S.I. No. 146/1994: SAFETY, HEALTH AND WELFARE AT WORK (BIOLOGICAL AGENTS) REGULATIONS, 1994.

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S.I. No. 146 of 1994.

SAFETY, HEALTH AND WELFARE AT WORK (BIOLOGICAL AGENTS) REGULATIONS, 1994.

I, RUAIRÍ QUINN, Minister for Enterprise and Employment, in exercise of the powers conferred on me by section 28 of the Safety, Health and Welfare at Work Act, 1989 (No. 7 of 1989), and the Labour (Transfer of Departmental Administration and Ministerial Functions) Order, 1993 (S.I. No. 18 of 1993), and for the purpose of giving effect to Council Directive 90/679/EEC[1] of 26 November, 1990 as amended by Council Directive 93/88/EEC[2] of 12 October, 1993, after consulation with the National Authority for Occupational Safety and Health, hereby make the following Regulations:—

Short Title and Commencement.

**1.** (1) These Regulations may be cited as the Safety, Health and Welfare at Work (Biological Agents) Regulations, 1994.

(2) These Regulations shall come into operation on the 23rd day of May, 1994.

Interpretation.

**2.** (1) In these Regulations:—

"the Act" means the Safety, Health and Welfare at Work Act, 1989 (No. 7 of 1989);

"biological agent" means a micro-organism, including those which have been genetically modified, a cell culture and a human endoparasite, which may be able to

provoke any infection, allergy or toxicity, classified into four risk groups according to their level of risk of infection, as follows:—

— a "group 1 biological agent", that is one that is unlikely to cause human disease;

— a "group 2 biological agent", that is one which can cause human disease and might be a hazard to employees, although it is unlikely to spread to the community and in respect of which there is usually effective prophylaxis or treatment available;

[1]O.J. No. L 374 of 32/12/1990, pp. 1-12.

[2]O.J. No. L 268 of 29/10/93 pp. 71-82.

— a "group 3 biological agent", that is one which can cause severe human disease and presents a serious hazard to employees and which may present a risk of spreading to the community, though there is usually effective prophylaxis or treatment available;

— a "group 4 biological agent", that is one which causes severe human disease and is a serious hazard to employees and which may present a high risk of spreading to the community and in respect of which there is usually no effective prophylaxis or treatment available;

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

"containment level" means the containment level specified in columns 2, 3 and 4 of the Seventh and Eighth Schedules as appropriate;

"employer" means, for the purpose of these Regulations, any employer of employees who are in contact with or at risk of being exposed to a biological agent as a result of work;

"micro-organism" means a microbiological entity, cellular or non-celular, capable of replication or of transferring genetic material;

"responsible medical practitioner" means the registered medical practitioner employed, or otherwise engaged, by an employer to be responsible for health surveillance of employees under these Regulations;

"the Principal Regulations" means the Safety, Health and Welfare at Work (General Application) Regulations, 1993 (S.I. No. 44 of 1993).

(2) In these Regulations a reference to a paragraph is to a paragraph in the Regulation in which the reference occurs, unless it is indicated that reference to some other Regulation is intended, and a reference to a Regulation or a Schedule is to a Regulation of, or a Schedule to,

these Regulations, unless it is indicated that reference to some other Regulation or Schedule is intended.

(3) The provisions of Regulations 2 and 4 and of Part II of the Principal Regulations shall apply to the application of the provisions of these Regulations.

Duties of Employers.

**3.** It shall be the duty of every employer—

( *a* ) to 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, eliminates or reduces the risk to the health of employees,

( *b* ) to prevent the exposure of employees to a biological agent at a place of work where the results of the risk assessment under Regulation 4 reveal a risk to employees' health and safety,

( *c* ) to ensure that the level of exposure of employees is reduced to as low a level as necessary in order to protect adequately the health and safety of the employees concerned, where it is not technically possible to prevent exposure,

( *d* ) to apply the measures specified in the Second Schedule where the results of the risk assessment under Regulation 4 reveal that it is not technically possible to prevent exposure,

( *e* ) where the results of the risk assessment under Regulation 4 show that the exposure or potential exposure (or both) is to a group 1 biological agent, including live attenuated vaccines, with no identifiable health risk to employees to provide that where a biological agent is being handled as part of an industrial process, to ensure that the principles of good occupational safety and hygiene are applied,

( *f* ) where the results of the assessment under Regulation 4 show that the activity does not involve a deliberate intention to work with or use a biological agent but may result in employees being exposed to a biological agent, as in the course of the activities for which an indicative list is given in the First Schedule, to comply with Regulations 3 (*a*), 5, 6, 7 (iii), 7 (iv), 8, 9 and 10, unless the results of such assessment show such compliance to be unnecessary,

( *g* ) to apply these Regulations to activities in which employees are likely to be exposed to biological agents as a result of their work.

Risk Assessment.

**4.** It shall be the duty of every employer—

( *a* ) to assess any risk to the health and safety of employees resulting from any activity at that employer's place of work likely to involve a risk of exposure of any employee to a biological agent and for that purpose to determine the nature, degree and duration of any employee's exposure to a biological agent and to lay down the measures to be taken to ensure the safety and health of such employees,

( *b* ) to keep the risk assessment referred to in paragraph (*a*) in written form as required by Regulation 10 of the Principal Regulations,

( *c* ) when carrying out the risk assessment required by paragraph (*a*), to assess the risk, in the case of activities involving exposure to several groups of a biological agent, on the basis of the danger presented by all hazardous biological agents present,

( *d* ) to renew the risk assessment required by paragraph (*a*) regularly and in any event whenever there is a change in conditions at the place of work which may affect any employee's exposure to a biological agent, and

( *e* ) to conduct the risk assessment referred to in paragraph (*a*) on the basis of all available information, including—

(i) the classification of a biological agent which is or may be a hazard to human health referred to in the Fourth Schedule,

(ii) information on diseases which may be contracted as a result of the work of the employees,

(iii) potential allergenic or toxigenic effects as a result of the work of the employees,

(iv) knowledge of a disease from which an employee is found to be suffering and which has a direct connection with his work, and

(v) any recommendations which may be made by the Authority indicating that a particular biological agent should be controlled in order to protect employees' health where employees are or may be exposed to such a biological agent as a result of their work.

