HEALTH AND SAFETY AUTHORITY

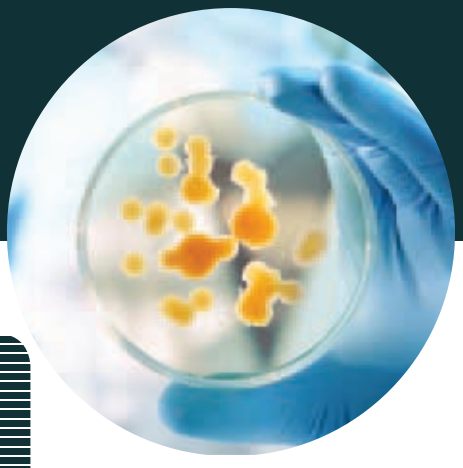
2013 Code of Practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013

(S.I. No. 572 of 2013)

Our vision:

A country where worker safety, health and welfare and the safe management of chemicals are central to successful enterprise

HEALTH AND SAFETY AUTHORITY



2013 Code of Practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013

(S.I. No. 572 of 2013)

Contents

Published in February 2014 by the Health and Safety Authority, The Metropolitan Building James Joyce Street, Dublin 1.

Foreword

The Health and Safety Authority, with the consent of Richard Bruton TD, Minister for Jobs, Enterprise and Innovation, and following public consultation, publishes this Code of Practice entitled "Code of Practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 (S.I. No. 572 of 2013)", hereafter referred to as the Biological Agents Regulations 2013, in accordance with section 60 of the Safety, Health and Welfare at Work Act 2005 (No. 10 of 2005).

This Code of Practice, in accordance with Regulation 3 (1) of the above Regulations, contains the approved list of biological agents and their classifications listed in Schedule 1, the containment levels, and minimum containment measures in Schedules 2 & 3, and the dispensations from minimum containment measures in Schedule 4.

This Code of Practice comes into effect on 20th December 2013.

Notice of publication of this Code of Practice was published in the Iris Oifigiúil of 18th February 2014.

As regards the use of Codes of Practice in criminal proceedings, section 61 of the Safety, Health and Welfare at Work 2005 Act provides as follows -

> "61.—(1) Where in proceedings for an offence under this Act relating to an alleged contravention of any requirement or prohibition imposed by or under a relevant statutory provision being a provision for which a code of practice had been published or approved by the Authority under section 60 at the time of the alleged contravention, subsection (2) shall have effect with respect to that code of practice in relation to those proceedings.
>
> (2) (a) Where a code of practice referred to in subsection (1) appears to the court to give practical guidance as to the observance of the requirement or prohibition alleged to have been contravened, the code of practice shall be admissible in evidence.
>
> (b) Where it is proved that any act or omission of the defendant alleged to constitute the contravention—
>
> (i) is a failure to observe a code of practice referred to in subsection (1), or
>
> (ii) is a compliance with that code of practice, then such failure or compliance is admissible in evidence.
>
> (3) A document bearing the seal of the Authority and purporting to be a code of practice or part of a code of practice published or approved of by the Authority under this section shall be admissible as evidence in any proceedings under this Act.".

A revision of the Code of Practice, to reflect current knowledge concerning the health hazards and classification of the biological agents listed in Schedule 1, the containment levels, and minimum containment measures in Schedules 2 & 3, and the dispensation from minimum containment measures in Schedule 4, will be undertaken by the Health and Safety Authority, where and when appropriate, under the normal consultation process.

Comments concerning any of the classifications and containment measures may be made in writing to the Chemical and Prevention Division of the Health and Safety Authority at Hebron House, Hebron Road, Kilkenny or its headquarters, Metropolitan Building, James Joyce Street, Dublin 1 or electronically through www.hsa.ie.

Gavin Lonergan
Secretary to the Board

1. Introduction

The Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and this related Code of Practice, inter alia, transpose and implement the requirements of Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of employees from risks related to exposure to biological agents at work.

This Code of Practice, contains the approved list of biological agents, their classification, minimum containment measures and dispensation from minimum containment measures, where appropriate.

Directive 2000/54/EC requires the classification of biological agents that are or may be a hazard to human health. Annex III of the Directive contains a list of community classifications of biological agents and the approved list of agents in Schedule 1 of this Code of Practice is based on annex III of the Directive with additions from the approved list as published by the UK Advisory Committee on Dangerous Pathogens in 2013.

"Authority" means the Health and Safety Authority;

"Biological Agent" 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, classified into 4 risk groups according to their level of risk of infection, as follows (if the biological agent to be assessed cannot be classified clearly in one of the following groups, it shall be classified in the highest risk group among the alternatives) :

(a) a "group 1 biological agent" means one that is unlikely to cause human disease to employees;

(b) a "group 2 biological agent" means one that 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;

(c) a "group 3 biological agent" means one that 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;

(d) a "group 4 biological agent" means one that 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;

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

"PPE" stands for personal protective equipment. PPE means all equipment designed to be worn or held by an employee for protection against one or more hazards likely to endanger the employee's safety and health at work;

"spp" refers to other species for biological agents appearing in this Code of Practice which are known pathogens in humans.

3. Schedule 1 - Introductory Notes

Only agents that are known to infect humans are included in Schedule 1 and classifications are based on the effect of those agents on healthy employees. Animal and plant pathogens which are known not to affect humans are excluded.

The list does not give consideration to genetically modified organisms (GMO's).

Biological Agents listed in this Code of Practice are classified into four different groups based on their ability to cause disease by infection. Only agents in groups 2, 3 and 4 are listed in Schedule 1. Agents not listed in these groups are not classified as group 1 agents by default.

Regulation 15 of the Biological Agents Regulations 2013 requires the employer to maintain a list of employees exposed to hazard group 2 agents specified in this Code of Practice and all group 3 and group 4 biological agents for at least 10 years after the last exposure. This requirement applies to the following group 2 agents:

- Human herpesvirus type 8 (HHV8)
- BK polyomavirus
- JC polyomavirus
- Human papillomaviruses

In the case of certain biological agents with chronic health effects this list shall be kept for an appropriately longer time, not exceeding 40 years, following the last known exposure of the employee concerned.

Schedule 1, in the notes column, where appropriate, gives an indication of those biological agents that are capable of causing allergic or toxic reactions, where there is an effective vaccine available or where it is advisable to keep a list of exposed employees for more than 10 years.

The following notations are used:

A: Possible allergic effects

T: Toxin production

V: Effective vaccine available

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

3. Schedule 1 - Introductory Notes Cont'd

When biological agents are allocated to a hazard group, no account is taken of any additional risks to employees, whose susceptibility to infection may be compromised, for example, because of medication, pre-existing disease, compromised immunity, pregnancy or breast-feeding. These risks should be considered as part of the overall risk assessment required by the Safety, Health and Welfare at Work Act 2005.

