HEALTH AND SAFETY AUTHORITY

2020 Biological Agents Code of Practice

Code of Practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and 2020

(S.I. No. 572 of 2013 as amended by S.I. No. 539 of 2020)

Our Vision:
Healthy, safe and productive lives and enterprises

HEALTH AND SAFETY AUTHORITY

2020 Biological Agents Code of Practice

Contents

Update published in November 2020 by the Health and Safety Authority, The Metropolitan Building James Joyce Street, Dublin 1.

Foreword

The Health and Safety Authority (the 'Authority'), with the consent of Leo Varadkar TD, Tánaiste and Minister for Enterprise, Trade and Employment, 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 and 2020 (S.I. No. 572 of 2013 as amended by S.I. No. 539 of 2020)*, hereafter referred to as the *2020 Biological Agents Code of Practice*, 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 Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and 2020, applies to activities in a place of work where existing or potential – whether deliberate or incidental – exposure to a biological agent has occurred or may occur. The code of practice contains the list of classified biological agents in Schedule 1. The minimum containment measures for the specific containment levels for laboratories, rooms for laboratory animals and human and animal isolation facilities are detailed in Schedule 2 while Schedule 3 details those for industrial processes. Where applicable, dispensations from minimum containment measures for laboratories and animal rooms are detailed in Schedule 4.

This code of practice comes into effect on November 24th 2020 and revokes and replaces all previous versions of the code of practice.

Notice of the publication of this code of practice was published in the *Iris Oifigiúil* of November 27th 2020.

As regards the use of codes of practice in criminal proceedings, Section 61 of the Safety, Health and Welfare at Work Act 2005 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.

Dr. Marie Dalton

Secretary to the Board
Health and Safety Authority

1. Introduction

Background

The Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and 2020 (S.I. No. 572 of 2013 as amended by S.I. No. 539 of 2020) (hereafter the 'Biological Agents Regulations') and this Code of Practice, inter alia, transpose and implement the requirements of:

- Commission Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000,

as amended by

- Commission Directive (EU) 2019/1833 of 24 October 2019, and
- Commission Directive (EU) 2020/739 of 3 June 2020,

on the protection of workers from the risks related to exposure to biological agents at work.

Schedule 1 of this code of practice implements Annex III of the Directive and contains the list of community classifications of biological agents. Schedule 2 implements Annex V of the Directive and specifies the minimum required control measures as appropriate for isolation facilities for healthcare and veterinary care, laboratories and animal rooms. Schedule 3 implements Annex VI of the Directive and specifies the minimum required control measures for industrial processes.

Schedule 4 details, where appropriate, dispensations for laboratories and animal rooms from minimum containment measures for specified biological agents in line with Article 16(1)(c) of the Directive (as transposed and implemented by Regulation 17(2)(c)(ii) of the Biological Agents Regulations).

Status and Scope of this Code of Practice

This code of practice is published by the Health and Safety Authority under Section 60 of the Safety, Health and Welfare at Work Act 2005 (No. 10 of 2005) – hereafter the '2005 Act' – and with the consent of Leo Varadkar TD, Tánaiste and Minister for Enterprise, Trade and Employment.

The purpose of the code of practice is to list the risk group classification of specific biological agents that are harmful to workers' health. The biological agent's risk group classification will assist in determining the minimum containment levels and containment measures required to safeguard the health and safety of employees when exposed to the listed biological agent. The information in the

code of practice must be used as the basis for the risk assessment for exposure to biological agents at work. In conducting the risk assessment, the employer must determine whether the minimum containment level and containment measures provide adequate worker protection for the planned work or whether enhanced or heightened control measures or a higher containment level is required.

Code of Practice – Third Version

This is the third version of this code of practice. In this version, the main changes are to Schedule 1 and involve changes to the nomenclature and classification of a large number of biological agents, restructuring of the virus taxonomy with viruses now listed according to Order, Family and Genus and addition of new biological agents such as *Clostridium difficile*, MERS and SARS-CoV-2 viruses. Some biological agents such as *Mycoplasma caviae* and Hepatitis G virus have been removed from the list. The nomenclature of the classified agents in this Schedule reflects, and is in conformity with, the latest international agreements on the taxonomy and nomenclature of the agents and reflects the state of knowledge at the time the list was prepared.