Information and Notification to be provided to the Authority.

**5.** It shall be the duty of every employer—

( *a* ) to provide the Authority when requested with the

information used for making any risk assessment carried out under Regulation 4 and with the findings of any such assessment,

( *b* ) where the risk assessment carried out under Regulation 4 reveals a risk to any employee's health or safety, to provide the Authority, when requested, with appropriate information in writing relating to—

(i) the results of the risk assessment,

(ii) the activities in which employees have been exposed or may have been exposed to a biological agent,

(iii) the number of employees exposed,

(iv) the name and capabilities of the person responsible for safety and health at work,

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

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

( *c* ) without prejudice to Part X of the Principal Regulations, to inform the Authority of any accident or incident which may have resulted in the release of a biological agent and which could cause both severe human infection and human illness or both,

( *d* ) to deliver the list required by Regulation 9 to the Authority in cases where he ceases to be an employer,

( *e* ) to notify the Authority—

(i) thirty days prior to the commencement of work involving the use for the first time of a group 2 or 3 or 4 biological agent,

(ii) subject to subparagraph (i), thirty days prior to the commencement of work involving the use for the first time of each subsequent group 4 biological agent and any subsequent new group 3 biological agent, where the employer himself provisionally classifies that biological agent,

(iii) for the first time only, as required by subparagraph (i), in the case of laboratories providing a purely diagnostic service in relation to a group 4 biological agent, and

(iv) in any case where there are substantial changes of importance to safety and health at work to processes or procedures which render the notifications required by subparagraph (i), (ii) or (iii) out of date,

( *f* ) to include in the notification required by

paragraph (*e*)—

(i) the name and address of the undertaking or the establishment (or both),

(ii) the name and capabilities of the person responsible for safety and health at work,

(iii) the results of the risk assessment under Regulation 4,

(iv) the species of the biological agent, and

(v) the protective and preventive measures that are envisaged,

( *g* ) To make available to the Authority the list referred to in Regulation 9 in cases where the undertaking or the establishment (or both) ceases activity.

Hygiene, Individual Protection and Vaccination.

**6.** (1) It shall be the duty of every employer, in the case of any activity in relation to which there is a risk to the health or safety of employees caused by working with a biological agent, to take appropriate measures to ensure that—

( *a* ) employees do not eat or drink in any place of work where there is a risk of contamination by a biological agent,

( *b* ) employees are provided with suitable personal protective equipment,

( *c* ) employees are provided with suitable washing and toilet facilities, which may include eye washes and skin antiseptics (or both),

( *d* ) any necessary personal protective equipment is—

(i) properly stored in a designated place,

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

(iii) repaired, where defective, or replaced, before further use,

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

( *f* ) working clothes and personal protective equipment, referred to in subparagraphs (*b*) and (*d*), which may be contaminated by a biological agent, are removed on leaving the working areas and, before taking the measures referred to in subparagraph (*g*), kept separately from other

clothing, and

( *g* ) the working clothes and personal protective equipment referred to in subparagraph (*f*) are decontaminated and cleaned or, if necessary, destroyed.

(2) It shall be the duty of every employer to—

( *a* ) apply any special protective measures to employees identified as requiring these by the risk assessment under Regulation 4,

( *b* ) make effective vaccines available, when necessary, to those employees who are not already immune to the biological agent to which they are exposed or are likely to be exposed, taking account of the Fourth Schedule, and

( *c* ) take account of the recommendations set out in the Fifth Schedule when making vaccines available to employees.

Information, Training and Consultation of Employees.

**7.** It shall be the duty of every employer in the case of any activity in relation to which there is a risk to the health or safety of employees due to work with a biological agent—

(i) without prejudice to the provisions of Regulations 11 and 13 of the Principal Regulations, to take appropriate steps to ensure that employees or their safety representative (or both) receive sufficient and appropriate training and information concerning—

( *a* ) potential risks to health,

( *b* ) precautions to be taken to prevent exposure,

( *c* ) hygiene requirements,

( *d* ) the wearing and use of personal protective equipment,

( *e* ) the steps to be taken by employees in the case of incidents and to prevent incidents,

(ii) to provide information in accordance with paragraph (i) to any employer of other employees or to any self employed person who may be affected by exposure to a biological agent arising from the conduct of his undertaking,

(iii) to give, at the beginning of work involving contact with a biological agent, the training referred to in paragraph (i) and to ensure that such training is adapted to take account of new or changed risks and, if necessary, is repeated periodically,

(iv) to provide written instructions at the place of work, 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, or

( *b* ) the handling of a group 4 biological agent, and

(v) to ensure, without prejudice to the provisions of Regulation 9 of the Principal Regulations, that his employees or their safety representative (or both)—

( *a* ) are informed as quickly as possible 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 (or both),

( *b* ) are informed, as quickly as possible, when a serious accident or incident occurs of the causes thereof and of the measures taken in relation thereto,

(vi) without prejudice to the provisions of Regulation 12 of the Principal Regulations, to consult his employees or their safety representative (or both) in relation to the matters referred to in subparagraphs (*a*) to (*e*) of paragraph (i) and in the Schedules.