If more than one species of a particular genus is known to be pathogenic to humans, the agent most frequently responsible for diseases is named. Where other species of the same genus may be hazardous to health, the wider reference "spp" is used. However, if a whole genus is indicated in this way, it is implied that species and strains that are non-pathogenic to humans are excluded.

Certain biological agents classified in group 3, which are indicated in the list by an asterisk (*), may present a limited risk of infection for employees because they are not normally infectious by the airborne route. The need to use all the containment measures for such group 3 agents may not be necessary, due to the nature of the agent and/or the nature of the work that is being undertaken. An employer may, for biological agents so specified, having completed an appropriate risk assessment, dispense with some group 3 containment measures. Schedule 4 indicates measures that may be dispensed with for specified biological agents.

Where a biological agent has been attenuated or has lost known virulence, then the containment required by the classification of its parent strain need not necessarily apply, subject to risk assessment appropriate for the workplace. For example, if an agent is to be used in a product for prophylactic or therapeutic purposes.

All viruses which have been isolated from humans but which do not have an approved classification should be classified as group 2 agents at a minimum, unless there is evidence that they are unlikely to cause disease in humans.

The containment measures for work with parasites apply only to the stages in the life cycle of the parasite during which it is possible to cause infection in humans.

Vaccination should be carried out in accordance with the recommended immunisation guidelines for Ireland issued by the National Immunisation Advisory Committee (NIAC) of the Royal College of Physicians of Ireland (RCPI).

Taxonomic revisions, notes and additional agents as identified by the UK Advisory Committee on Dangerous Pathogens in 2004 and 2013 have been included to update the original list of classified biological agents published in Annex III of Directive 2000/54/EC (indicated by superscript 1 in Schedule 1).

4. Further Information

1. Health and Safety Authority: **Guidelines to the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013**

2. **Directive 2000/54/EC** OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 September 2000 on the protection of employees 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)

3. The Advisory Committee on Dangerous Pathogens (UK) (ACDP); **The Approved List of biological agents as approved by the UK Health and Safety Commission in February 2004**

4. HSE UK: **The Approved List of biological agents, as approved by the Advisory Committee on Dangerous Pathogens, July 2013**

5. World Health Organization **Laboratory biosafety manual – 3rd ed.,** ISBN: 92 4 154650 6

6. **Biological agents: Managing the risks in laboratories and healthcare premises,** Health and Safety Executive (UK)

7. Advisory Committee on Dangerous Pathogens, **Transmissible spongiform encephalopathies: Safe working and the prevention of infection**

8. **Protection against blood-borne infections in the workplace: HIV and hepatitis,** Health and Safety Executive (UK)

9. Advisory Committee on Dangerous Pathogens, **Guidance on work with Hazard Group 3 enteric pathogens**

10. **HSE Health Protection Surveillance Centre** (HPSC), www.hpsc.ie

PART 1: BACTERIA

Biological Agent	Classification	Notes
Arcobacter butzleri (formerly Campylobacter butzleri)[1]	2	
Actinobacillus actinomycetemcomitans	2	
Actinomadura madurae	2	
Actinomadura pelletieri	2	
Actinomyces gerencseriae	2	
Actinomyces israelii	2	
Actinomyces pyogenes	2	*See Arcanobacterium pyogenes*
Actinomyces spp	2	
Alcaligenes spp [1]	2	
Arcanobacterium haemolyticum (Corynebacterium haemolyticum)	2	
Arcanobacterium pyogenes (formerly Actinomyces pyogenes)[1]	2	
Bacillus anthracis	3	*V*
Bacillus cereus[1]	2	
Bacteriodes fragilis	2	
Bacteriodes spp [1]	2	
Bartonella bacilliformis	2	
Bartonella quintana (Rochalimaea quintana)	2	
Bartonella (Rochalimaea) spp	2	
Bordetella bronchiseptica	2	
Bordetella parapertussis	2	
Bordetella pertussis	2	*V*
Bordetella spp	2	
Borrelia burgdorferi	2	
Borrelia duttonii	2	
Borrelia recurrentis	2	
Borrelia spp	2	
Brachispira spp (formerly Serpulina spp)[1]	2	
Brucella abortus	3	
Brucella canis	3	
Brucella melitensis	3	
Brucella suis	3	
Burkholderia cepacia[1]	2	
Burkholderia mallei (formerly Pseudomonas mallei)	3	
Burkholderia pseudomallei (formerly Pseudomonas pseudomallei)	3	
Campylobacter fetus	2	
Campylobacter jejuni	2	
Campylobacter spp	2	
Cardiobacterium hominis	2	

[1] *Taxonomic revisions, notes and additional agents as recommended by the UK Advisory Committee on Dangerous Pathogens.*

Schedule 1- List of Biological Agents

Regulations 7 (1)(e)(i)

PART 1: BACTERIA

Biological Agent	Classification	Notes
Chlamydophila pneumonia[1]	2	
Chlamydophila psittaci (avian strains)[1]	3	
Chlamydophila psittaci (non avian strains)[1]	2	
Chlamydophila trachomatis[1]	2	
Clostridium botulinum	2	T[1]
Clostridium perfringens	2	
Clostridium tetani	2	T, V
Clostridium spp	2	
Corynebacterium diptheriae	2	T, V
Corynebacterium haemolyticum[1]	2	See Arcanobacterium haemolyticum
Corynebacterium minutissimum	2	
Corynebacterium pseudotuberculosis	2	
Corynebacterium pyogenes[1]	2	See Arcanobacterium pyogenes
Corynebacterium spp	2	
Corynebacterium ulcerans[1]	2	
Coxiella burnetii	3	
Edwardsiella tarda	2	
Ehrlichia sennetsu (Rickettsia sennetsu)	3[1]	
Ehrlichia spp	2	
Eikenella corrodens	2	
Elizabethkingia meningoseptia (formerly Flavobacterium meningosepticum)[1]	2	
Enterobacter aerogenes/cloacae	2	
Enterobacter spp	2	
Entercoccus spp	2	
Erysipelothrix rhusiopathiae	2	
Escherichia coli (with the exception of non-pathogenic strains)	2	
Escherichia coli, verocytotoxigenic strains (e.g. O157:H7 or O103)	3 (*)	T
Flavobacterium meningosepticum[1]	2	See Elizabethkingia meningoseptia
Fluoribacter bozemanae (formerly Legionella)	2	
Francisella tularensis (Type A)	3	
Francisella tularensis (Type B)	2	
Fusobacterium necrophorum	2	
Fusobacterium spp[1]	2	
Gardenerella vaginalis	2	
Haemophilus ducreyi	2	
Haemophilus influenzae	2	
Haemophilus spp	2	
Helicobacter pylori	2	
Klebsiella oxytoca	2	
Klebsiella pneumoniae	2	

[1] *Taxonomic revisions, notes and additional agents as recommended by the UK Advisory Committee on Dangerous Pathogens.*