Schedules 2 and 3 have been realigned to ensure consistency, as far as reasonably possible, with the Genetically Modified Organisms (Contained Use) Regulations 2001 to 2010. Definitions, updated descriptions and additional containment measures have also been included. Schedule 4 has been updated to include nomenclature changes and a special dispensation for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the causative agent of the disease COVID-19.

Revision of the Code of Practice

The code of practice will be periodically reviewed as appropriate, taking account of current knowledge concerning the health hazards and classification of the biological agents listed in Schedule 1 and new scientific data or new developments in technology aimed at improving the protection of workers' health and safety. Any updates to the code of practice will be carried out in line with the Authority's consultation process.

2. Definitions

The definitions given here are for the Biological Agents Regulations and this code of practice only and selected terms are explained in this context. The Biological Agents Regulations are made and enforced under the 2005 Act. Definitions in the 2005 Act are in general not redefined in the Biological Agents Regulations.

Airlock means a chamber isolated from the laboratory or controlled area. Where required, entry to a laboratory or controlled area must be through an airlock with the clean side of the airlock separated from the restricted side by changing or showering facilities and preferably by interlocking doors.

Animal room refers to a room for laboratory animals who have been deliberately infected with a group 2, 3 or 4 biological agent or are suspected to be carriers of such an agent.

Antiseptic refers to a disinfectant that is safe to apply to living tissue.

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 four 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):

- **group 1 biological agent** means one that is unlikely to cause human disease to employees;
- **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;
- **group 3 biological agent** means one that can cause severe human disease and presents a serious hazard to employees and that may present a risk of spreading to the community, though there is usually effective prophylaxis or treatment available;
- **group 4 biological agent** means one that causes severe human disease and is a serious hazard to employees and that 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.

Closed system means a system that physically separates the process from the environment.
For example, incubator vats, tanks, bioreactors and fermentation vessels.

Chronic health effect refers to where the biological agent causes an infection that:

- is persistent or latent;
- in light of present knowledge, is not diagnosable until illness develops many years later;
- has particularly long incubation periods before illness develops;
- results in illness that recrudesces at times over a long period despite treatment; or
- results in illness that may have serious long-term sequelae.

Containment level refers to the four biosafety levels ranging from basic containment level 1 [CL1] to the maximum containment level 4 [CL4]. Containment levels may also be referred to as biosafety levels [BSL-1 to BSL-4].

Containment measures refer to the design features, construction, containment facilities, equipment, practices and operational procedures required for working with biological agents from the various risk groups.

Controlled area refers to an area that is physically or electronically designed to restrict access to authorised employees only.

Decontamination is a general term and refers to a process or combination of processes that reduce a biological agent's concentration to a degree that does not present a health risk. Such processes can range from physical cleaning to sterilisation.

Diagnostic work refers to any activity undertaken in a diagnostic laboratory with the sole intention of analysing specimens or samples from a human patient or animal in which a biological agent may be, is or is suspected of being present for purposes relating to the assessment of the clinical progress, or assistance in the clinical management, of that patient or animal.

Diagnostic laboratory refers to a medical, clinical or veterinary laboratory (for example, a clinical chemistry, cytology, haematology, histopathology, transfusion microbiology, immunology, or serology laboratory) where tests are usually carried out on clinical specimens in order to obtain information about the health of a patient (human or animal) as pertaining to the diagnosis, treatment and prevention of disease.

Disinfection refers to a decontamination process that involves the targeted treatment of materials, objects or surfaces with physical or chemical processes.

Endoparasite refers to a parasite that lives inside its host.

Fumigation refers to a gaseous decontamination process.

2. Definitions

Genetically modified micro-organism is as defined in the Genetically Modified Organisms (Contained Use) Regulations 2001 to 2010 (S.I. No. 73 of 2001 as amended by S.I No. 442 of 2010) and means an organism in which the genetic material has been altered in a way that does not occur naturally by mating or natural recombination, or by a combination of both.

HEPA means high efficiency particulate air.

Helminth refers to parasitic worms.

Host refers to an organism in which a pathogen lives, multiplies and causes disease.

Inactivation refers to the irreversible destruction of the reproductive and infectious ability of a biological agent.

