

Subsidiary Legislation made under ss. 58 and 81.

## **Factories (Protection of workers from risks related to exposure to biological agents at work) Regulations 2006**

**LN. 2006/082**

*Commencement*                      **1.6.2006**

**Transposing:**  
Directive 2000/54/EC

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*In exercise of the powers conferred on him by sections 58 and 81 of the Factories Act and of all other enabling powers, and for the purposes of transposing into the Law of Gibraltar Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC), the Governor has made the following Regulations:*

**PART I  
PRELIMINARY**

**Title.**

1. These Regulations may be cited as the Factories (Protection of workers from risks related to exposure to biological agents at work) Regulations 2006.

**Interpretation.**

2. In these regulations, unless the context otherwise requires—

“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;

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

“competent authority” means the Factories Inspector appointed under section 77 of the Factories Act;

“group 1 biological agent” means one that is unlikely to cause human disease;

“group 2 biological agent” means one—

- (a) that can cause human disease and might be a hazard to workers;
- (b) that is unlikely to spread to the community; and
- (c) for which there is usually effective prophylaxis or treatment available;

“group 3 biological agent” means one—

- (a) that can cause severe human disease and present a serious hazard to workers;

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- (b) that may present a risk of spreading to the community; and
- (c) for which there is usually effective prophylaxis or treatment available;

“group 4 biological agent” means one–

- (a) that causes severe human disease and is a serious hazard to workers;
- (b) that may present a high risk of spreading to the community; and
- (c) for which there is usually no effective prophylaxis or treatment available;

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

**PART II**  
**GENERAL PROVISIONS**

**Application of these Regulations.**

3.(1) These Regulations shall apply in order to ensure the protection of 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.

(2) The provisions of the following Regulations in so far as they transpose Directive 89/391/EEC shall apply fully to the whole area referred to in subregulation (1), without prejudice to more stringent and/or specific provisions contained in these Regulations–

- (a) Factories (Safety) Regulations 1995;
- (b) Management of Health and Safety at Work Regulations 1996;
- (c) Employment (Maternity and Health and Safety) Regulations 1996; and
- (d) Factories (Control of Carcinogens and Mutagens at Work) Regulations 2003.

(3) These Regulations shall apply without prejudice to the provisions of the Public Health (Genetically Modified Organisms) Regulations 1995.

**Determination and assessment of health risks.**

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4.(1) Every employer shall, in the case of any activity that is likely to involve a risk of exposure to biological agents, determine the nature, degree and duration of workers' exposure 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.

(2) In the case of activities involving exposure to several groups of biological agents, the employer shall assess the risk referred to in subregulation (1) on the basis of the danger presented by all hazardous biological agents present.

(3) The assessment made pursuant to subregulation (2) shall be renewed regularly and in any event when any change occurs in the conditions which may affect workers' exposure to biological agents.

(4) The employer shall supply the competent authority, at its request, with the information used for making the assessment under this regulation.

(5) The assessment required by this regulation shall be conducted on the basis of all available information including—

- (a) classification of biological agents which are or may be a hazard to human health, as referred to in regulation 18;
- (b) recommendations from the competent authority which indicate that the biological agent should be controlled in order to protect workers' health when workers are or may be exposed to such a biological agent as a result of their work;
- (c) information on diseases which may be contracted as a result of the work of the workers;
- (d) potential allergenic or toxigenic effects as a result of the work of the workers;
- (e) knowledge of a disease from which a worker is found to be suffering and which has a direct connection with his work.

**Application of other provisions of these Regulations in relation to assessment of risks.**

5.(1) Where the results of the assessment made pursuant to regulation 4 show that the exposure or potential exposure or both exist to a group 1 biological agent, with no identifiable health risk to workers, the provisions of regulations 6 to 17 shall not apply but point 1 of Schedule 6 shall be observed.

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(2) Where the results of the assessment made pursuant to regulation 4 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 1, the provisions of regulations 6, 8, 9, 11, 12, 13, 14 and 15 shall apply unless the results of the assessment show them to be unnecessary.

**PART III**  
**EMPLOYERS' OBLIGATIONS**

**Replacement of biological agent.**

6. Every 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 which, under its conditions of use, is not dangerous or is less dangerous to workers' health, as the case may be, in the present state of knowledge.