PART 1: BACTERIA

Biological Agent	Classification	Notes
Klebsiella spp	2	*See also Fluoribacter bozemanae (formerly Legionella)*
Legionella pneumophila	2	
Legionella spp	2	
Leptospira interrogans (all serovars)	2	
Listeria ivanovii	2	
Listeria monocytogenes	2	
Moraxella catarrhalis[1]	2	
Morganella morganii	2	
Mycobacterium africanum	3	V
Mycobacterium avium/intracellulare	2	
Mycobacterium bovis (except BCG strain)	3	V
Mycobacterium bovis (BCG strain)[1]	2	
Mycobacterium chelonae	2	
Mycobacterium fortuitum	2	
Mycobacterium kansasii	2	
Mycobacterium leprae	3	V[1]
Mycobacterium malmoense	3[1]	
Mycobacterium marinum	2	
Mycobacterium microti	3 (*)	
Mycobacterium paratuberculosis	2	
Mycobacterium scrofulaceum	2	
Mycobacterium simiae	2	
Mycobacterium szulgai	3[1]	
Mycobacterium tuberculosis	3	V
Mycobacterium ulcerans	3 (*)	
Mycobacterium xenopi	2	
Mycoplasma caviae	2	
Mycoplasma hominis	2	
Mycoplasma pneumoniae	2	
Neisseria gonorrhoeae	2	
Neisseria meningitidis	2	V
Nocardia asteroides	2	
Nocardia brasiliensis	2	
Nocardia farcinica	2	
Nocardia nova	2	
Nocardia otitidiscaviarum	2	
Pasteurella multocida	2	
Pasteurella spp	2	
Peptostreptococcus anaerobius	2	
Peptostreptococcus spp[1]	2	
Plesiomonas shigelloides	2	
Porphyromonas spp	2	

[1] *Taxonomic revisions, notes and additional agents as recommended by the UK Advisory Committee on Dangerous Pathogens.*

Schedule 1- List of Biological Agents

Regulations 7 (1)(e)(i)

PART 1: BACTERIA

Biological Agent	Classification	Notes
Prevotella spp	2	
Proteus mirabilis	2	
Proteus penneri	2	
Proteus vulgaris	2	
Providencia alcalifaciens	2	
Providencia rettgeri	2	
Providencia spp	2	
Pseudomonas aeruginosa	2	
Pseudomonas mallei (Burkholderia mallei)[1]	3	
Pseudomonas pseudomallei (Burkholderia pseudomallei)[1]	3	
Rhodococcus equi	2	
Rickettsia akari	3 (*)	
Rickettsia canada	3 (*)	
Rickettsia conorii	3	
Rickettsia montana	3 (*)	
Rickettsia prowazekii	3	
Rickettsia rickettsii	3	
Rickettsia sennetsu[1]	3	*See Ehrlicia sennetsu*
Rickettsia tsutsugamushi	3	
Rickettsia typhi (Rickettsia mooseri)	3	
Rickettsia spp	3[1]	
Rochalimaea quintana (Bartonella Quintana)[1]	2	
Rochalimaea spp[1]	2	
Salmonella arizonae	2	
Salmonella enterica serovar enteritidis[1]	2	
Salmonella enterica serovar typhimurium 2[1]	2	
Salmonella paratyphi A[1]	3 (*)	
Salmonella paratyphi B/java1	3 (*)	
Salmonella paratyphi C/Choleraesuis[1]	3 (*)	
Salmonella spp[1]	2	*Serovars other than Arizonae, enterica serovar enteritidis, enterica serovar typhimurium 2, paratyphi A, B, C, typhi*
Salmonella typhi[1]	3 (*)	*V*
Serpulina spp	2	
Shigella boydii	2	
Shigella dysenteriae (Type 1)	3 (*)	*T*
Shigella dysenteriae, other than Type 1	2	
Shigella flexneri	2	
Shigella sonnei	2	
Staphylococcus aureus	2	*T*[1]
Streptobacillus moniliformis	2	

[1] *Taxonomic revisions, notes and additional agents as recommended by the UK Advisory Committee on Dangerous Pathogens.*

PART 1: BACTERIA

Biological Agent	Classification	Notes
Streptococcus agalactiae[1]	2	
Streptococcus dysgalactiae equisimilis[1]	2	
Streptococcus pneumoniae	2	
Streptococcus pyogenes	2	
Streptococcus suis	2	
Streptococcus spp	2	
Treponema carateum	2	
Treponema pallidum	2	
Treponema pertenue	2	
Treponema spp	2	
Ureaplasma parvum[1]	2	
Ureaplasma urealyticum[1]	2	
Vibrio cholerae (including El Tor)	2	*T*[1], *V*[1]
Vibrio parahaemolyticus	2	
Vibrio spp	2	
Yersinia enterocolitica	2	
Yersinia pestis	3	
Yersinia pseudotuberculosis	2	
Yersinia spp	2	

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[1] *Taxonomic revisions, notes and additional agents as recommended by the UK Advisory Committee on Dangerous Pathogens.*

Schedule 1- List of Biological Agents

Regulations 7 (1)(e)(i)

PART 2: FUNGI

Biological Agent	Classification	Notes
Absidia corymbifera[1]	2	See *Lichtheimia corymbifera*
Ajellomyces dermatitidis[1]	3	See *Blastomyces dermatitidis*
Aspergillus fumigatus	2	A
Aspergillus spp[1]	2	
Blastomyces dermatitidis (Ajellomyces dermatitidis)	3	
Candida albicans	2	A
Candida spp[1]	2	
Candida tropicalis	2	
Cladophialophora bantinia (formerly: Xylophypha bantiana, Cladosphorium bantianum)	3	
Cladophialophoriumbantianum (formerly: Xylophypha bantiana)[1]	3	See *Cladophialophora bantinia*
Coccidioides immitis	3	A
Coccidioides posadasii[1]	3	A
Cryptococcus neoformans var gatii (Filobasidiella bacillispora)	2	A
Cryptococcus neoformans var. neoformans (Filobasidiella neoformansvar var neoformans)	2	A
Emmonsia crescens[1]	2	
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 var. farcinimosum[1]	3	
Histoplasma capsulatum duboisii	3	
Madurella grisea	2	
Madurella mycetomatis	2	
Microsporum spp	2	A
Neotestudina rosatii	2	
Paracoccidioides brasiliensis	3	
Penicillium marneffei	3[1]	A
Scedosporium apiospermum (Pseudallescheria boydii)	2	
Scedosporium prolifirans (inflatum)	2	
Sporothrix schenckii	2	
Trichophyton rubrum	2	
Trichophyton spp	2	

[1] *Taxonomic revisions, notes and additional agents as recommended by the UK Advisory Committee on Dangerous Pathogens.*