Industrial process refers to the production or use of biological agents at a large scale or volume (generally greater than 10 litres in volume, but smaller volumes of higher risk group biological agents may also be considered an industrial process) and includes pilot plant scale and commercial production.

Infection refers to the entry, establishment and multiplication of a pathogen within a host.

Intentional exposure or **deliberate exposure** refers to where an employee works directly with a biological agent such as in a laboratory, research facility or the biotechnology industry.

Isolation facility refers to a room, unit or suite where human patients or animals who are or are suspected of being infected with a group 3 or group 4 biological agent are sequestered in order to minimise the risk of infection.

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

Opportunistic infection refers to an infection by a micro-organism that only causes an illness when the person's ability to defend themselves is impaired, for example by immunosuppression.

Parasite refers to an organism that lives in or on an organism of another species and derives nutrients from that species.

Pathogen refers to a biological agent that causes disease or illness.

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.

Prion refers to a small proteinaceous infectious particle generally considered responsible for causing a group of neurodegenerative diseases known as transmissible spongiform encephalopathies.

Prophylaxis refers to treatment or measures taken to prevent a disease from occurring and includes vaccination.

Protozoa refers to single celled organisms.

Safety cabinet refers to a biological or microbiological safety cabinet – a primary containment device that provides protection for employees, the environment and the product (depending on cabinet class) when working with biological agents.

spp. means other species belonging to the genus that have not been included in the classification list but which are known pathogens in humans.

Toxin refers to poisonous substances that are a natural product of the metabolic activities of certain micro-organisms such as bacteria.

Unintentional exposure or **incidental exposure** refers to where an employee is exposed to the biological agent due to their work, for example a healthcare worker who is exposed to a blood borne virus or a veterinarian who is exposed to a zoonose.

Vector refers to an organism that carries and transmits a pathogen from a host to another host. For example, certain species of mosquitoes are vectors that transmit the biological agent responsible for malaria.

Virulence refers to the relative ability of a biological agent to produce disease.

Zoonose refers to a biological agent that causes an animal disease, which can also affect humans.

3.0 The Biological Agents Regulations

The Biological Agent Regulations lay down minimum requirements for the protection of workers from risks related to exposure to biological agents at work.

The Regulations and Their Application

The objective of the Regulations is to protect workers against risks to their health and safety and the prevention of such risks arising or likely to arise from exposure to biological agents at work.

The Regulations apply:

- To activities in a place of work where actual or potential exposure to a biological agent may occur or has occurred.
- When workers are exposed to biological agents intentionally or deliberately [intentional or deliberate exposure] and when they are exposed unintentionally or incidentally [unintentional or incidental exposure].
- To all work sectors where workers are exposed but specific measures are required for health and veterinary care facilities, laboratories, industrial processes and animal rooms.

The Regulations are divided into five parts:

Part 1 – Preliminary and general (Regulations 1 to 4)

- The Biological Agents Regulations apply to all workplaces where there is a potential for exposure to biological agents, either deliberate (for example when working with an agent in a laboratory), or incidental (for example through work in a sewage treatment plant).
- In this Part of the Regulations, the classification of biological agents into hazard groups is detailed (Schedule 1 of this code of practice lists agents classified into groups 2 to 4).
- Regulation 4 indicates that the Health and Safety Authority may prohibit a specific use of a biological agent or require the application of additional control measures.

Part 2 – Duties of employers and employees (Regulations 5 and 6)

- The first duty of the employer is the all-encompassing one to apply the Biological Agents Regulations and the relevant provisions of this code of practice.
- The duties include carrying out a risk assessment and putting in place the appropriate measures to protect employees' health and safety and to prevent exposure to biological agents where the risk assessment reveals a risk to employees' health and safety.

- Avoid the use of harmful biological agents, if possible by substituting with less harmful biological agents, which under their conditions of use eliminate or reduce the risk to employees' health.
- Comply with the provisions of this code of practice. For example, if using a group 2 biological agent in a laboratory, the employer must determine whether the minimum containment level 2 measures listed in Schedule 2 of this code of practice are appropriate for the work being carried out.
- Consult with, inform and train their employees.
- Notify the Health and Safety Authority as per Part 4 of the Regulations below.
- Employees must report immediately any accident or incident of which they are aware. This duty is in addition to employees' duties under the 2005 Act.