**Reduction of health risks.**

7.(1) Where the results of the assessment referred to in regulation 4 reveal a risk to workers' health or safety, workers' exposure shall be prevented.

(2) Where this is not technically practicable, having regard to the activity and the risk assessment referred to in regulation 4, the risk of exposure shall be reduced to as low a level as necessary in order to protect adequately the health and safety of the workers concerned.

(3) In taking action under subregulation (2) the following measures shall be applied in the light of the results of the assessment referred to in regulation 4—

- (a) keeping as low as possible the number of workers exposed or likely to be exposed;
- (b) 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) collective protection measures or, where exposure cannot be avoided by other means, individual protection measures;
- (d) 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) use of the biohazard sign depicted in Schedule 2 and other relevant warning signs;
- (f) drawing up plans to deal with accidents involving biological agents;

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- (g) testing, where it is necessary and technically possible, for the presence, outside the primary physical confinement, of biological agents used at work;
- (h) 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) arrangements for the safe handling and transport of biological agents within the workplace.

**Information for the competent authority.**

8.(1) Where the results of the assessment referred to in regulation 4 reveal risk to workers' health or safety, every employer shall, if requested, make available to the competent 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 safety and health 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) Every employer shall inform forthwith the competent authority of any accident or incident which may have resulted in the release of a biological agent and which could cause severe human infection or illness.

(3) The list referred to in regulation 12 and the medical record referred to in regulation 15 shall be handed over to the competent authority by an employer whose undertaking is to cease activity.

**Hygiene and individual protection.**

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9.(1) Every employer 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 or skin antiseptics or both;
- (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, and
  - (iii) is repaired, where defective, or is replaced before further use; and
- (e) procedures are specified for taking, handling and processing samples of human or animal origin.

(2) Working clothes and protective equipment, including protective clothing referred to in subregulation (1), which may be contaminated by biological agents, shall be removed on leaving the working area and, before taking the measures referred to in subregulation (3), kept separately from other clothing.

(3) The employer shall ensure that clothing and protective equipment referred to in subregulation (2) is decontaminated and cleaned or, if necessary, destroyed.

(4) Workers shall not be charged for the cost of the measures required by this regulation.

**Information and training of workers.**

10.(1) Every employer shall take appropriate measures to ensure that workers and any workers' representatives in the undertaking or establishment receive sufficient and appropriate training, on the basis of all available information, in particular in the form of information and instructions, concerning—

- (a) potential risks to health;



- (b) precautions to be taken to prevent exposure;
  - (c) hygiene requirements;
  - (d) wearing and use of protective equipment and clothing;
  - (e) steps to be taken by workers in the case of incidents and to prevent incidents.
- (2) The training referred to in subregulation (1) shall be—
- (a) given at the beginning of work involving contact with biological agents;
  - (b) adapted to take account of new or changed risks; and
  - (c) repeated periodically if necessary.

**Worker information in particular cases.**

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

- (a) a serious accident or incident involving the handling of a biological agent; and
  - (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 safety and health at work.
- (3) The employer shall inform forthwith the workers 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 or illness.
- (4) The employer shall also inform the workers and 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.
- (5) Each worker shall have access to the information on the list referred to in regulation 12 which relates to him personally.

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

(7) Every employer shall provide workers and their representatives, at their request, with the information provided for in regulation 8(1).

**List of exposed workers.**

12.(1) Every employer shall keep a list of workers exposed to group 3 and 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) The employer shall maintain the list referred to in subregulation (1) for at least 10 years following the end of exposure.

(3) In the case of those exposures which may result in infections–

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

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

(4) The doctor referred to in regulation 15, the competent authority and any other person responsible for health and safety at work, shall have access to the list referred to in subregulation (1).

**Consultation and participation of workers.**

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13.(1) Every employer shall consult workers and their representatives and allow them to take part in discussions on all questions relating to safety and health at work that is covered by these Regulations.

(2) The consultation and participation required by subregulation (1) shall take place in accordance with regulation 8 of the Management of Health and Safety at Work Regulations 1996.

**Notification to the competent authority.**

14.(1) Every employer shall make a prior notification to the competent authority of the use for the first time of—

- (a) group 2 biological agents;
- (b) group 3 biological agents;
- (c) group 4 biological agents.