PART 3: HELMINTHS

Biological Agent	Classification	Notes
Ancylostoma duodenale[1]	2	
Angiostrongylus cantonensis	2	
Angiostrongylus costaricensis	2	
Anisakis simplex[1]	2	
Ascaris lumbricoides	2	A
Ascaris suum	2	A
Brugia malayi	2	
Brugia pahangi	2	
Brugia timori[1]	2	
Capillaria philippinensis	2	
Capillaria spp	2	
Clonorchis[1]	2	See *Opisthorchis*
Contracaecum osculatum[1]	2	
Dicrocoelium dendriticum[1]	2	
Dipetalonema[1]	2	See *Mansonella*
Diphyllobothrium latum	2	
Dracunculus medinensis	2	
Echinococcus granulosus	3 (*)	
Echinococcus multilocularis	3 (*)	
Echinococcus vogeli	3 (*)	
Enterobius vermicularis[1]	2	
Fasciola gigantica	2	
Fasciola hepatica	2	
Fasciolopsis buski	2	
Heterophyes spp[1]	2	
Hymenolepis diminuta	2	
Hymenolepis nana	2	
Loa loa	2	
Mansonella ozzardi	2	
Mansonella perstans	2	
Mansonella streptocerca[1]	2	
Metagonimus spp[1]	2	
Necator americanus	2	
Onchocerca volvulus	2	
Opisthorchis felineus	2	
Opisthorchis sinensis (Clonorchis sinensis)[1]	2	
Opisthorchis spp	2	
Opisthorchis viverrini (Clonorchis viverrini)[1]	2	
Paragonimus spp[1]	2	
Paragonimus westermani	2	
Pseudoterranova decipiens[1]	2	

[1] *Taxonomic revisions, notes and additional agents as recommended by the UK Advisory Committee on Dangerous Pathogens.*

Schedule 1- List of Biological Agents

Regulations 7 (1)(e)(i)

PART 3: HELMINTHS CONT'D

Biological Agent	Classification	Notes
Schistosoma haematobium	2	
Schistosoma intercalatum	2	
Schistosoma japonicum	2	
Schistosoma mansoni	2	
Schistosoma mekongi	2	
Schistosoma spp[1]	2	
Strongyloides spp	2	
Strongyloides stercoralis	2	
Taenia saginata	2	
Taenia solium	3 (*)	
Toxocara canis	2	
Toxocara cati[1]	2	
Trichinella nativa[1]	2	
Trichinella nelsoni[1]	2	
Trichinella pseudospiralis[1]	2	
Trichinella spiralis	2	
Trichostrongylus orientalis[1]	2	
Trichostrongylus spp[1]	2	
Trichuris trichiura	2	
Wuchereria bancrofti	2	

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[1] *Taxonomic revisions, notes and additional agents as recommended by the UK Advisory Committee on Dangerous Pathogens.*

Unconventional agents associated with the Transmissible Spongiform Encephalopathies (TSEs):

PART 4: PRIONS

Biological Agent	Classification	Notes
Human TSEs		
Sporadic forms of human TSE		
Sporadic Creutzfeld-Jakob disease agent[1]	3 (*)	D
Sporadic fatal insomnia agent[1]	3 (*)	D
Variably protease-resistant prionopathy agent[1]	3 (*)	D
Genetic forms of human TSE		
Familial Creutzfeld-Jakob disease agent[1]	3 (*)	D
Fatal familial insomnia agent1	3 (*)	D
Gerstmann-Straussler-Scheinker syndrome agent[1]	3 (*)	D
Acquired forms of human TSE		
Variant Creutzfeldt-Jakob disease (vCJD) agent	3 (*)	D
Iatrogenic Creutzfeld-Jakob disease agent[1]	3 (*)	D
Kuru agent	3 (*)	
Animal TSEs		
Bovine spongiform encephalopathy (BSE) agent and other related animal TSEs	3 (*)	D
All strains related to or derived from BSE (including feline spongiform encephalopathy agent and spongiform encephalopathy agent in exotic ungulates)[1]	3 (*)	D
H-type BSE agent[1]	3 (*)	D
L-type BSE agent[1]	3 (*)	D
Scrapie and scrapie-related agents[1]	2	D
Atypical scrapie agent[1]	2	D
Chronic Wasting Disease agent[1]	2	D
Laboratory strains of TSEs		
Any strains propogated in primates, mice expressing PrP gene or mice encoding human familial mutations in PrP[1]	3 (*)	D
Human strains propagated in any species[1]	3 (*)	D

[1] *Taxonomic revisions, notes and additional agents as recommended by the UK Advisory Committee on Dangerous Pathogens.*

Schedule 1- List of Biological Agents

Regulations 7 (1)(e)(i)

PART 5: PROTOZOA

Biological Agent	Classification	Notes
Acanthamoeba castellanii	2	
Acanthamoeba spp[1]	2	
Babesia divergens	2	
Babesia microti	2	
Babesia spp[1]	2	
Balantidium coli	2	
Blastocystis hominis[1]	2	
Cryptosporidium hominis[1]	2	
Cryptosporidium parvum	2	
Cryptosporidium spp	2	
Cyclospora cayetanensis	2	
Cyclospora spp[1]	2	
Dientamoeba fragilis[1]	2	
Encephalitozoon cuniculi	2	
Encephalitozoon hellem	2	
Encephalitozoon intestinalis[1]	2	
Entamoeba histolytica	2	
Enterocytozoon bieneusi[1]	2	
Giardia lamblia (Giardia intestinalis)	2	
Isopora belli[1]	2	
Leishmania aethiopica	2	
Leishmania brasiliensis	3	
Leishmania donovani	3 (*)	
Leishmania major	2	
Leishmania mexicana	2	
Leishmania peruviana	2	
Leishmania spp	2	
Leishmania tropica	2	
Naegleria fowleri	3	
Plasmodium falciparum	3 (*)	
Plasmodium spp (human & simian)	2	
Sarcocystis suihominis	2	
Toxoplasma gondii	2	
Trichomonas vaginalis[1]	2	
Trypanosoma brucei brucei	2	
Trypanosoma brucei gambiense	2	
Trypanosoma brucei rhodesiense	3 (*)	
Trypanosoma cruzi	3	

[1] *Taxonomic revisions, notes and additional agents as recommended by the UK Advisory Committee on Dangerous Pathogens.*

PART 6: VIRUSES[1]