Part 3 – Protective and preventive measures (Regulations 7–13)

- The Biological Agents Regulations require that a specific biological agent's written risk assessment is completed and measures put in place to protect the health and safety of employees.
- If possible, substitute harmful biological agents with less harmful biological agents. Where substitution with a less harmful biological agent is not possible, prevent exposure and at least, reduce exposure to as low a level as necessary to protect the health and safety of employees.
- The Regulations require that employees receive appropriate training and information on:
    - potential health risks;
    - precautions to be taken;
    - hygiene requirements;
    - the wearing and use of personal protective equipment (PPE);
    - the benefits and drawbacks of vaccination and non-vaccination (where effective vaccines are applicable and available); and
    - steps to be taken by employees in the case of accidents and to prevent incidents.

- In line with the requirements of the Safety, Health and Welfare at Work (General Application) Regulations 2007 to 2020, the Biological Agents Regulations require that certain hygiene measures are in place. Employees must not eat or drink in any area where there is a risk of contamination from biological agents. Employees must be provided with suitable washing and toilet facilities to prevent contamination or re-contamination. Employers must consider the appropriate use of skin antiseptics and put in place clear procedures, such as written standard operating procedures (SOPs), for the taking, handling and processing of samples of human or animal origin.

- Suitable individual protective equipment must be provided, managed, cleaned or disposed of to prevent contamination. Where there is a risk to safety and health, an appropriate health surveillance programme must be in place and any issues arising from the programme must be acted upon. The Regulations also detail matters on keeping individual employee's health and medical records.

- Under Regulation 13 where there is a risk to the health and safety of employees due to work with a biological agent, employers are required to have emergency procedures and plans in place. This is in addition to the general requirement for emergency plans and procedures under Sections 8 and 11 of the 2005 Act.

Part 4 – Notification and Record-keeping (Regulations 14 and 15)

- Employers must:

    - Provide to the Authority, when requested, and only when requested, any information used to complete the risk assessment.

    - Provide information to employees on the risk assessments carried out.

    - Inform the Authority of any accident or incident resulting in a release that could cause serious infection or illness to any person. An online dangerous occurrence notification form should be completed in such cases – see www.hsa.ie/eng/Topics for further information.

    - Notify the Authority 30 days in advance of using for the first time group 2, 3 or 4 biological agents. The use of subsequent self-classified group 3 biological agents and all subsequent group 4 biological agents must also be notified. Some dispensations exist for diagnostic laboratories providing purely diagnostic services.

- Keep an occupational exposure list of employees who may be exposed to any group 3 or 4 biological agent and a select number of group 2 agents as specified in Section 5 of this code of practice.

- Deliver the occupational exposure list and the individual health records, as required by Regulation 14, to the Authority if the employer's undertaking ceases activity.

- Employees or their safety representative must have access to the collective information in the occupational exposure list, provided the information is not identifiable to any one employee.

Part 5 – Special measures (Regulations 16 and 17)

- Regulations 16 and 17 list extra considerations that must be included when carrying out a risk assessment regarding biological agents in the healthcare or veterinary sectors, laboratories, animal rooms and industrial processes.

- Isolation facilities where there are human patients or animals, who are (or are suspected of being) infected with group 3 or 4 biological agents, animal rooms and laboratories must apply the minimum containment measures as specified in Schedule 2 of this code of practice.

- For industrial processes, the minimum containment measures in Schedule 3 of this code of practice must be applied.

Part 6 – Revocations

- Regulation 18 revokes the Safety, Health and Welfare at Work (Biological Agents) Regulations 1994 (S.I. No. 146 of 1994) and the Safety, Health and Welfare at Work (Biological Agents) (Amendment) Regulations, 1998 (S.I. No. 248 of 1998).

The Biological Agents Regulations include five Schedules, which expand on the requirements of the Regulations:

(1) Schedule 1 provides a non-exhaustive indicative list of activities where incidental exposure to biological agents may occur, for example food production, agriculture and healthcare.

(2) Schedule 2 outlines prevention and risk reduction measures that may be put in place where it is not technically possible to prevent exposure, such as the use of engineering controls, for example, the use of a safety cabinet.

