |  |
| Leishmania tropica                                         | 2     |  |
| Leishmania spp.                                            | 2     |  |
| Loa loa                                                    | 2     |  |
| Mansonella ozzardi                                         | 2     |  |
| Mansonella perstans                                        | 2     |  |
| Mansonella streptocerca                                    | 2     |  |
| Metagonimus spp.                                           | 2     |  |
| Naegleria fowleri                                          | 3     |  |
| Necator americanus                                         | 2     |  |
| Onchocerca volvulus                                        | 2     |  |
| Opisthorchis felinus                                       | 2     |  |
| Opisthorchis spp.                                          | 2     |  |
| Paragonimus westermani                                     | 2     |  |
| Paragonimus spp.                                           | 2     |  |
| Plasmodium falciparum                                      | 3 (*) |  |
| Plasmodium knowlesi                                        | 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     |  |
| Taenia saginata                                | 2     |  |
| Taenia solium                                  | 3 (*) |  |
| Toxocara canis                                 | 2     |  |
| Toxocara cati                                  | 2     |  |
| Toxoplasma gondii                              | 2     |  |
| Trichinella nativa                             | 2     |  |
| Trichinella nelsoni                            | 2     |  |
| Trichinella pseudospiralis                     | 2     |  |
| Trichinella spiralis                           | 2     |  |
| Trichomonas vaginalis                          | 2     |  |
| Trichostrongylus orientalis                    | 2     |  |
| Trichostrongylus spp.                          | 2     |  |
| Trichuris trichiura                            | 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

NB: For biological agents appearing on this list, the entry of the whole genus with the addition of 'spp.' refers to other species belonging to this genus that have not specifically been included in the list, but which are known pathogens in humans. See introductory note 3 for further details.

| Biological Agent                                    | Classification | Notes |
|-----------------------------------------------------|----------------|-------|
| Aspergillus flavus                                  | 2              | A     |
| Aspergillus fumigatus                               | 2              | A     |
| Aspergillus spp.                                    | 2              |       |
| Blastomyces dermatitidis (Ajellomyces dermatitidis) | 3              |       |
| Blastomyces gilchristii                             | 3              |       |
| Candida albicans                                    | 2              | A     |
| Candida dubliniensis                                | 2              |       |

|                                                                                                                       |   |   |
|-----------------------------------------------------------------------------------------------------------------------|---|---|
| <i>Candida glabrata</i>                                                                                               | 2 |   |
| <i>Candida parapsilosis</i>                                                                                           | 2 |   |
| <i>Candida tropicalis</i>                                                                                             | 2 |   |
| <i>Cladophialophora bantiana</i> ( <i>Xylohypha bantiana</i> ,<br><i>Cladosporium bantianum</i> , <i>trichoides</i> ) | 3 |   |
| <i>Cladophialophora modesta</i>                                                                                       | 3 |   |
| <i>Cladophialophora</i> spp.                                                                                          | 2 |   |
| <i>Coccidioides immitis</i>                                                                                           | 3 | A |
| <i>Coccidioides posadasii</i>                                                                                         | 3 | A |
| <i>Cryptococcus gattii</i> ( <i>Filobasidiella neoformans</i> var.<br><i>bacillispora</i> )                           | 2 | A |
| <i>Cryptococcus neoformans</i> ( <i>Filobasidiella</i><br><i>neoformans</i> var. <i>neoformans</i> )                  | 2 | A |
| <i>Emmonsia parva</i> var. <i>parva</i>                                                                               | 2 |   |
| <i>Emmonsia parva</i> var. <i>crescens</i>                                                                            | 2 |   |
| <i>Epidermophyton floccosum</i>                                                                                       | 2 | A |
| <i>Epidermophyton</i> spp.                                                                                            | 2 |   |
| <i>Fonsecaea pedrosoi</i>                                                                                             | 2 |   |
| <i>Histoplasma capsulatum</i>                                                                                         | 3 |   |
| <i>Histoplasma capsulatum</i> var. <i>farcinosum</i>                                                                  | 3 |   |
| <i>Histoplasma duboisii</i>                                                                                           | 3 |   |
| <i>Madurella grisea</i>                                                                                               | 2 |   |
| <i>Madurella mycetomatis</i>                                                                                          | 2 |   |
| <i>Microsporum</i> spp.                                                                                               | 2 | A |
| <i>Nannizzia</i> spp.                                                                                                 | 2 |   |
| <i>Neotestudina rosatii</i>                                                                                           | 2 |   |
| <i>Paracoccidioides brasiliensis</i>                                                                                  | 3 | A |
| <i>Paracoccidioides lutzii</i>                                                                                        | 3 |   |
| <i>Paraphyton</i> spp.                                                                                                | 2 |   |
| <i>Rhinocladiella mackenziei</i>                                                                                      | 3 |   |
| <i>Scedosporium apiospermum</i>                                                                                       | 2 |   |
| <i>Scedosporium prolificans</i> ( <i>inflatum</i> )                                                                   | 2 |   |
| <i>Sporothrix schenckii</i>                                                                                           | 2 |   |
| <i>Talaromyces marneffei</i> ( <i>Penicillium marneffei</i> )                                                         | 2 | A |
| <i>Trichophyton rubrum</i>                                                                                            | 2 | A |
| <i>Trichophyton tonsurans</i>                                                                                         | 2 | A |
| <i>Trichophyton</i> 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.