Biological Agent	Classification	Notes
VIRUSES		
Order **Herpesvirales**		
Family **Herpesviridae**		
Subfamily **Alpha-herpesvirinae**		
Genus ***Simplexvirus:***		
B virus	4	See Macacine herpesvirus 1
Herpesvirus simiae	4	See Macacine herpesvirus 1
Human herpes simplex viruses 1 and 2	2	
Macacine herpesvirus 1	4	Synonyms: Herpesvirus simiae; B virus
Genus ***Varicellovirus:***		
Human herpesvirus 3	2	Synonym: Varicella-zoster virus
Varicella-zoster virus	2	See Human herpesvirus 3
Subfamily **Beta-herpesvirinae**		
Genus ***Cytomegalovirus:***		
Human herpesvirus 5	2	Synonym: Human cytomegalovirus
Human cytomegalovirus	2	Human herpesvirus 5
Genus ***Roseolavirus:***		
Human herpesvirus type 6 – HHV6	2	
Human herpesvirus type 7 – HHV7	2	
Subfamily **Gamma-herpesvirinae**		
Genus ***Lymphocryptovirus:***		
Human herpesvirus 4	2	Synonym: Epstein-Barr virus
Epstein-Barr virus	2	See Human herpesvirus 4
Genus ***Rhadinovirus:***		
Human herpesvirus type 8 – HHV8 (Kaposi's sarcoma-associated herpesvirus)	2	D
Order **Mononegavirales**		
Family **Bornaviridae**		
Genus ***Bornavirus:***		
Borna disease virus	3	
Family **Filoviridae**		
Genus ***Ebolavirus:***		
Bundibugyo ebolavirus	4	
Reston ebolavirus	4	Includes strain Siena
Sudan ebolavirus	4	
Tai Forest ebolavirus	4	Previously known as Ebola Cote d'Ivoire virus
Zaire ebolavirus	4	
Genus ***Marburgvirus:***		
Marburg marburgvirus	4	
Family **Paramyxoviridae**		
Subfamily **Paramyxovirinae**		

[1] *Taxonomic revisions, notes and additional agents as recommended by the UK Advisory Committee on Dangerous Pathogens.*

Schedule 1- List of Biological Agents

Regulations 7 (1)(e)(i)

PART 6: VIRUSES[1]

Biological Agent	Classification	Notes
*Genus **Avulavirus:***		
Newcastle disease virus	2	
*Genus **Henipavirus:***		
Hendra virus (formerly equine morbillivirus)	4	
Nipah virus	4	
*Genus **Morbillivirus:***		
Measles virus	2	V
*Genus **Respirovirus:***		
Human parainfluenza virus (Types 1 and 3)	2	
*Genus **Rubulavirus:***		
Mumps virus	2	V
Human parainfluenza virus (Types 2 and 4)	2	
Subfamily **Pneumovirinae**		
*Genus **Metapneumovirus:***		
Human metapneumovirus	2	
*Genus **Pneumovirus:***		
Human respiratory syncytial virus	2	
Family **Rhabdoviridae**		
*Genus **Lyssavirus:***		
Australian bat lyssavirus	3	Rabies vaccine provides protection
Duvenhage virus	3	Rabies vaccine provides protection
European bat lyssaviruses 1 & 2	3	Rabies vaccine provides protection
Lagos bat virus	3	
Mokola virus	3	
Rabies virus	3 (*)	V
Other lyssavirus species not listed above	3	
*Genus **Vesiculovirus:***		
Piry virus	3	
Vesicular stomatitis virus	2	
Order **Nidovirales**		
Family **Coronaviridae**		
Subfamily **Coronavirinae**		
*Genus **Alphacoronavirus:***		
Human coronavirus 229E	2	
OC43 virus	2	
*Genus **Betacoronavirus:***		
SARS-related coronavirus	3	
Subfamily **Torovirinae**		
*Genus **Torovirus:***		
Bovine torovirus subspecies Breda virus	2	
Equine torovirus subspecies Berne virus	2	
Human torovirus	2	
Porcine torovirus	2	

[1] *Taxonomic revisions, notes and additional agents as recommended by the UK Advisory Committee on Dangerous Pathogens.*

PART 6: VIRUSES[1]

Biological Agent	Classification	Notes
Other Coronaviridae	2	
Order **Picornavirales**		
Family **Picornaviridae**		
*Genus **Enterovirus:***		
Acute haemorrhagic conjunctivitis virus (AHC)	2	Synonyms: Coxsackievirus CA24 (A24); Enterovirus 70
Coxsackieviruses (A and B)	2	See Human enteroviruses A and B
Echoviruses	2	Subspecies of Human enterovirus B
Human enteroviruses A and B	2	Synonym: Coxsackieviruses A and B
Human enterovirus C	2	Synonym: Poliovirus V
Human rhinoviruses	2	
Polioviruses	2	See Human enterovirus C
*Genus **Hepatovirus:***		
Hepatitis A virus (human enterovirus type 72)	2	V
*Genus **Parechovirus:***		
Parechoviruses	2	
Virus Families not assigned to an Order		
Family **Adenoviridae**		
Adenoviridae	2	
Family **Anelloviridae**		
*Genus **Alphatorquevirus:***		
Torque teno virus (TTV)	2	Previously listed as Transfusion Transmitted virus
Transfusion transmitted virus	2	See Torque teno virus (TTV)
Family **Arenaviridae**		
*Genus **Arenavirus:***		
Amapari virus	2	
Chapare virus	4	
Flexal virus	3	
Guanarito virus	4	
Ippy virus	2	
Junin virus	4	
Lassa fever virus	4	
Latino virus	2	
Lujo virus	4	
Lymphocytic choriomeningitis virus LCMV (all strains other than Armstrong)	3	
Lymphocytic choriomeningitis virus LCMV (Armstrong strain)	2	
Machupo virus	4	
Mobala virus	3	
Mopeia virus	*2*	

[1] *Taxonomic revisions, notes and additional agents as recommended by the UK Advisory Committee on Dangerous Pathogens.*

Schedule 1- List of Biological Agents

Regulations 7 (1)(e)(i)

PART 6: VIRUSES[1]

Biological Agent	Classification	Notes
Mopeia virus	2	
Parana virus	2	
Pichinde virus	2	
Sabia virus	4	
Tamiami virus	2	
Whitewater Arroyo virus	2	
Other LCM-Lassa complex viruses	2	Includes Kodoko, Morogoro, Merino Walk viruses
Other New World arenaviruses	2	Includes Allpahuayo, Bear Canyon, Cupixi, Oliveros, Pirital, Tacaribe
Family **Astroviridae**	*2*	
Family **Bunyaviridae**		
*Genus **Hantavirus:***		
Andes virus	3	
Belgrade (Dobrava) virus	3	
Hantaan virus (Korean haemorrhagic fever)	3	
Prospect Hill virus	2	
Puumala virus	*2*	
Seoul virus	*3*	
Sin Nombre virus(formerly Muerto Canyon)	*3*	
*Genus **Nairovirus:***		
Crimean/Congo haemorrhagic fever virus	4	
Dugbe virus	2	
Ganjam virus	2	Varient of Nairobi Sheep Disease virus
Hazara virus	2	Subspecies of Crimean Congo haemorrhagic fever virus
Nairobi Sheep Disease virus	2	Subspecies of Dugbe virus
*Genus **Orthobunyavirus:***		
Akabane virus	2	
Bunyamwera virus	2	
Bunyavirus germiston	3	Synonym: Germiston virus Subspecies of Bunyamwera virus
California encephalitis virus	2	
Germiston virus	3	See Bunyavirus germiston
La Crosse virus	3	Subspecies of California encephalitis virus
Ngari virus	3	Subspecies of Bunyamwera virus
Oropouche virus	3	
Snowshoe hare virus	3	Subspecies of California encephalitis virus
*Genus **Phlebovirus:***		
Punta Toro virus	2	
Rift Valley fever virus	3	