Duties of employees to report accidents and incidents.

**8.** It shall be the duty of every employee to report to his employer or his immediate supervisor any accident or incident, of which he becomes aware, involving the exposure to, or release of, a biological agent likely to involve a risk to the health and safety of employees.

Keeping of lists of exposed employees.

**9.** It shall be the duty of every employer to—

( *a* ) keep a list of the employees who may be exposed to a group 3 or a group 4 biological agent (or both), indicating the type of work done by each employee, and, whenever possible, the biological agent to which they have been exposed, as well as records of exposures accidents and incidents, as appropriate,

( *b* ) keep the list referred to in paragraph (*a*) for at least ten years following the end of exposure,

( *c* ) keep the list referred to in paragraph (*a*) for a longer period not exceeding forty years, depending on

the likely duration of risk to the health and safety of employees determined during the risk assessment referred to in Regulation 4, following the last known exposure in the case of those exposures which may result in infections—

(i) with a biological agent known to be capable of establishing persistent or latent infections,

(ii) that in the light of present knowledge, are indiagnoseable until illness later develops,

(iii) that have particularly long incubation periods before illness develops,

(iv) that result in an illness which recrudesce at times over a long period despite treatment, and

(v) that result in illnesses that may have serious long-term sequelae,

( *d* ) ensure that each employee has access to the information on the list which relates to him,

( *e* ) ensure that the employees or their safety representative (or both) have access to collective information which does not identify information relating to any individual employee,

( *f* ) ensure that the list is made available, on request, to the responsible medical practitioner or the Authority or person designated under Regulation 8 of the Principal Regulations for inspection,

( *g* ) ensure that the employees or their safety representative (or both) have access, on request, to the information provided for in Regulation 5.

Health Surveillance.

**10.** (1) It shall be the duty of every employer—

( *a* ) to make provision for relevant health surveillance as defined in Regulation 15 (3) of the Principal Regulations, to be made available, under the responsibility of a responsible medical practitioner where appropriate, for those employees for whom the results of any of the risk assessment under Regulation 4 reveal a risk to their health or safety,

( *b* ) to ensure that the health surveillance required by subparagraph (*a*), where appropriate, includes health surveillance made available prior to exposure and at regular intervals thereafter and that these arrangements are such that it is directly possible to implement individual and occupational hygiene measures,

( *c* ) to ensure that, where an employee is found

to be suffering from an infection or illness (or both) which is suspected to be the result of exposure to a biological agent, health surveillance is made available to other employees, who have been similarly exposed, whenever requested by a responsible medical practitioner or by the Authority,

( *d* ) to ensure that where the health surveillance required by subparagraph (*c*) is undertaken, a further reassessment of the risk of exposure is made in accordance with Regulation 4 *(a)*,

( *e* ) to ensure that, where an employee receives health surveillance under this Regulation, an individual record is kept of such matters, and

( *f* ) to ensure that any employee may request a review of the results of any health surveillance he undergoes.

(2) It shall be the duty of every employer to ensure that employees are provided with information and advice regarding any health surveillance which they may undergo following the end of exposure.

(3) It shall be the duty of the responsible medical practitioner in respect of paragraph (4) (*a)* and the employer in respect of paragraph (1) (*e*) to give access to an employee to the results of his own health surveillance.

(4) It shall be the duty of any responsible medical practitioner under whose responsibility an employee receives health surveillance under this Regulation when carrying out relevant health surveillance required by this Regulation—

( *a* ) to keep an individual confidential medical record and to retain that record for the appropriate period, taking account of the periods referred to in Regulation 9 (*b*) and 9 (*c*),

( *b* ) to take account of the recommendations in the Sixth Schedule,

( *c* ) to propose any protective or preventive measures to be taken in respect of any individual employee,

( *d* ) to allow access to the individual confidential medical record to an occupational medical adviser who is designated under section 34 (4) (*a*) of the Act, and

( *e* ) to make available to an occupational medical adviser who is designated under section 34 (4) (*a*) of the Act, the individual confidential medical record in cases where the undertaking or

establishment (or both) ceases activity.

(5) It shall be the duty of an employer who becomes aware of, or of any registered medical practitioner (including a responsible medical practitioner), who diagnoses a case of disease or death resulting from occupational exposure to a biological agent to notify such case to the Authority.

Health care and veterinary care.

**11.** It shall be the duty of every employer when carrying out a risk assessment under Regulation 4 to—

( *a* ) pay particular attention to the risks posed by the nature of the work,

( *b* ) pay particular attention to uncertainties about the presence of a biological agent in human patients or animals and the materials and specimens taken from them,

( *c* ) pay particular attention to the hazard represented by a biological agent known or suspected to be present in human patients or animals and the materials and specimens taken from them,

( *d* ) to protect the health and safety of employees at a place of work which is either a health care facility or veterinary care facility including, in particular, by—

(i) specifying appropriate decontamination and disinfection procedures,

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

( *e* ) to apply appropriate containment measures in accordance with the Seventh Schedule in order to minimise the risk of infection at a place of work which is an isolation facility where there are either human patients or animals who are or who are suspected of being infected with a group 3 or a group 4 biological agent.

Laboratories, industrial processes and animal rooms.