(2) The notification referred to in subregulation (1) shall be made at least 30 days before the commencement of the work.

(3) Subject to subregulation (4), every employer shall also make prior notification 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.

(4) Where a laboratory provides a diagnostic service in relation to group 4 biological agents, it shall only be required to make an initial notification of its intention.

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

(6) A notification required by this regulation shall include—

- (a) the name and address of the undertaking or establishment;
- (b) the name and capabilities of the person responsible for safety and health at work;
- (c) the results of the assessment referred to in regulation 4;
- (d) the species of the biological agent;

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(e) the protection and preventive measures that are envisaged.

**PART 4**  
**MISCELLANEOUS PROVISIONS**

**Health surveillance.**

15.(1) Every employer shall make arrangements for carrying out relevant health surveillance of workers for whom the results of the assessment referred to in regulation 4 reveal a risk to health or safety.

(2) The arrangements referred to in subregulation (1) shall be such that—

(a) each worker shall be able to undergo, if appropriate, relevant health surveillance—

(i) prior to exposure; and

(ii) at regular intervals thereafter; and

(b) it is directly possible to implement individual and occupational hygiene measures.

(3) The assessment referred to in regulation 4 should identify those workers for whom special protective measures may be required and 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.

(4) When employers make vaccines available pursuant to subregulation (3), they shall take account of the recommended code of practice set out in Schedule 7.

(5) If a worker is found to be suffering from an infection or illness which is suspected to be the result of exposure, the doctor or authority responsible for health surveillance of workers shall offer such surveillance to other workers who have been similarly exposed and in that event, a reassessment of the risk of exposure shall be carried out in accordance with regulation 4.

(6) In cases where health surveillance is carried out, an individual medical record shall be kept by the employer for at least 10 years following the end of exposure, and in the special cases referred to in regulation 12(3), an individual medical record shall be kept for an appropriately longer time up to 40 years following the last known exposure.

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(7) The doctor or authority responsible for health surveillance shall propose any protective or preventive measures to be taken in respect of any individual worker.

(8) The employer shall ensure that information and advice are given to workers regarding any health surveillance which they may undergo following the end of exposure.

(9) Every worker shall have access to the results of the health surveillance which concern them, and the workers concerned or the employer may request a review of the results of the health surveillance by the doctor or authority responsible for health surveillance.

(10) Practical recommendations for the health surveillance of workers are given in Schedule 4.

(11) All cases of diseases or death identified as resulting from occupational exposure to biological agents shall be notified to the competent authority by the employer.

**Health and veterinary care facilities other than diagnostic laboratories.**

16.(1) For the purpose of the assessment referred to in regulation 4, particular attention shall 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; and
- (c) the risks posed by the nature of the work.

(2) Every employer shall take appropriate measures in health and veterinary care facilities in order to protect the health and safety of the workers concerned.

(3) The measures to be taken pursuant to subregulation (2) shall include in particular—

- (a) specifying appropriate decontamination and disinfection procedures; and
- (b) implementing procedures enabling contaminated waste to be handled and disposed of without risk.

(4) 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 5, column A, in order to minimise the risk of infection.

**Special measures for industrial processes, laboratories and animal rooms.**

17.(1) The measures prescribed by this regulation shall 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.

(2) 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 5, in order to minimise the risk of infection.

(3) Following the assessment referred to in regulation 4, measures shall be determined in accordance with Schedule 5, after fixing the physical containment level required for the biological agents according to the degree of risk.

(4) Activities involving the handling of a biological agent shall be carried out only in working areas corresponding to at least–

- (a) containment level 2, for a group 2 biological agent,
- (b) containment level 3, for a group 3 biological agent, and
- (c) containment level 4, for a group 4 biological agent.

(5) 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) shall adopt containment level 2 at least and containment levels 3 or 4 shall be used, when appropriate, where it is known or it is suspected that they are necessary, except where guidelines provided by the competent authority show that, in certain cases, a lower containment level is appropriate.

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

- (a) the containment principles set out in subregulation (4) shall also apply to industrial processes on the basis of the practical measures and appropriate procedures given in Schedule 6; and

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

(7) For all activities covered by this regulation 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.