[1] *Taxonomic revisions, notes and additional agents as recommended by the UK Advisory Committee on Dangerous Pathogens.*

PART 6: VIRUSES[1]

Biological Agent	Classification	Notes
Sandfly fever Naples virus	*2*	
Toscana virus	2	Subspecies of Sandfly fever Naples virus
Unclassified **Phlebovirus**:		
Bhanja virus	3	
Severe fever with thrombocytopoenia syndrome virus (SFTS)	3	
Other Bunyaviridae not listed above	2	
Family **Caliciviridae**		
*Genus **Norovirus:***		
Noroviruses	2	Synonyms: Norwalk calicivirus, human calicivirus, human calicivirus NLV
*Genus **Sapovirus:***		
Sapporo viruses	2	Synonym: Human calicivirus NLV
Other Caliciviridae	2	
Family **Flaviviridae**		
*Genus **Flavivirus:***		
Absettarov virus	3	Strain of Central European tick-borne encephalitis virus (Far Eastern subgroup)
Alkhurma haemorrhagic fever virus	3	Subspecies of Kyasanur Forest disease virus
Central European tick-borne encephalitis virus	3	V European subtype of tick-borne encephalitis virus also including Siberian tick-borne encephalitis virus
Dengue viruses types 1–4	3	
Far Eastern tick-borne encephalitis virus	4	V See Russian spring-summer encephalitis virus
Hanzalova virus	3	V Strain of Central European tick-borne encephalitis virus
Hypr virus	3	V Synonym: tick-borne encephalitis virus strain Hypr
Israel turkey meningitis meningoencephalomyelitis virus	3	
Japanese encephalitis virus	3	V
Kumlinge virus	3	Species in tick-borne encephalitis virus group
Kyasanur Forest disease virus	4	
Louping ill virus	3 (*)	
Murray Valley encephalitis virus	3	

[1] *Taxonomic revisions, notes and additional agents as recommended by the UK Advisory Committee on Dangerous Pathogens.*

Schedule 1- List of Biological Agents

Regulations 7 (1)(e)(i)

PART 6: VIRUSES[1]

Biological Agent	Classification	Notes
Negishi virus	3	Species in tick-borne encephalitis virus group
Omsk haemorrhagic fever virus	4	
Powassan virus	3	
Rocio virus	3	Subspecies of Ilheus strain of mosquito-borne virus
Russian spring–summer encephalitis virus	4	Synonym: Far Eastern tick-borne encephalitis virus; subtype of Tickborne encephalitis virus
Sal Vieja virus	3	
San Perlita virus	3	
Siberian tick-borne encephalitis virus	3	V See Central European tick-borne encephalitis virus
Spondweni virus	3	Subspecies of Zika virus
St Louis encephalitis virus	3	
Tick-borne encephalitis virus	3	
Wesselsbron virus	3 (*)	
West Nile fever virus	3	
Yellow fever virus	3	V
Zika virus	3	See Spondweni virus
Genus ***Hepacivirus:***		
Hepatitis C virus	3 (*)	D
Unclassified Flaviviridae		
Genus ***Pegivirus:***		
Human pegivirus	3 (*)	D Formerly known as GB virus C; or Hepatitis G virus
Other Flaviviridae known to be pathogenic	2	
Family **Hepadnaviridae**		
Genus ***Orthohepadnavirus:***		
Hepatitis B virus	3 (*)	V, D
Hepatitis D virus (delta)	3 (*)	V, D Synonym: Deltavirus Hepatitis delta virus
Family **Hepeviridae**		
Genus ***Hepevirus:***		
Hepatitis E virus	3 (*)	D
Family **Orthomyxoviridae**		
Genus ***Influenzavirus A***		
Genus ***Influenzavirus B***		
Genus ***Influenzavirus C***		

[1] *Taxonomic revisions, notes and additional agents as recommended by the UK Advisory Committee on Dangerous Pathogens.*

PART 6: VIRUSES[1]

Biological Agent	Classification	Notes
Influenza types A, B and C	2	V Potentially pandemic strains
Genus ***Thogotovirus:***		
Dhori virus	2	
Thogoto virus	2	
Family **Papillomaviridae**		
Human papillomaviruses	2	D
Family **Parvoviridae**		
Subfamily **Parvovirinae**		
Genus ***Bocavirus:***		
Human bocavirus	2	
Genus ***Erythrovirus:***		
Human parvovirus B19	2	
Genus ***Parvovirus***		
Unclassified Parvovirus:		
Human parvoviruses 4 and 5	2	Synonyms: Human partetravirus (Parv4/Parv5)
Family **Polyomaviridae**		
Genus ***Polyomavirus:***		
BK polyomavirus	2	D
JC polyomavirus	2	D
Simian virus 40 (SV40)	2	
Unclassified Polyomavirus:		
KI polyomavirus	2	
WU polyomavirus	2	
Family **Poxviridae**		
Subfamily **Chordopoxvirinae**		
Genus ***Molluscipox:***		
Molluscum contagiosum virus	2	
Genus ***Orthopox:***		
'Buffalopox' Vaccinia virus	2	
Cowpox virus	2	
Monkeypox virus	3	V Vaccinia virus
Variola virus (major and minor)	4	V All strains including Whitepox virus
Genus ***Parapox:***		
Orf virus	2	
Pseudocowpox virus (Milker's nodes virus	2	
Genus ***Yatapox:***		
Tanapox virus	2	
Yaba monkey tumour virus	2	
Family **Reoviridae**		

[1] *Taxonomic revisions, notes and additional agents as recommended by the UK Advisory Committee on Dangerous Pathogens.*

Schedule 1- List of Biological Agents

Regulations 7 (1)(e)(i)

PART 6: VIRUSES[1]