*Substituted by:  
L.N. 4 of 2022.*

## SCHEDULE V

INDICATIONS CONCERNING CONTAINMENT MEASURES AND  
CONTAINMENT LEVELS

(Regulations 15(3) and 16(1)(a) and (b))

*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.

In the table, "Recommended" means that the measures should in principle be applied, unless the results of the assessment referred to in Regulation 3(2) indicate otherwise.

| A. Containment measures                                                            | B. Containment levels |             |     |
|------------------------------------------------------------------------------------|-----------------------|-------------|-----|
|                                                                                    | 2                     | 3           | 4   |
| Workplace                                                                          |                       |             |     |
| 1. The workplace is to be separated from any other activities in the same building | No                    | Recommended | Yes |
| 2. The workplace is to be sealable to permit fumigation                            | No                    | Recommended | Yes |
| Facilities                                                                         |                       |             |     |

|                                                                                                                                                                                                                                                                                                                      |                          |                                                                        |                                          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|------------------------------------------------------------------------|------------------------------------------|
| 3. 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                                      |
| Equipment                                                                                                                                                                                                                                                                                                            |                          |                                                                        |                                          |
| 4. Input air and extract air to the workplace are to be filtered using (HEPA <sup>(1)</sup> ) or likewise                                                                                                                                                                                                            | No                       | Yes, on extract air                                                    | Yes, on input and extract air            |
| 5. The workplace is to be maintained at an air pressure negative to atmosphere                                                                                                                                                                                                                                       | No                       | Recommended                                                            | Yes                                      |
| 6. Surfaces impervious to water and easy to clean                                                                                                                                                                                                                                                                    | Yes, for bench and floor | Yes, for bench, floor and other surfaces determined by risk assessment | Yes, for bench, walls, floor and ceiling |
| 7. Surfaces resistant to acids, alkalis, solvents, disinfectants                                                                                                                                                                                                                                                     | Recommended              | Yes                                                                    | Yes                                      |
| System of work                                                                                                                                                                                                                                                                                                       |                          |                                                                        |                                          |
| 8. Access is to be restricted to nominated workers only                                                                                                                                                                                                                                                              | Recommended              | Yes                                                                    | Yes, via airlock <sup>(2)</sup>          |
| 9. Efficient vector control, for example rodents and insects                                                                                                                                                                                                                                                         | Recommended              | Yes                                                                    | Yes                                      |
| 10. Specified disinfection procedures                                                                                                                                                                                                                                                                                | Yes                      | Yes                                                                    | Yes                                      |
| 11. Safe storage of a biological agent                                                                                                                                                                                                                                                                               | Yes                      | Yes                                                                    | Yes, secure storage                      |
| 12. Personnel should shower before leaving the contained area                                                                                                                                                                                                                                                        | No                       | Recommended                                                            | Recommended                              |
| Waste                                                                                                                                                                                                                                                                                                                |                          |                                                                        |                                          |
| 13. Validated inactivation process for the safe disposal of animal carcasses                                                                                                                                                                                                                                         | Recommended              | Yes, on or off site                                                    | Yes, on site                             |
| Other measures                                                                                                                                                                                                                                                                                                       |                          |                                                                        |                                          |
| 14. A laboratory is to contain its own equipment                                                                                                                                                                                                                                                                     | No                       | Recommended                                                            | Yes                                      |
| 15. An observation window, or, alternative, is to be present, so that occupants can be seen                                                                                                                                                                                                                          | Recommended              | Recommended                                                            | Yes'                                     |
| <sup>(1)</sup> HEPA: High efficiency particulate air<br><sup>(2)</sup> Airlock: Entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors. |                          |                                                                        |                                          |