**Classification of biological agents.**

18.(1) The competent authority shall classify biological agents that are or may be a hazard to human health on the basis of the definition of “biological agents” and the definitions of group 2, 3 and 4 biological agents as set out in regulation 2, pending any Community classification of such biological agents in accordance with Schedule 3.

(2) The Community classification referred to in subregulation (1) shall apply once such classification has been made.

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

**Repeal.**

19. The Factories (Control of Biological Agents at Work) Regulations 1999 are repealed.

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**SCHEDULE 1**

Regulation 5(2)

**INDICATIVE LIST OF ACTIVITIES**

1. Work in food production plants.
2. Work in agriculture.
3. Work activities where there is contact with animals 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 2**

Regulation 7(3)(e)

**BIOHAZARD SIGN**



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**SCHEDULE 3**

Regulation 18

**COMMUNITY CLASSIFICATION**

**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 17 of these Regulations.
3. Biological agents which have not been classified for inclusion in groups 2 to 4 of the list are not implicitly classified in group 1. For agents where more than one species is 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.

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

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

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

These indications are shown by the following letters:

A: Possible allergic effects

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

T: Toxin production

V: Effective vaccine available

The application of preventive vaccination should take account of the code of practice given in Schedule 7.

**BACTERIA**

**and similar organisms**

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

Biological agent	Classification	Notes

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<i>Actinobacillus actinomycetemcomitans</i>	2	
<i>Actinomadura madurae</i>	2	
<i>Actinomadura pelletieri</i>	2	
<i>Actinomyces gerencseriae</i>	2	
<i>Actinomyces israelii</i>	2	
<i>Actinomyces pyogenes</i>	2	
<i>Actinomyces spp.</i>	2	
<i>Arcanobacterium haemolyticum (Corynebacterium haenolyticum)</i>	2	
<i>Bacillus anthracis</i>	3	
<i>Bacteroides fragilis</i>	2	
<i>Bartonella bacilliformis</i>	2	
<i>Bartonella quintana (Rochalimaea quintana)</i>	2	
<i>Bartonella (Rochalinea) spp.</i>	2	
<i>Bordetella bronchiseptica</i>	2	
<i>Bordetella parapertussis</i>	2	
<i>Bordetella pertussis</i>	2	V
<i>Borrelia burgdorferi</i>	2	
<i>Borrelia duttonii</i>	2	
<i>Borrelia recurrentis</i>	2	
<i>Borrelia spp.</i>	2	
<i>Brucella abortus</i>	3	
<i>Brucella canis</i>	3	
<i>Brucella melitensis</i>	3	
<i>Brucella suis</i>	3	
<i>Burkholderia mallei (Pseudomonas mallei)</i>	3	
<i>Burkholderia pseudomallei (Pseudomonas pseudomallei)</i>	3	
<i>Campylobacter fetus</i>	2	
<i>Campylobacter jejuni</i>	2	
<i>Campylobacter spp.</i>	2	
<i>Cardiobacterium hominis</i>	2	
<i>Chlamydia pneumoniae</i>	2	
<i>Chlamydia trachomatis</i>	2	
<i>Chlamydia psittaci (avian strains)</i>	3	
<i>Chlamydia psittaci (other strains)</i>	2	
<i>Clostridium botulinum</i>	2	T
<i>Clostridium perfringens</i>	2	
<i>Clostridium tetani</i>	2	T,V
<i>Clostridium spp.</i>	2	
<i>Corynebacterium diphtheriae</i>	2	T,V
<i>Corynebacterium minutissimum</i>	2	
<i>Corynebacterium pseudotuberculosis</i>	2	
<i>Corynebacterium spp.</i>	2	
<i>Coxiella burnettii</i>	3	
<i>Edwardsiella tarda</i>	2	
<i>Ehrlichia sennetsu (Rickettsia sennetsu)</i>	2	
<i>Ehrlichia spp.</i>	2	
<i>Eikenella corrodens</i>	2	
<i>Enterobacter aerogenes/cloacae</i>	2	
<i>Enterobacter spp.</i>	2	
<i>Enterococcus spp.</i>	2	
<i>Erysipelothrix rhusiopathiae</i>	2	
<i>Escherichia coli (with the exception of non-pathogenic strains)</i>	2	
<i>Escherichia coli, verocytotoxigenic strains (eg 0157:H7 or 0103)</i>	3(**)	
<i>Flavobacterium meningosepticum</i>	2	
<i>Fluoribacter bozemanii (Legionella)</i>	2	
<i>Francisella tularensis (Type A)</i>	3	
<i>Francisella tularensis (Type B)</i>	2	
<i>Fusobacterium necrophorum</i>	2	
<i>Gardnerella vaginalis</i>	2	
<i>Haemophilus ducreyi</i>	2	
<i>Haemophilus influenzae</i>	2	