**12.** (1) It shall be the duty of every employer at a place of work which is a laboratory, including diagnostic laboratories and in rooms for laboratory animals which have been deliberately infected with a group 2, 3 or 4 biological agent or which are, or are suspected to be, carriers of such agent, to—

( *a* ) determine containment measures in

accordance with the Seventh Schedule, in order to minimise infection, in laboratories carrying out work which involves the handling of a group 2, 3 or 4 biological agent for research, development, teaching or diagnostic purposes,

( *b* ) carry out activities involving the handling of a biological agent having fixed the physical containment level required for that biological agent in accordance with the Seventh Schedule, following the risk assessment required by Regulation 4, only in—

(i) working areas corresponding to at least the containment level specified in column 2 of the Seventh Schedule for a group 2 biological agent,

(ii) working areas corresponding to at least the containment level specified in column 3 of the Seventh Schedule for a group 3 biological agent,

(iii) working areas corresponding to at least the containment level specified in column 4 of the Seventh Schedule for a group 4 biological agent, and

( *c* ) adopt—

(i) at least containment level specified in column 2 of the Seventh Schedule in laboratories handling materials in respect of which their exists uncertainties about the presence of a biological agent which may cause human disease, but which do not have as their aim working with a biological agent including cultivating or concentrating a biological agent,

(ii) containment levels specified in columns 3 or 4 of the Seventh Schedule, as and when appropriate, where it is known or it is suspected that it is necessary.

(2) It shall be the duty of every employer at a place of work where industrial processes using a group 2, 3 or 4 biological agent are carried out to—

( *a* ) apply the containment measures and containment levels set out in paragraph (1) (*b)* taking account of the Eighth Schedule,

( *b* ) apply whatever measures are considered necessary in accordance with the risk assessment required by Regulation 4 linked to the industrial use of a group 2, 3 or 4 biological agent,

( *c* ) apply at least the containment level specified in column 3 of the Seventh Schedule to carrying out any activity covered by this Regulation where it has not been possible to carry out a conclusive assessment of a biological agent but where it appears that the use envisaged might involve a serious health risk for employees, and

( *d* ) where appropriate to apply combined containment measures and containment levels in the Eighth Schedule on the basis of the risk assessment required by Regulation 4.

## *FIRST SCHEDULE*

### *Indicative List of Activities*

*Regulation 3 ( f )*

1. Work in food production plants.

2. Work in agriculture.

3. Work activities where there is contact with animals and products of animal origin (or both).

4. Work in health care, 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.

## *SECOND SCHEDULE*

### *Measures to be taken where it is not technically possible to prevent exposure*

*Regulation 3 ( d )*

1. The keeping as low as possible of the number of employees exposed or likely to be exposed to a biological agent.

2. The design of work processes and engineering control measures so as to avoid or minimise the release of a biological agent into the place of work.

3. The use of both collective protection measures, and individual protection measures where exposure cannot be avoided by other means.

4. The use of hygiene measures compatible with the aim of preventing or reducing the accidental transfer or release of a biological agent from the workplace.

5. The use of the biohazard sign depicted in the Third Schedule, and other relevant warning signs.

6. The drawing up of plans to deal with accidents involving a biological agent.

7. The testing, where it is necessary and technically possible, for the presence, outside the primary physical confinement, of a biological agent used at work.

8. The use of means for the safe collection, storage and disposal of waste by employees, including the use of secure and identifiable containers, after suitable treatment where appropriate.

9. The making of arrangements for the safe handling and transport of a biological agent within the workplace.

*THIRD SCHEDULE*

*Biohazard Sign*

Second Schedule

*FOURTH SCHEDULE*

*Classification of Biological Agents*

*Regulation 4 (e) (i) 6 (2) (b)*

1. Certain biological agents classified in group 3 which are indicated in the list by an asterisk (*), may present a limited risk of infection for workers because they are not normally infectious by the air-borne route.

2. The 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 employees 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.

N.B. For biological agents appearing on this list, "spp" refers to other species which are known pathogens in humans.

| Biological Agent | Classification | Notes |
|---|---|---|
| BACTERIA and similar organisms | | |
| Actinobacillus actinomycetemcomitans | 2 | |
| Actinomadura madurae | 2 | |
| Actinomadura pelletieri | 2 | |
| Actinomyces gerencseriae | 2 | |
| Actinomyces israelii | 2 | |
| Actinomyces pyogenes | 2 | |
| Actinomyces spp. | 2 | |
| Arcanobacterium haemolyticum (corynebacterium haemolyticum) | 2 | |
| Bacillus anthracis | 3 | |
| Bacteroides fragilis | 2 | |
| Bartonella baciliformis | 2 | |
| Bordetella brochiseptica | 2 | |
| Bordetella parapertussis | 2 | |
| Bordetella pertussis | 2 | V |
| Biological Agent | Classification | Notes |
| Borrelia burgdorferi | 2 | |
| Borrelia duttonii | 2 | |
| Borrelia recurrentis | 2 | |
| Borrelia spp. | 2 | |
| Brucella abortus | 3 | |
| Brucella canis | 3 | |
| Brucella melitensis | 3 | |
| Brucella suis | 3 | |
| Campylobacter fetus | 2 | |
| Campylobacter jejuni | 2 | |
| Campylobacter spp. | 2 | |
| Cardiobacterium hominis | 2 | |
| Chlamydia pneumoniae | 2 | |
| Chlamydia trachomatis | 2 | |
| Chlamydia psittaci (avian strains) | 3 | |
| Chylamydia psittaci (other strains) | 2 | |
| Clostridium botulinum | 2 | T |
| Clostridium perfringens | 2 | |
| Clostridium tetani | 2 | T, V |

| | | |
|---|---|---|
| Clostridium spp. | 2 | |
| Corynebacterium diphtheriae | 2 | T, V |
| Corynebacterium minutissiumum | 2 | |
| Corynebacterium pseudotuberculosis | 2 | |
| Corynebacterium spp. | 2 | |
| Coxiella burnetii | 3 | |
| Edwardsiella tarda | 2 | |
| Ehrlichia sennetsu (Rickettsia sennetsu) | 2 | |
| Ehrlichia spp. | 2 | |
| Eikenella corrodens | 2 | |
| Enterobacter aerogenes/cloacae | 2 | |