Biological Agent	Classification	Notes
Subfamily **Sedoreovirinae**		
Genus ***Orbivirus:***		
Orbiviruses	2	
Genus ***Rotavirus:***		
Human rotaviruses A, B and C	2	Vaccine available for group A
Genus ***Seadornavirus:***		
Banna virus	3	
Subfamily **Spinareovirinae**		
Genus ***Coltivirus:***		
Colorado tick fever virus	2	
Genus ***Orthoreovirus:***		
Mammalian orthoreoviruses 1 to 3	2	Synonyms: Mammalian orthoreovirus; subspecies Mammalian orthoreovirus 1 to 3; Reovirus types 1 to 3
Reoviruses types 1 to 3	2	See Mammalian orthoreoviruses 1 to 3
Family **Retroviridae**		
Subfamily **Orthoretrovirinae**		
Genus ***Deltaretrovirus:***		
Primate T-cell lymphotropic viruses types 1 & 2	3 (*)	D Synonyms: Human T-cell lymphotropic viruses (HTLV) types 1 & 2
Genus ***Gammaretrovirus:***		
Xenotropic murine leukaemia virus-related virus	2	
Genus ***Lentivirus:***		
Human immunodeficiency viruses	3 (*)	D
Simian immunodeficiency virus	3 (*)	
Family **Togaviridae**		
Genus ***Alphavirus:***		
Bebaru virus	2	
Chikungunya virus	3 (*)	
Eastern equine encephalomyelitis encephalitis virus	3	
Everglades virus	3 (*)	
Getah virus	3	
Mayaro virus	3	
Middelburg virus	3	
Mucambo virus	3 (*)	
Ndumu virus	3	
O'nyong-nyong virus	2	
Ross River virus	2	

[1] *Taxonomic revisions, notes and additional agents as recommended by the UK Advisory Committee on Dangerous Pathogens.*

PART 6: VIRUSES[1]

Biological Agent	Classification	Notes
Sagiyama virus	3	Subspecies of Ross River virus
Semliki Forest virus	2	
Sindbis virus	2	
Tonate virus	3 (*)	
Venezuelan equine encephalitis virus	3	
Western equine encephalitis virus	3	
Other known alphaviruses	2	
Genus ***Rubivirus:***		
Rubella virus	2	V

[1] *Taxonomic revisions, notes and additional agents as recommended by the UK Advisory Committee on Dangerous Pathogens.*

Schedule 2- Containment measures and containment levels

Regulations 16 (c) & 17 (2)

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.

A. CONTAINMENT MEASURES	B. CONTAINMENT LEVELS		
	2	3	4
1. The workplace is to be separated from any other activities in the same building	No	Recommended	Yes
2. Input air and extract air to the workplace are to be filtered using HEPA (High-efficiency particulate air filter) or likewise	No	Yes, on extract air	Yes, on input and extract air
3. Access is to be restricted to nominated employees 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

Schedule 3- Containment measures and containment levels for industrial processes

Regulations 5 (b) (v) &17(3)

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.

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

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.

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 been:	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means
5. Seals should be designed so as to:	Minimise release	Prevent release	Prevent release
6. Closed systems should be located within a controlled area	Optional	Optional	Yes, and purpose built
(a) Biohazard signs should be posted	Yes	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

Schedule 3- Containment measures and containment levels for industrial processes

Regulations 5 (b) (v)

CONTAINMENT MEASURES	CONTAINMENT LEVELS		
	2	3	4
(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 (High-efficiency particulate air filter) filtered	No	Optional	Yes
(j) The controlled area should be designed to contain spillage of the entire contents of the closed system	No	Optional	Yes
(k) The controlled area should be sealable to permit fumigation	No	Optional	Yes
(l) Effluent treatment before final discharge	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means

Schedule 4 - Biological Agents: Dispensation from minimum containment measures[2]

Regulation l7 (2) (a) & (b)

Certain biological agents classified as group 3 which are indicated in Schedule 1 by an asterisk (*), may present a limited risk of infection for employees because they are not normally infectious by the airborne route.

Prior to dispensing with any of the minimum containment measures a full risk assessment must be completed in compliance with Regulation 7 of the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013.

BIOLOGICAL AGENTS	DIAGNOSTIC WORK MEASURES	INTENTIONAL WORK MEASURES
Enteric bacteria: *Escherchia coli,* verocytotoxigenic strains (e.g. O157:H7 or O103) *Salmonella typhi Salmonella paratyphi, Shigella dysenteriae* (Type 1)	Points 1 to 4	All intentional work must be carried out at full containment level 3
Mycobacteria: *Mycobacterium microti, Mycobacterium ulcerans*	Points 5 & 6	Points 5 & 6
Parasites: (Helminths & Protozoa) *Echinococcus granulosus, E. multilocularis, E. vogeli, Leishmania braziliensis, L. donovani, Plasmodium falciparum, Taenia solium, Trypanosoma brucei rhodesiense*	Point 7	Point 8 to14
Blood-borne viruses: hepatitis B, hepatitis C, hepatitis D, hepatitis E, hepatitis G, human immunodeficiency viruses, human T-cell lymphotropic viruses, hepatitis viruses not yet identified, simian immunodeficiency virus	Points 15 & 16	All intentional work must be carried out at full containment Level 3
Transmissible spongiform encephalopathies (TSEs): the agents of Creutzfeldt-Jacob disease, variant Creutzfeldt-Jacob disease, fatal familial insomnia, kuru agent, Gerstmann-Sträussler Scheinker syndrome, bovine spongiform encephalopathy (BSE) and other related animal TSEs	Points 17 to 20	Points 17 to 20

[2] *Recommendations of the UK Advisory Committee on Dangerous Pathogens*

Schedule 4 - Biological Agents: Dispensation from minimum containment measures[2]

Containment Measures:

Group 3 enteric biological agents:

1. If there is a strong likelihood or indication that a group 3 enteric biological agent is present the following measures normally required at containment level 3 may not be required:
    a. the laboratory does not need to be maintained at an air pressure negative to atmosphere. In practice, negative pressure may be achieved if a microbiological safety cabinet is in use;
    b. the laboratory does not need to be sealable to permit fumigation;
    c. the laboratory does not need to have exhaust air extracted using HEPA (High-efficiency particulate air filter) filtration, although in practice this may be the case if a microbiological safety cabinet is in use. Any work that could give rise to an aerosol of infectious material must, in any case, be carried out in a microbiological safety cabinet (or equivalent containment).

2. The other procedural/management measures normally required at containment level 3 (above those required at containment level 2) must still be in place:
    a. separation of the work from other activities does not necessarily mean having a separate laboratory; the work could be carried out at the beginning or end of a work period or else on a separate bench. What is important is to separate the work from the routine diagnostic work that may also be carried out in the laboratory;
    b. if an observation window (or alternative) to allow occupants to be seen is not available, then there will need to be some means of checking on employees. Such measures will ensure that adequate supervision is in place when individuals are working alone.

3. The need for a microbiological safety cabinet (at containment level 2 and containment level 3) will depend on whether the work could produce aerosols or droplets that have the potential to contaminate.

4. Work that can be carried out under such conditions includes preliminary microbiological isolation from specimens and serological tests to identify presumptive isolates. Any further work involving the intentional culture or manipulation of these isolates or any other intentional work with group 3 enteric agents must be carried out under full containment level 3 conditions. However, sub-culturing (but not incubating) a primary isolate for the purposes of sending on to a reference laboratory may be done under the conditions outlined above if there are no containment level 3 facilities available. Ideally, the original clinical specimen should be sent to avoid the need for further handling at containment level 2.