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<i>Haemophilus spp.</i>	2		
<i>Helicobacter pylori</i>	2		
<i>Klebsiella oxytoca</i>	2		
<i>Klebsiella pneumoniae</i>	2		
<i>Klebsiella spp.</i>	2		
<i>Legionella pneumophila</i>	2		
<i>Legionella spp.</i>	2		
<i>Leptospira interrogans (all serovars)</i>	2		
<i>Listeria monocytogenes</i>	2		
<i>Listeria ivanovii</i>	2		
<i>Morganella morganii</i>	2		
<i>Mycobacterium africanum</i>	3	V	
<i>Mycobacterium avium/intracellulare</i>	2		
<i>Mycobacterium bovis (except BCG strain)</i>	3	V	
<i>Mycobacterium chelonae</i>	2		
<i>Mycobacterium fortuitum</i>	2		
<i>Mycobacterium kansasii</i>	2		
<i>Mycobacterium leprae</i>	3		
<i>Mycobacterium malmoense</i>	2		
<i>Mycobacterium marinum</i>	2		
<i>Mycobacterium microti</i>	3(**)		
<i>Mycobacterium paratuberculosis</i>	2		
<i>Mycobacterium scrofulaceum</i>	2		
<i>Mycobacterium simiae</i>	2		
<i>Mycobacterium szulgai</i>	2		
<i>Mycobacterium tuberculosis</i>	3	V	
<i>Mycobacterium ulcerans</i>	3 (**)		
<i>Mycobacterium xenopi</i>	2		
<i>Mycoplasma caviae</i>	2		
<i>Mycoplasma hominis</i>	2		
<i>Mycoplasma pneumoniae</i>	2		
<i>Neisseria gonorrhoeae</i>	2		
<i>Neisseria meningitidis</i>	2	V	
<i>Nocardia asteroides</i>	2		
<i>Nocardia brasiliensis</i>	2		
<i>Nocardia farcinica</i>	2		
<i>Nocardia nova</i>	2		
<i>Nocardia otitidiscaviarum</i>	2		
<i>Pasteurella multocida</i>	2		
<i>Pasteurella spp.</i>	2		
<i>Peptostreptococcus anaerobius</i>	2		
<i>Plesiomonas shigelloides</i>	2		
<i>Porphyromonas spp.</i>	2		
<i>Prevotella spp.</i>	2		
<i>Proteus mirabilis</i>	2		
<i>Proteus penneri</i>	2		
<i>Proteus vulgaris</i>	2		
<i>Providencia alcalifaciens</i>	2		
<i>Providencia rettgeri</i>	2		
<i>Providencia spp.</i>	2		
<i>Pseudomonas aeruginosa</i>	2		
<i>Rhodococcus equi</i>	2		
<i>Rickettsia akari</i>	3(**)		
<i>Rickettsia canada</i>	3(**)		
<i>Rickettsia conorii</i>	3		
<i>Rickettsia Montana</i>	3(**)		
<i>Rickettsia typhi (Rickettsia mooseri)</i>	3		
<i>Rickettsia prowazekii</i>	3		
<i>Rickettsia rickettsii</i>	3		
<i>Rickettsia tsutsugamushi</i>	3		
<i>Rickettsia spp.</i>	2		
<i>Salmonella arizonae</i>	2		
<i>Salmonella enteritidis</i>	2		