(3) Schedule 3 indicates the biohazard sign. This sign is required in the workplace at containment levels 2, 3 and 4. Safety signage must comply with Chapter 1, Part 7 of the Safety, Health and Welfare at Work (General Application) Regulations 2007 to 2020 (commonly known as the Safety Signs at Places of Work Regulations).

(4) Schedule 4 details requirements in relation to vaccination.

(5) Schedule 5 details matters to be taken account of in relation to health surveillance.

Application of this Code of Practice

This code of practice is principally aimed at employers and employees who deliberately work with biological agents and specific types of workplaces where workers may be exposed to biological agents during the course of their work. This includes persons involved in research, development, teaching, microbiological or diagnostic laboratories, animal rooms and industrial processes. In addition, the code of practice applies to isolation facilities in health care and veterinary care where workers may be exposed to humans or animals who are (or are suspected to be) infected with a group 3 or 4 biological agent. Schedule 1, which lists the biological agent's risk group, possible allergenic effects, toxin production and whether appropriate vaccination is available, is applicable to all workplaces where exposure to biological agents occurs either intentionally or unintentionally.

Other Relevant Legislation Enforced by the Health and Safety Authority

Biological agents are covered by a wide range of legislation. In addition to the Biological Agents Regulations and the 2005 Act (where references to a substance includes a micro-organism), other health and safety legislation may apply, including:

- Safety, Health and Welfare at Work (General Application) Regulations 2007 to 2020 (S.I. No. 299 of 2007 as amended) – especially Part 6 relating to sensitive risk groups, Part 7, Chapter 1 relating to signage and Part 10 covering pressure systems such as autoclaves.

- Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001 and 2015 (S.I. No. 619 of 2001 as amended) - in relation to safe use of disinfectants and biocides.

- Safety, Health and Welfare at Work (Construction) Regulations 2013 to 2020 (S.I. No. 291 of 2013 as amended) which refers to biological hazards and biological substances which is broader in scope than biological agents.

- European Union (Prevention of Sharps Injuries in the Healthcare Sector) Regulations 2014 (S.I. No 135 of 2014) which requires healthcare employers to manage the risk from sharps.
- European Communities (Carriage of Dangerous Goods by Road and Use of Transportable Pressure Equipment) Regulations 2011, as amended, which covers the transport of healthcare, risk waste and infectious substances.

It should not be assumed that compliance with the Biological Agents Regulations means compliance with all aspects of the law. The requirements of other legislation must be fulfilled, as appropriate. The Biological Agents Regulations need to be read in the general context of the 2005 Act, the associated Regulations and any other relevant laws. It is essential to place the safe management of exposure to biological agents in the context of the overall safe management of work as detailed in the safety statement, which is required under Section 20 of the 2005 Act.

Other Relevant Legislation Enforced by Other Departments or Agencies

Legislation enforced by other Government Departments and Agencies may also be applicable and may need to be taken account of with respect to biological agents such as the Genetically Modified Organisms (Contained Use) Regulations 2001 to 2010 (S.I. No.73 of 2001 as amended), which are enforced by the Environmental Protection Agency. As legislation is always under regular review, check the status of legislation on the Attorney General's website at www.irishstatutebook.ie.

4.0 Classification of Biological Agents

Risk Group Classification

To simplify how risks from different biological agents are managed they are categorised into four different risk groups [Groups 1 - 4], based on their ability to cause human disease by infection.

The classification is based on the level of risk of infection (**the classification criteria**) – that is the effect of the biological agent on healthy workers and:

- the likelihood that the agent will cause disease by infection and be a hazard to employees,
- how likely it is that the disease will spread to the community, and
- the availability of any prophylaxis or treatment.

Group 1 biological agents (for example, *Saccharomyces cerevisiae*) are not considered to pose a risk to human health in that they are unlikely to cause human disease whilst group 4 biological agents (for example, Ebolavirus) are considered a high risk to human health.

Unlisted Biological Agents

Only agents known to infect healthy humans are included in this code of practice. Schedule 1 covers biological agents in risk groups 2, 3 and 4. Biological agents not listed in this code of practice should not automatically be classified as risk group 1 agents by default.

Where a biological agent does not have an approved classification, the employer must assess the agent and apply the classification criteria above. The employer must provisionally classify the agent having regard to the nature of the agent and the properties of which the employer is reasonably expected to be aware of – for example via established databases, through relevant research or available scientific data. When provisionally classifying the biological agent, the employer must assign the biological agent to one of the four groups according to the level of risk of infection and if in doubt as to which group in the case of two alternative groups, assign to the higher risk group.