| Biological Agent | Classification | Notes |
|---|---|---|
| Enterobacter spp. | 2 | |
| Enterococcus spp. | 2 | |
| Erysipelothrix rhusiopaethiae | 2 | |
| Escherichia coli (with the exception of non-pathogenic strains) | 2 | |
| Flavobacterium meningosepticum | 2 | |
| Fluoribacter bozemanae (Legionella) | 2 | |
| Francisella tularensis (Type A) | 3 | |
| Francisella tularensis (Type B) | 2 | |
| Fusobacterium necrophorum | 2 | |
| Gardnerella vaginalis | 2 | |
| Haeomophilus ducreyi | 2 | |
| Haemophilus influenzae | 2 | |
| Haemophilus spp. | 2 | |
| Helicobacter pylori | 2 | |
| Klebsiella oxytoca | 2 | |
| Klebsiella pneumoniae | 2 | |
| Klebsiella spp. | 2 | |
| Legionella pneumophila | 2 | |
| Legionella spp. | 2 | |
| Leptospira interrogans (all serovars) | 2 | |
| Listeria monocytogenes | 2 | |
| Listeria ivanovii | 2 | |
| Morganeila morganii | 2 | |
| Mycobacterium africanum | 3 | V |
| Mycobacterium avium/intracellulare | 2 | |
| Mycobacterium bovis (except BCG strain) | 3 | V |
| Mycobacterium chelonae | 2 | |
| Mycobacterium fortuitum | 2 | |
| Mycobacterium kansasii | 2 | |

| | | |
|---|---|---|
| Mycobacterium leprae | 3 | |
| Biological Agent | Classification | Notes |
| Mycobacterium maimoense | 2 | |
| Mycobacterium marinum | 2 | |
| Mycobacterium microti | 3(*) | |
| Mycobacterium paratuberculosis | 2 | |
| Mycobacterium scrofulaceum | 2 | |
| Mycobacterium simiae | 2 | |
| Mycobacterium szulgai | 2 | |
| Mycobacterium tuberculosis | 3 | V |
| Mycobacterium ulcerans | 3(*) | |
| Mycobacterium xenopi | 2 | |
| Mycobacterium pneumoniae | 2 | |
| Neisseria gonorrhoeae | 2 | |
| Neisseria meningitidis | 2 | V |
| Nocardia asteroides | 2 | |
| Nocardia brasiliensis | 2 | |
| Nocardia farcinica | 2 | |
| Nocardia nova | 2 | |
| Nocardia otitdiscaviarum | 2 | |
| Pasteurella multocida | 2 | |
| Pasteurella spp. | 2 | |
| Peptostreptococcus anaerobus | 2 | |
| Plesiomonas shigelloides | 2 | |
| Porphyromonas spp. | 2 | |
| Prevotella spp. | 2 | |
| Proteus mirabilis | 2 | |
| Proteus penneri | 2 | |
| Proteus vulgaris | 2 | |
| Providencia alcaifaciens | 2 | |
| Providencia rettgeri | 2 | |

(*) As appropriate some measure required by classification as group 3 may be dispensed with.

| Biological Agent | Classification | Notes |
|---|---|---|
| Providencia spp. | 2 | |
| Pseudomonas aeruginosa | 2 | |
| Pseudomonas mallei | 3 | |
| Pseudomonas pseudomallei | 3 | |
| Rhodococcus equi | 2 | |
| Rickettsia akari | 3(*) | |

| | | |
|---|---|---|
| Rickettsia canada | 3(*) | |
| Rickettsia conorii | 3 | |
| Rickettsia montana | 3(*) | |
| Rickettsia typhi (Rickettsia mooseri) | 3 | |
| Rickettsia prowazeki | 3 | |
| Rickettsia Rickettsii | 3 | |
| Rickettsia tsutsugamushi | 3 | |
| Rickettsia spp. | 2 | |
| Rochalimaea quintana | 2 | |
| Salmonella Arizonae | 2 | |
| Salmonella Enteritidis | 2 | |
| Salmonella Typhimurium | 2 | |
| Salmonella Paratyphi A, B, C | 2 | V |
| Salmonella Typhi | 3(*) | V |
| Salmonella (other serovars) | 2 | |
| Serpulina spp. | 2 | |
| Shigella boydii | 2 | |
| Shigella dysenteriae (Type 1) | 3(*) | T |
| Shigella flexneri | 2 | |
| Shigella sonnei | 2 | |
| Staphylococcus aureus | 2 | |
| Streptobacillus moniliformis | 2 | |
| Streptococcus pneumoniae | 2 | |

(*) As appropriate some measure required by classification as group 3 may be dispensed with.