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<i>Salmonella typhimurium</i>	2	
<i>Salmonella paratyphi A, B, C</i>	2	V
<i>Salmonella typhi</i>	3(**)	V
<i>Salmonella (other serovars)</i>	2	
<i>Serpulina spp</i>	2	
<i>Shigella boydii</i>	2	
<i>Shigella dysenteriae (Type 1)</i>	3(**)	T
<i>Shigella dysenteriae, other than Type 1</i>	2	
<i>Shigella flexneri</i>	2	
<i>Shigella sonnei</i>	2	
<i>Staphylococcus aureus</i>	2	
<i>Streptobacillus moniliformis</i>	2	
<i>Streptococcus pneumoniae</i>	2	
<i>Streptococcus pyogenes</i>	2	
<i>Streptococcus suis</i>	2	
<i>Streptococcus spp.</i>	2	
<i>Treponema carateum</i>	2	
<i>Treponema pallidum</i>	2	
<i>Treponema pertenue</i>	2	
<i>Treponema spp.</i>	2	
<i>Vibrio cholerae (including El Tor)</i>	2	
<i>Vibrio parahaemolyticus</i>	2	
<i>Vibrio spp.</i>	2	
<i>Yersinia enterocolitica</i>	2	
<i>Yersinia pestis</i>	3	V
<i>Yersinia pseudotuberculosis</i>	2	
<i>Yersinia spp.</i>	2	

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

**VIRUSES(\*)**

Biological agent	Classification	Notes
<i>Adenoviridae</i>	2	
<i>Arenaviridae</i>		
LCM-Lassa-virus complex (old world arena viruses):		
Lassa-virus	4	
Lymphocytic (strains)	3	
Lymphocytic choriomeningitis virus (other strains)	2	
Mopeia virus	2	
Other LCM-Lassa complex viruses	2	
Tacaribe-Virus-complex (new world arena viruses):		
Gunarito virus	4	
Jumin virus	4	
Sabia virus	4	
Machupo virus	4	
Flexal virus	3	
Other Tacaribe complex viruses	2	
<i>Astroviridae</i>	2	
<i>Bunyaviridae</i>		
Belgrade (also known as Dobrava)	3	
Bhanja	2	
Bunyamwera virus	2	
Germiston	2	
Oropouche virus	3	
Sin nombre (formerly Muerto Canyon)	3	
California encephalitis virus	2	
Hantaviruses:		
Hantaan (Korean haemorrhagic fever)	3	
Seoul virus	3	
Puumala virus	2	

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Prospect Hill virus	2	
Other hantaviruses	2	
Nairoviruses:		
Crimean-Congo haemorrhagic fever	4	
Hazara virus	2	
Phleboviruses:		
Rift Valley fever	3	V
Sandfly fever	2	
Toscana virus	2	
Other bunyaviridae known to be pathogenic	2	
<i>Caliciviridae</i>		
Hepatitis E virus	3(**)	
Norwalk virus	2	
Other Calciviridae	2	
<i>Coronaviridae</i>	2	
<i>Filoviridae</i>		
Ebola virus	4	
Marburg virus	4	
<i>Flaviviridae</i>		
Australia encephalitis (Murray Valley encephalitis)	3	
Central European tick-borne encephalitis virus	3(**)	V
Absettarov	3	
Hanzalova	3	
Hypr	3	
Kumlinge	3	
Dengue virus type 1-4	3	
Hepatitis C virus	3(**)	D
Hepatitis G virus	3	D
Japanese B encephalitis	3	V
Kysanur Forest	3	V
Louping ill	3(**)	
Omsk(a)	3	V
Powassan	3	
Rocio	3	
Russian spring-summer encephalitis (TBE) (a)	3	V
St Louis encephalitis	3	
Wesselsbron virus	3(**)	
West Nile fever virus	3	
Yellow fever	3	V
Other flaviviruses known to be pathogenic	2	
<i>Hepadnaviridae</i>		
Hepatitis B virus	3(**)	V,D
Hepatitis D virus (Delta) (b)	3(**)	V,D
<i>Herpesviridae</i>		
Cytomegalovirus	2	
Epstein-Barr virus	2	
Herpesvirus simiae (B virus)	3	
Herpes simplex virus types 1 and 2	2	
Herpesvirus varicella-zoster	2	
Human B-Lymphotropic virus (HBLV-HHV6)	2	
Human herpes virus 7	2	
Human herpes virus 8	2	D
<i>Orthomyxoviridae</i>		
Influenza viruses type A, B and C	2	V(c)
Tick-borne orthomyxoviridae: Dhori and Thogoto	2	
<i>Papovaviridae</i>		
BK and JC viruses	2	D(d)
Human Paillomaviruses	2	D(d)
<i>Paramyxoviridae</i>		
Measles virus	2	V
Mumps virus	2	V
Newcastle disease virus	2	
Parainfluenza viruses types 1 to 4	2	