Group 3 Mycobacteria:

5. All work (intentional and diagnostic) with M. microti should be carried out at full containment level 3, as it can cause severe pulmonary disease in immunocompetent humans and is classified as part of the M. tuberculosis complex. Subject to a risk assessment of the likelihood of shedding of the agent, infected animals could be housed at containment level 2, with procedures such as taking blood and post-mortem examination taking place in a microbiological safety cabinet or other suitable containment.

6. Diagnostic work with clinical material that is known or suspected of containing M. ulcerans can be carried out at containment level 2, as can intentional work with the agent (subject to local assessment) although the additional precautions shown in the checklist at the end of point 7 should be used.

Group 3 parasites:

7. For diagnostic work where there is no intention to propagate or concentrate the agents, the work may be conducted at containment level 2. However, additional measures will be required to protect against sharps injury, other forms of skin penetrating injury and ingestion.

Additional precautions include:

a. cuts/lesions should be covered with waterproof dressings;
b. gloves should be worn and discarded before handling items likely to be used by others, e.g. telephones;
c. the use of sharps including glassware should be avoided as far as is reasonably practicable;
d. work should be carried out in a designated area of the laboratory with sufficient space to work safely;
e. the workspace should be kept clear of any unnecessary equipment;
f. eye protection should be used if there is a risk of splashing.

Note: Controls such as the restriction of access to the working area and the use of a microbiological safety cabinet (if infectious aerosols are produced) should already be in place for routine containment level 2 work.

8. When working with certain group 3 parasites *(Echinococcus granulosus, E.multilocularis, E. vogeli, Leishmania braziliensis, L. donovani, Plasmodium falciparum, Taenia solium, Trypanosoma brucei rhodesiense, Rickettsia akari, R. canada, R. montana)*, there may be circumstances where not all of the requirements of containment level 3 are necessary for the work to be carried out safely. However, this must be determined on the basis of an assessment of the risks associated with the work in question. (See point 1 for measures that may not be required).

9. The other procedural/management measures normally required at containment level 3 (above those required at containment level 2) must still be in place:
    a. it is important to separate work with parasites from the routine work that may also be carried out in the laboratory so as to control potential exposure. Ideally, a separate room should be used. If this is not possible, the work can be carried out in a designated area of a larger laboratory but could be separated temporally, e.g. the work could be carried out at the beginning or end of a work period. If work with group 3 parasites is required to take place at the same time as other work in the laboratory, you need to ensure that the designated area is away from the main thoroughfare, i.e. not in the middle of a busy diagnostic bench. The use of a spillage tray will help denote the specified work area as well as contain any spills;
    b. if an observation window (or alternative) to allow occupants to be seen is not available, then there will need to be some means of checking on employees. Such measures will ensure that adequate supervision is in place when individuals are working alone.

Schedule 4 - Biological Agents: Dispensation from minimum containment measures[2]

10. The need for a microbiological safety cabinet (at containment level 2 and containment level 3) will depend on whether the work could produce aerosols or droplets that have the potential to contaminate skin or mucous membranes. The need for additional containment should be informed by the risk assessment, and should include a consideration of:

    a. whether the work involves the infectious and/or transmissive stage of the parasite;
    b. whether the work involves tissue culture;
    c. whether the work involves passaging the parasite in an intermediate host (vertebrate and/or invertebrate);
    d. potential means of transmission of the parasite from host to host (including humans).

11. Where work involves tissue culture of the parasite, the most likely means of accidental transmission to laboratory employees is via percutaneous injury. Therefore, glassware and sharps should be excluded as far as is practicable.

12. Where work requires an intermediate animal host to maintain the parasite, infected and non-infected hosts should be stored separately, ideally in separate rooms. Consideration should be given to when and how the animal is likely to shed infectious particles, e.g. in faeces, blood, saliva or other secretions/excretions, and precautions taken to control the risk of transmission by these routes.

13. The need and type of PPE will depend on the likely route of transmission of the individual parasite and stage in its life cycle. Lesions on exposed skin should be covered with waterproof dressings and a high standard of personal hygiene should be in place for all work with parasites. For some work, disposable waterproof gloves should be worn as many laboratory-acquired parasite infections have occurred where no percutaneous injury had been noted and where there were no obvious visible signs of pre-existing skin lesion or abrasion. For all work there must be a safe means of effective disinfection of surfaces, and treatment and disposal of clinical waste.

14. For invertebrate animal hosts, additional consideration should be given to whether they fly, jump, crawl, live in water or are amphibious, and should be reflected in the containment measures used. Where invertebrates are known to be infected or may be infected with biological agents, animal room containment must be applied (See Laboratory Biosafety Manual, World Health Organisation). A risk assessment is necessary, based on the intended nature of the work.

Group 3 blood-borne viruses:

15. Routine diagnostic work with specimens that contain or may contain blood-borne viruses can be carried out at containment level 2. However, additional measures will be required to control the risk of sharps injuries and contamination of the skin and mucous membranes (see checklist at point 7). The risk assessment should reflect whether the work procedures could otherwise increase the risk of exposure by virtue of the nature of the work.

16. Intentional work with these viruses must be carried out at full containment level 3.

Hazard group 3 TSE agents:

17. As with intentional work with this agent, not all the containment measures normally required by containment level 3 may be necessary. As before, the main containment measures that might not be required are the need for a sealable laboratory and the requirement for an inward airflow. Brain and spinal cord samples present the greatest risk of exposure to the TSE agent as compared to other diagnostic specimens and although certain containment measures may be dispensed with, additional protective measures will need to be taken as follows:
    a. care should be taken to avoid accidental inoculation or injury, e.g. when preparing samples for microscopy or culture;
    b. disposable equipment should be used wherever practicable, e.g. cell counting chambers etc.;
    c. any items contaminated by the specimens should be either destroyed by incineration, autoclaved or disinfected to the required standard;
    d. any residual contamination of automated equipment should be minimised and dealt with before servicing;
    e. delicate equipment such as microscopes should be cleaned and maintained regularly to avoid accumulation of potentially contaminated debris.

18. 'Low' risk specimens such as cerebrospinal fluid, blood, urine and faeces can be handled in accordance with the guidance in point 2 of this Schedule.

19. TSE agents such as BSE and CJD are classified as group 3 biological agents. However, because of the unique properties of the infectious agents, not all the containment measures normally required at containment level 3 may be needed. Any decision to change the containment measures must be on the basis of a risk assessment.

20. The main physical containment level 3 measure that might not be required is the need to use a laboratory that is sealable to allow fumigation since the TSE agents are not affected by normal fumigants.

Notes

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ISBN No: 978-1-84496-197-9

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