| Biological Agent | Classification | Notes |
|---|---|---|
| Streptococcus pyogenes | 2 | |
| Streptococcus spp. | 2 | |
| Treponema carateum | 2 | |
| Treponema pallidum | 2 | |
| Treponema pertenue | 2 | |
| Treponema spp. | 2 | |
| Vibrio cholerae (including El Tor) | 2 | |
| Vibrio parahaemolyticus | 2 | |
| Vibrio spp. | 2 | |
| Yersinia enterocolitica | 2 | |
| Yersinia pestis | 3 | V |
| Yersinia pseudotuberculosis | 2 | |
| Yersina spp. | 2 | |
| VIRUS | | |

| | | |
|---|---|---|
| Adenoviridae | 2 | |
| Arenaviridae | | |
| Junin virus | 4 | |
| Lymphocytic choriomeningitis virus (neurotropic strains) | 3 | |
| Lymphocytic choriomeningitis virus (other strains) | 2 | |
| Machupo virus | 4 | |
| Mopeia virus and other Tacaribe viruses | 2 | |
| Astroviridae | 2 | |
| Astroviridae | 2 | |
| Bunyaviridae: | | |
| Bunyamwera virus | 2 | |
| Oropouche virus | 3 | |
| California encephalitis virus | 2 | |
| Hantaviruses: | 2 | |
| Hantaan (Korean haemorrhagic fever) | 3 | |
| Biological Agent | Classification | Notes |
| Seoul virus | 3 | |
| Puumala virus | 2 | |
| Prospect Hill virus | 2 | |
| Other hantaviruses | 2 | |
| Nairoviruses: | | |
| Crimean-Congo haemorrhagic fever | 4 | |
| Hazara virus | 2 | |
| Phleboviruses: | | |
| Rift Valley fever | 3 | V |
| Sandfly fever | 2 | |
| Toscana virus | 2 | |
| Other bunyaviridae known to be pathogenic | 2 | |
| Calciviridae: | | |
| Norwalk virus | 2 | |
| Other Caliciviridae | 2 | |
| Coronaviridae | 2 | |
| Filoviridae: | | |
| Ebola virus | 4 | |
| Marburg virus | 4 | |
| Flaviviridae: | | |
| Australia enciphalitis (Murray Valley encephalitis) | 3 | |
| Central European tick-borne encephalitis virus | 3(*) | V |
| Absettarov | 3 | |
| Hanzalova | 3 | |
| Hypr | 3 | |

| | | |
|---|---|---|
| Kuminge | 3 | |
| Dengue virus type 1 - 4 | 3 | |
| Hepatitis C virus | 3(*) | D |
| Japanese B encephalitis | 3 | V |

(*) As appropriate some measure required by classification as group 3 may be dispensed with.

| Biological Agent | Classification | Notes |
|---|---|---|
| Kyasanur Forest | 3 | V |
| Louping ill | 3 | |
| Omsk (ª) | 3 | V |
| Powassan | 3 | |
| Roccio | 3 | |
| Russian spring-summer encephalitis (TBE) (ª) | 3 | V |
| St Louis encephalitis | 3 | |
| Wesselbron virus | 3(*) | |
| West Nile fever virus | 3 | |
| Yellow fever | 3 | V |
| Other flaviviruses known to be pathogenic | 2 | |
| Hepadnaviridae: | | |
| Hepatitis B virus | 3(*) | V, D |
| Hepatitis D virus (Delta) (b) | 3 | V, D |
| Herpesviridae | | |
| Cytomegalovirus | 2 | |
| Epsteir-Barr virus | 2 | |
| Herpesvirus simiae (B virus) | 3 | |
| Herpes simplex viruses types 1 and 2 | 2 | |
| Herpesvirus varicella-zoster | 2 | |
| Human B-lymphotropic virus (HBLV-HHV6) | 2 | |
| Orthomyxoviridae | | |
| Influenza viruses types A, B and C | 2 | V[(c)] |
| Tick-borne orthomyxovirdae: | | |
| Dhori and Thogoto viruses | 2 | |

[(a)]Tick-borne encephalitis.

[(b)]Hepatitis D virus is pathogenic in workers only in the presence of simultaneous or secondary infection caused by hepatitis B virus.

Vaccination against hepatitis B virus will therefore protect workers who are not affected by hepatitis B virus against hepatitis D virus (Delta).

[(c)] Only for types A and B.

| Biological Agent | Classification | Notes |
|---|---|---|
| Papovaviridae | | |
| BK and JC viruses | 2 | D[(d)] |
| Human papillomaviruses | 2 | D(d) |
| Paramyxovirdae | | |
| Measles virus | 2 | V |
| Mumps virus | 2 | V |
| Newcastle disease virus | 2 | |
| Parainfluenza viruses types 1 to 4 | 2 | |
| Respiratory scncytial virus | 2 | |
| Parvoviridae | | |
| Human parvovirus (B19) | 2 | |
| Picornaviridae | 2 | |
| Acute haemorrhagic conjunctivitis virus (AHC) | 2 | |
| Coxsacki viruses | 2 | |
| Echo viruses | 2 | |
| Hepatitis A virus (human enterovirus type 72) | 2 | V |
| Polioviruses | 2 | V |
| Rhinoviruses | 2 | |
| Poxvirdae | | |
| Buffalopox virus (e) | 2 | |
| Cowpox virus | 2 | |
| Elephantopox virus (f) | 2 | |
| Milkers' node virus | 2 | |
| Molluscum contagiosum virus | 2 | |
| Monkeypox virus | 3 | V |
| Orf virus | 2 | |

[(d)] Recommended for work involving direct contact with these agents.

[(e)] Two viruses are identified: one a Buffalopox type and the other a variant of the vaccinia virus.