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Respiratory syncytial virus	2	
<i>Parvoviridae</i>		
Human parvovirus (B19)	2	
<i>Picomaviridae</i>		
Acute haemorrhagic conjunctivitis virus (AHC)	2	
Coxsackie viruses	2	
Echo viruses	2	
Hepatitis A virus (human enterovirus type 72)	2	V
Polioviruses	2	V
Rhinoviruses	2	
<i>Poxviridae</i>		
Buffalopox virus(e)	2	
Cowpox virus	2	
Elephantpox virus(f)	2	
Milkers' node virus	2	
<i>Molluscum contagiosum virus</i>	2	
Monkeypox virus	3	V
Orf virus	2	
Rabbitpox virus (g)	2	
Vaccinia virus	2	
Variola (major and minor) virus	4	V
Whitepox virus ('Variola virus)	4	V
Yatapox virus (Tana & Yaba)	2	
<i>Reoviridae</i>		
Coltivirus	2	
Human rotaviruses	2	
Orbiviruses	2	
Reuviruses	2	
<i>Retroviridae</i>		
Human immunodeficiency viruses	3(**)	D
Human T-cell lymphotropic (HTLV), types 1 and 2	3(**)	D
SIV (h)	3(**)	
<i>Rhabdoviridae</i>		
Rabies virus	3(**)	V
Vesicular stomatitis virus	2	
<i>Togaviridae</i>		
Alphaviruses		
Eastern equine encephalomyelitis	3	V
Bebaru virus	2	
Chikungunya virus	3(**)	
Everglades virus	3(**)	
Mayaro virus	3	
Mucambo virus	3(**)	
Ndumu virus	3	
O'nyong-nyong virus	2	
Ross River virus	2	
Semliki Forest virus	2	
Sindbis virus	2	
Tonate virus	3(**)	
Venezuelan equine encephalomyelitis	3	V
Western equine encephalomyelitis	3	V
Other known alphaviruses	2	
Rubivirus (rubella)	2	V
<i>Toroviridae</i>	2	
Unclassified viruses		
Equine morbillivirus	4	
Hepatitis viruses not yet identified	3(**)	D
Unconventional agents associated with the transmissible spongiform encephalopathies (TSEs)		
Creutzfeldt-Jakob disease	3(**)	D(d)
Variant Creutzfeldt-Jakob disease	3(**)	D(d)
Bovine spongiform encephalopathy (BSE) and other related animal TSEs(i)	3(**)	D(d)



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

### PARASITES

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

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Leishmania tropica	2	
Leishmania major	2	
Leishmania spp.	2	
Loa loa	2	
Masonella ozzardi	2	
Mansonella perstans	2	
Naegleria fowleri	3	
Necator americanus	2	
Onchocerca volvulus	2	
Opisthorchis felineus	2	
Opisthorchis spp.	2	
Paragonimus westermani	2	
Plasmodium falciparum	3(**)	
Plasmodium spp. (human and simian)	2	
Sarcocystis suihominis	2	
Schistosoma haematobium	2	
Schistosoma intercalatum	2	
Schistosoma japonicum	2	
Schistosoma mansoni	2	
Schistosoma mekongi	2	
Strongyloides stercoralis	2	
Strongyloides spp.	2	
Taenia saginata	2	
Taenia solium	3(**)	
Toxocara canis	2	
Toxoplasma gondii	2	
Trichinella spiralis	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**