Purpose of Classification

The primary role of the classification of biological agents is to determine what precautions are required to safeguard employees' health and safety when exposed to the biological agent in question. The control measures required depend on the risk group with higher risk groups requiring more extensive control measures. This means that a group 3 or 4 biological agent will require more stringent control measures including a higher containment level and containment measures than a group 2 biological agent will. A group 4 biological agent will require the highest containment levels and measures.

Before planning to use any biological agent that is harmful to health, the employer must check whether the biological agent can be replaced by a less harmful alternative, for example, by using a less pathogenic strain.

Minimum Containment Levels

There are four containment levels [CL1 – CL4]. Containment levels are relevant to isolation facilities in human and animal care, animal rooms, laboratories and industrial processes. The Code of Practice refers specifically to three of the containment levels CL2, CL3 and CL4, with each containment level building on the containment measures of the level preceding it.

The risk group classification correlates but does not equate to the containment level. The containment level required must be determined by risk assessment taking account of the minimum acceptable containment levels. The **minimum** containment levels are:

- Containment Level 2 [CL2] when handling a group 2 biological agent.
- Containment Level 3 [CL3] when handling a group 3 biological agent.
- Containment Level 4 [CL4] when handling a group 4 biological agent.
- Containment Level 2 for laboratories handling materials and it is uncertain whether there are pathogens present and the laboratory does not plan to intentionally cultivate, concentrate or otherwise increase the risk of exposure to a biological agent.
- Containment level 3 [or 4 where appropriate] for laboratories where it is known or strongly suspected that a group 3 [or 4] biological agent is present even if the laboratory has no plan to intentionally propagate, concentrate or otherwise increase the risk of exposure to the group 3 or group 4 biological agent.
- Containment Level 3 for industrial processes where it has not been possible to carry out a conclusive assessment of the biological agent but there is concern that the use of the biological agent might involve a serious health risk for employees.

Schedule 4 of this code details, where appropriate, dispensations for laboratories and animal rooms from minimum containment measures for specified biological agents. The use of any such dispensation must be subject to a full and thorough risk assessment.

What the Classification Does Not Take Account Of

- Other adverse health effects: The ability to cause disease by infection is the principle criterion used for classification purposes, even though a biological agent may have toxic, allergenic or other harmful properties such as being carcinogenic (causing or promoting cancer), reprotoxic (damaging the reproductive process) or teratogenic (producing physical or functional defects in the human embryo or foetus). Certain fungi and parasites are recognised as allergenic whilst certain bacteria are known to be toxigenic. These biological agents are annotated as such in the notes section in Schedule 1 for risk groups 2 to 4. A biological agent that is in risk group 1 is unlikely to cause disease in healthy humans but this does not mean that it cannot be toxic, allergenic or cause opportunistic infection. Biological agents with sensitising, toxic or other harmful effects to health may retain this potential even after inactivation.

- Opportunistic pathogens: There are also biological agents that only pose a health risk when the host is temporarily or chronically more susceptible to the agent (opportunistic pathogens). These agents do not cause disease in healthy humans and so are not included in the classification list.

- The work being carried out: Classification does not consider factors such as the type of work being carried out with the agent, the amount or volume, titre used, procedures undertaken (for example aerosol generating procedures) or the route of transmission.

- Multi-drug resistant agents: when working with such agents, more stringent controls may be required as treatment may not be readily available.

All of above need to be taken into account when conducting the written risk assessment and deciding on the appropriate containment level.

Vulnerable or Sensitive Risk Group

When biological agents are allocated to a risk group, no account is taken of any additional risks to employees, whose resistance to infection may be reduced or compromised, for example, because of medication, pre-existing disease or compromised immunity. It also does not take account of age-related factors or those who are pregnant or breastfeeding.