[(f)] Variant of cowpox virus.

| Biological Agent | Classification | Notes |
|---|---|---|
| Rabbitpox virus (g) | 2 | |
| Vaccinia virus | 2 | |

| | | |
|---|---|---|
| Variola (major and minor) virus | 4 | V |
| White pox virus ("Variola virus") | 4 | V |
| Yatapox virus (Tana and Yaba) | 2 | |
| Reoviridae | | |
| Coltiviruses | 2 | |
| Human rotaviruses | 2 | |
| Orbiviruses | 2 | |
| Reoviruses | 2 | |
| Retroviridae (h) | | |
| Human immunodeficiency viruses | 3 | D |
| Human T-cell lymphotropic viruses (HLTV) types 1 and 2 | 3 | D |
| Rhabdoviridae: | | |
| Rabies virus | 3(*) | V |
| Vesicular stomatitis virus | 2 | |
| Togaviridae | | |
| Alfaviruses: | | |
| Eastern equine encephalomyelitis | 3 | V |
| Bebaru virus | 2 | |
| Chikungunya virus | 3(*) | |
| Everglades virus | 3(*) | |
| Mayaro virus | 3 | |
| Mucambo virus | 3 | |
| Ndumu virus | 3 | |
| O'nyong-nyong virus | 2 | |
| Ross River virus | 2 | |

(*) As appropriate some measure required by classification as group 3 may be dispensed with.

[(g)] Variant of Vaccinia.

[(h)] At present there is no evidence of disease in humans caused by retroviruses of simian origin.

As a precaution containment level 3 is recommended for work with them.

| Biological Agent | Classification | Notes |
|---|---|---|
| Semlike Forest virus | 2 | |
| Sindbis virus | 2 | |
| Tonate virus | 3(*) | |
| Venezuelan equine encephalomyelitis | 3 | V |
| Western equine encephalomyelitis | 3 | V |

| | | |
|---|---|---|
| Other known alfaviruses: | 2 | |
| Rubivirus (rubella) | 2 | V |
| Toroviridae | 2 | |
| Unclassified viruses | | |
| Blood-borne hepatitis viruses not yet identified | 3(*) | D |
| Hepatitis E virus | 3(*) | |
| Unconventional agents associated with[(i):] | | |
| Creuzfeld-Jakob disease | 3 | D [(j)] |
| Gerstmann-Sträussler-Scheinker syndrome | 3 | D [(j)] |
| Kuru | 3 | D [(j)] |
| PARASITES | | |
| Acanthamoeba castellani | 2 | |
| Ancylostoma duodenale | 2 | |
| Angiostrongylus cantonensis | 2 | |
| Angiostrongylus Costaricensis | 2 | |
| Ascaris lumbriocoides | 2 | A |
| Ascaris suum | 2 | A |
| Babesia divergens | 2 | |
| Babesia microti | 2 | |
| Balantidium coli | 2 | |
| Brugia malayi | 2 | |
| Brugia pahangi | 2 | |

(*) As appropriate some measure required by classification as group 3 may be dispensed with.

[(i)]There is no evidence in humans of infections caused by the agents responsible for bovine spongiform encephalitis. Nevertheless, containment level 2 is recommended at least as a precaution for laboratory work.

[(j)] For work involving direct contact with these agents.

| Biological Agent | Classification | Notes |
|---|---|---|
| Capillaria philippinensis | 2 | |
| Capillaria spp. | 2 | |
| Clonorchis sinensis | 2 | |
| Clonorchis viverrini | 2 | |
| Cryptosporidium parvum | 2 | |
| Cryptosporidium spp. | 2 | |
| Dipetalonema streptocerca | 2 | |
| Diphyllobothrium latum | 2 | |
| Dracunculus medinensis | 2 | |
| Echinococcus granulosus | 3 | |

| | | | |
|---|---|---|---|
| Echinococcus multilocularis | 3 | | |
| Echinococcus vogeli | 3 | | |
| Entamoeba histolytica | 2 | | |
| Fasciola gigantica | 2 | | |
| Fasciola hepatica | 2 | | |
| Fasciolopsis buski | 2 | | |
| Giardia lamblia (Giardia intestinalis) | 2 | | |
| Hymenolepis diminuta | 2 | | |
| Hymenolepisnana | 2 | | |
| Leishmania brasiliensis | 3 | | |
| Leishmania donovani | 3 | | |
| Leishmania ethiopica | 2 | | |
| Leishmania mexicana | 2 | | |
| Leishmania peruviana | 2 | | |
| Leishmania tropica | 2 | | |
| Leishmania major | 2 | | |
| Leishmania spp. | 2 | | |
| Loa Loa | 2 | | |
| Mansonello ozzardi | 2 | | |
| Mansonella perstans | 2 | | |
| Biological Agent | | Classification | Notes |
| Naegleria flowleri | | 3 | |
| Necator americanus | | 2 | |
| Onchocerca volvulus | | 2 | |
| Opisthorchis felineus | | 2 | |
| Opisthorchis spp. | | 2 | |
| Paragonimus westermani | | 2 | |
| Plasmodium falciparum | | 3 | |
| Plasmodiums spp (human and simian) | | 2 | |
| Sarcocystis suihominis | | 2 | |
| Schistosoma haematobium | | 2 | |
| Schistosoma intercalatum | | 2 | |
| Schistosoma japonicum | | 2 | |
| Schistosoma mansoni | | 2 | |
| Strongyloides stercoralis | | 2 | |
| Strongyloides spp. | | 2 | |
| Taenia saginata | | 2 | |
| Taenia solium | | 3 | |
| Toxocara canis | | 2 | |
| Toxoplasma gondii | | 2 | |
| Trichinella spiralis | | 2 | |