Biological agent	Classification	Notes
Aspergillus fumigatus	2	A
Blastomyces dermatitidis (Ajellomyces dermatitidis)	3	
Candida albicans	2	A
Candida tropicalis	2	
Cladophialophora bantiana (formerly: Xylohypha bantiana, Cladosporium bantianum or trichoides)	3	
Coccidioides imunitis	3	A
Cryptococcus neoformans var. neofonnans (Filobasidiella neofonnans var. neofonnans)	2	A
Cryptococcus neoformans var. gattii (Filobasidiella bacillispora)	2	A
Emmonsia parva var. parva	2	
Emmonsia parva var. crescens	2	
Epidermophyton floccosum	2	A
Fonsecaea compacta	2	
Fonsecaea pedrosoi	2	
Histoplasma capsulatum var. capsulatum (Ajellomyces capsulatus)	3	
Histoplasma capsulatum duboisii	3	
Madurella grisea	2	
Madurella mycetomatis	2	
Microsporium spp.	2	A
Neotestudina rosatii	2	

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Paracoccidioides brasiliensis	3	
Penicillium marneffei	2	A
Scedosporium apiospermum (Pseudallescheria boydii)	2	
Scedosporium prolificans (inflatum)	2	
Sporothrix schenckii	2	
Trichophyton rubrum	2	
Trichophyton spp.	2	

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**SCHEDULE 4**

Regulation 15(9)

**PRACTICAL RECOMMENDATIONS FOR THE HEALTH SURVEILLANCE OF WORKERS**

1. The doctor and the authority responsible for the health surveillance of workers exposed to biological agents 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 and it must include at least the following measures–

- (a) keeping records of a worker's medical and occupational history;
- (b) a personalised assessment of the worker's state of health; and
- (c) where appropriate, biological monitoring, as well as detection of early and reversible effects.

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

## SCHEDULE 5

Regulations 16(4) and 17(2) and 17(3).

## INDICATIONS CONCERNING CONTAINMENT MEASURES AND CONTAINMENT LEVELS

*Preliminary note*

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

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

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**SCHEDULE 6**

Regulations 5(1) and 17(6)(a)

**CONTAINMENT FOR INDUSTRIAL PROCESSES**

*Group 1 biological agents*

For work with group 1 biological agents including life 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.

	B. Containment levels		
	2.	3.	4.
1. Viable organisms should be handled in a system which physically separates the process from the environment	Yes	Yes	Yes
2. Exhaust gases from the closed system should be treated so as to:	Minimise release	Prevent release	Prevent release
3. Sample collection, addition of materials to a closed system and transfer of viable organisms to another closed system, should be performed so as to:	Minimise release	Prevent release	Prevent release
4. Bulk culture fluids should not be removed from the closed system unless the viable organisms have been:	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means
5. Seals should be designed so as to:	Minimise release	Prevent release	Prevent release

A. Containment measures	B. Containment levels	A. Containment measures	B. Containment levels
6. Closed systems should be located within a controlled area	Optional	Optional	Yes, and purpose-built
(a) Biohazard signs should be posted	Optional	Yes	Yes
(b) Access should be restricted to nominated personnel only	Optional	Yes	Yes, via an airlock
(c) Personnel should wear protective clothing	Yes, work clothing	Yes	A complete change
(d) Decontamination and washing facilities should be provided	Yes	Yes	Yes
(e) Personnel should shower before leaving the controlled area	No	Optional	Yes

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(f)	Effluent from sinks and showers should be collected and inactivated before release	No	Optional	Yes
(g)	The controlled area should be subsequently ventilated to minimize air contamination	Optional	Optional	Yes
(h)	The controlled area should be maintained at an air pressure negative to atmosphere	No	Optional	Yes
(i)	Input air and extract air to the controlled area should be HEPA filtered	No	Optional	Yes
(j)	The controlled area should be designed to contain spillage of the entire contents of the closed system	No	Optional	Yes
(k)	The controlled area should be sealable to permit fumigation	No	Optional	Yes
(l)	Effluent treatment before final discharge	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means

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**SCHEDULE 7**

Regulation 15(4)

**RECOMMENDED CODE OF PRACTICE ON VACCINATION**

1. If the assessment referred to in regulation 4 reveals that there is a risk to the health and safety of workers due to their exposure to biological agents for which effective vaccines exist, their employers should offer them vaccination.
2. Vaccination should be carried out in accordance with Gibraltar law and practice. Workers should be informed of the benefits and drawbacks of both vaccination and non-vaccination.
3. Vaccination must be offered free of charge to workers.
4. A vaccination certificate may be drawn up which should be made available to the worker concerned and, on request, to the competent authority.