Substituted by:  
L.N. 4 of 2022.

## SCHEDULE VI

### CONTAINMENT FOR INDUSTRIAL PROCESSES

#### (Regulation 4(1) and Regulation 16(2)(a))

##### *Preliminary note*

In the table, "Recommended" means that the measures should in principle be applied, unless the results of the assessment referred to in Regulation 3(2) indicate otherwise.

##### 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.

##### Groups 2, 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                                                   |
| <b>General</b>                                                                                                                                          |                                                     |                                                     |                                                     |
| 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 chemical or physical 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. The controlled area should be designed to contain spillage of the entire contents of the closed system                                               | No                                                  | Recommended                                         | Yes                                                 |
| 7. The controlled area should be sealable to permit fumigation                                                                                          | No                                                  | Recommended                                         | Yes                                                 |
| Facilities                                                                                                                                              |                                                     |                                                     |                                                     |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                     |                                                     |                                                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|-----------------------------------------------------|-----------------------------------------------------|
| 8. Decontamination and washing facilities should be provided for personnel                                                                                                                                                                                                                                                                                                                                                                                    | Yes                                                 | Yes                                                 | Yes                                                 |
| Equipment                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                     |                                                     |                                                     |
| 9. Input air and extract air to the controlled area should be HEPA <sup>(1)</sup> filtered                                                                                                                                                                                                                                                                                                                                                                    | No                                                  | Recommended                                         | Yes                                                 |
| 10. The controlled area should be maintained at an air pressure negative to atmosphere                                                                                                                                                                                                                                                                                                                                                                        | No                                                  | Recommended                                         | Yes                                                 |
| 11. The controlled area should be adequately ventilated to minimize air contamination                                                                                                                                                                                                                                                                                                                                                                         | Recommended                                         | Recommended                                         | Yes                                                 |
| System of work                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                     |                                                     |                                                     |
| 12. Closed systems <sup>(2)</sup> should be located within a controlled area                                                                                                                                                                                                                                                                                                                                                                                  | Recommended                                         | Recommended                                         | Yes, and purpose-built                              |
| 13. Biohazard signs should be posted                                                                                                                                                                                                                                                                                                                                                                                                                          | Recommended                                         | Yes                                                 | Yes                                                 |
| 14. Access should be restricted to nominated personnel only                                                                                                                                                                                                                                                                                                                                                                                                   | Recommended                                         | Yes                                                 | Yes, via an airlock <sup>(3)</sup>                  |
| 15. Personnel should shower before leaving the controlled area                                                                                                                                                                                                                                                                                                                                                                                                | No                                                  | Recommended                                         | Yes                                                 |
| 16. Personnel should wear protective clothing                                                                                                                                                                                                                                                                                                                                                                                                                 | Yes, work clothing                                  | Yes                                                 | Yes, complete change                                |
| Waste                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                     |                                                     |                                                     |
| 17. Effluent from sinks and showers should be collected and inactivated before release                                                                                                                                                                                                                                                                                                                                                                        | No                                                  | Recommended                                         | Yes                                                 |
| 18. Effluent treatment before final discharge                                                                                                                                                                                                                                                                                                                                                                                                                 | Inactivated by validated chemical or physical means | Inactivated by validated chemical or physical means | Inactivated by validated chemical or physical means |
| <sup>(1)</sup> HEPA: High efficiency particulate air<br><sup>(2)</sup> Closed system: A system that physically separates the process from the environment (e.g. incubator vats, tanks, etc.).<br><sup>(3)</sup> Airlock: Entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors. |                                                     |                                                     |                                                     |