| | | | |
|---|---|---|---|
| Trichuris trichiuria | 2 | | |
| Trypanosoma brucei brucei | 2 | | |
| Trypanosoma brucei gambiense | 2 | | |
| Trypanosoma brucei rhodesiense | 3 | | |
| Trypanosoma cruzi | 3 | | |
| Wuchereria bancrofti | 2 | | |
| FUNGI | | | |
| Aspergillus fumigatus | 2 | | A |
| Blastomyces dermatitidis (Ajellomyces dermatidis) | 3 | | |
| Candida albicans | 2 | | A |
| Biological Agent | | Classification | Notes |
| Coccidioides immitis | | 3 | A |
| Cryptococcus neoformans var. neoformans (Filobasidiella neoformans var. neoformans) | | 2 | A |
| Cryptococcus neoformans var. gattii (Filobasidiella bacillispora) | | 2 | A |
| Emmonsia parva var. parva | | 2 | |
| Emmonsia parva var. crescens | | 2 | |
| Epidermophyton floccosum | | 2 | A |
| Fonsecaea compacta | | 2 | |
| Fonsecaea pedrosoi | | 2 | |
| Histoplasma Capsulatum var. Capsulatum (Ajelomyces Capsulatus) | | 3 | |
| Histoplasma capsulatum duboisii | | 3 | |
| Madurella grisea | | 2 | |
| Madurella mycetomatis | | 2 | |
| Microsporum spp. | | 2 | A |
| Neotestudina rosatii | | 2 | |
| Paracoccidioides brasiliensis | | 3 | |
| Penicillium marneffei | | 2 | A |
| Sporothrix schenckii | | 2 | |
| Trichophyton rubrum | | 2 | |
| Trichophyton spp. | | 2 | |

*FIFTH SCHEDULE*

RECOMMENDATIONS ON VACCINATION PRACTICE

Regulation 6 (2) (*c*)

(1) If the risk assessment referred to in Regulation (4) (*a*), (*b*) and (*c*) reveals that there is a risk to the health and safety of employees due to their exposure to a

biological agent for which effective vaccines exist, the employer should offer them vaccination.

(2) Vaccination should be carried out in accordance with any guideline issued or approved by the Authority and employees should be informed of the benefits and drawbacks of both vaccination and non-vaccination.

(3) Vaccination must be offered free of charge to employees.

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

*SIXTH SCHEDULE*

RECOMMENDATIONS FOR THE HEALTH SURVEILLANCE OF EMPLOYEES

Regulation 10 (4) (*b*)

1. Where appropriate the responsible medical practitioner should be familiar with the exposure conditions or circumstances of each employee.

2. Health surveillance of employees 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 an employee's medical and occupational history,

— a personalised assessment of the employee's state of health,

— where appropriate, biological monitoring as well as detection of early and reversible effects.

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

*SEVENTH SCHEDULE*

INDICATIONS CONCERNING CONTAINMENT MEASURES AND CONTAINMENT LEVELS

Regulations 11 (*e*) and 12 (1)

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

| Containment Measures | Containment Levels | | |
|---|---|---|---|
| | 2 | 3 | 4 |

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

| | | | |
|---|---|---|---|
| 12. A laboratory is to contain own equipment | No | Recommended | Yes |
| 13. Infected material including any animal is to be handled in a safety cabinet or isolator or other suitable containment | Where appropriate | Yes, where infection is by airborne route | Yes |
| 14. Incinerator for disposal of animal carcases | Recommended | Yes (available) | Yes, on site |

*EIGHTH SCHEDULE*

CONTAINMENT MEASURES AND CONTAINMENT LEVELS FOR INDUSTRIAL PROCESSES

Regulations 12 (2) (*a*) and 12 (2) (*d*)

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

| Containment Measures | 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 | Inactivated by validated means | Inactivated by validated chemical or | Inactivated by validated chemical or |

| | | | |
|---|---|---|---|
| been: | | physical means | physical means |
| 5. Seals should be designed so as to: | Minimise release | Prevent release | Prevent release |
| 6. Closed systems should be located within a controlled area | Optional | Optional | Yes and purpose built |
| ( a ) Biohazard signs should be posted | Optional | Yes | Yes |
| ( b ) Access should be restricted to nominated personnel only | Optional | Yes | Yes, via an airlock |
| ( c ) Personnel should wear protective clothing | Yes, work clothing | Yes | A complete change |
| ( d ) Decontamination and washing facilities should be provided for personnel | Yes | Yes | Yes |
| ( e ) Personnel should shower before leaving the controlled area | No | Optional | Yes |
| ( f ) Effluent from sinks and showers should be collected and inactivated before release | No | Optional | Yes |
| ( g ) The controlled area should be adequately ventilated to minimise air contamination | Optional | Optional | Yes |
| ( h ) The controlled area should be maintained at an air pressure negative to atmosphere | No | Optional | Yes |

| | | | |
|---|---|---|---|
| ( i ) Input air and extract air to the controlled area should be HEPA filtered | No | Optional | Yes |
| ( j ) The controlled area should be designed to contain spillage of the entire contents of the closed system | No | Optional | Yes |
| ( k ) The controlled area should be sealable to permit fumigation | No | Optional | Yes |
| ( l ) Effluent treatment before final discharge | Inactivated by validated means | Inactivated by validated chemical or physical means | Inactivated by validated chemical or physical means |

GIVEN under my Official Seal, this 17th day of May, 1994.

RUAIRÍ QUINN,

Minister for Enterprise and

Employment.

EXPLANATORY NOTE.

These Regulations implement Council Directives 90/679/EEC of 26 November, 1990, and 93/88/EEC of 12 October, 1993, on the protection of workers from risks related to exposure to a biological agent at work. The Regulations define biological agents. Biological agents thus include bacteria, viruses and fungi. The Regulations draw a distinction between incidental exposure to a biological agent and exposure arising from their deliberate use (Regulation 3 (*f*)). Employers must identify the biological agent to which workers are, or may be, exposed. They must assess the risk, making use of the classification referred to in Regulation 2 and the Fourth Schedule, and proceed in accordance with the remaining Regulations where appropriate. Specific Regulations set out action to be taken in Veterinary and Health Care facilities and in industrial processes.