Some biological agents may impair fertility in men and women or cause adverse effects during pregnancy. For example, Mumps rubulavirus can affect men's sterility and cause miscarriage in pregnant women. Human betaherpes virus 5 (Cytomegalovirus) can cause birth defects, low birth weight and developmental disorders. Other biological agents such as *Chlamydia abortus, Listeria monocytogenes, Coxiella burnetii* and *Toxoplasma gondii*, which are associated with animals, particularly

with sheep, cattle and goats, can also affect pregnancy. The exposure of sensitive or vulnerable risk groups to harmful biological agents needs to be considered when conducting the written risk assessment.

Animal and Plant Pathogens

When deciding on containment levels and measures consideration may need to be given to other legislation, for example, potential adverse effects on animals, plants and the environment. Animal and plant pathogens that are known not to affect humans are excluded from Schedule 1. However, if working with such biological agents appropriate controls may need to be put in place to protect animals and plants from the agents.

Genetically Modified Micro-Organisms

The list does not consider genetically modified micro-organisms (GMMs). When assessing a GMM any genetic manipulation that may extend the host range or alter the biological agent's sensitivity to known, effective treatment regimes must be considered. Where a strain is attenuated or has lost virulence due to genetic modification it could, based on the risk assessment and taking into account that attenuated strains may act as opportunistic pathogens or revert to virulence, be reclassified to a lower risk group. Reliable scientific data and knowledge must be available to support the decision to reclassify to a lower risk group. Alternatively where an agent is modified in such a way that it becomes more hazardous it may need to be reclassified into a higher risk group.

In addition, when planning to work or working with GMMs account must be taken of the relevant genetic modification legislation, which is enforced by the Environmental Protection Agency (principally the Genetically Modified Organisms (Contained Use) Regulations). For example, a biological agent that falls into risk group 1 under the Biological Agents Regulations may be a class 2 GMM because of the environmental risks associated with it and as a result require higher control measures. Where there is inconsistency of this kind, the more stringent legal requirements apply.

Risk Assessment

The risk group classification gives an initial guide to the **minimum** containment level and measures required to work with a particular biological agent but a risk assessment is still required to ensure the level of protection is adequate. For example, if working with a group 2 biological agent then containment level 2 [CL2] measures would be the minimum acceptable containment level. However, if working with the group 2 agent and the work involves the generation of a high concentration of aerosols, high concentrations or large volumes of the infectious agent, the risk assessment may deem that containment level 3 [CL3] provides greater protection and the work should be carried out at the higher containment level.

4.0 Classification of Biological Agents

When carrying out the risk assessment the hazards presented by all biological agents that may be present must be considered. For example, if working with a specific biological agent in cell culture, the presence of passenger or contaminating pathogens such as a latent virus in the cell culture must be considered.

Consideration must also be given to who is carrying out the work (their competence and experience working with the pathogen and at the specific containment level) and who may be affected by the work.

Any additional risks and whether it is possible to rely on the **minimum** containment measures to provide adequate protection for employees must be considered as part of conducting a biological agents risk assessment and as part of the overall risk assessment required by the Safety, Health and Welfare at Work Act 2005 and associated Regulations.

Risk Assessment Review

In line with Regulation 7(1)(e) of the Biological Agents Regulations, the employer must review the risk assessment as often as necessary and whenever there is a change in conditions at the place of work which may affect the employees' exposure to a biological agent. For example, if new procedures, equipment, technology, personnel or biological agents are introduced, the risk assessment must be reviewed to ensure it still remains valid and that appropriate protective measures are in place.

These notes must be taken into account when reading Schedule 1 and when conducting the written risk assessment and determining control measures and containment levels.

Notations

The notes column in Schedule 1, 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 the list of exposed employees for **more than** 10 years.

The following notations are used:

A Possible allergic effects.

D The list of employees exposed to the annotated biological agent is to be kept for **more than** 10 years after the end of the last known exposure

(The biological agents annotated with **D** are in addition to the requirement to have occupational exposure lists for at least 10 years for employees (see below) who have been or may have been exposed to any group 3 or group 4 biological agents as required under Regulation 15 of the Biological Agents Regulations).

T Toxin production.

V Effective vaccine available and registered within the EU – see below.

****** Certain biological agents classified in group 3, which are indicated in the list by two asterisks (**), 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 or the nature of the work that is being undertaken. An employer may for such annotated biological agents, having completed an appropriate risk assessment, dispense with some level 3 containment measures. Schedule 4 indicates measures for laboratories and animal rooms that may be dispensed with for some of these annotated biological agents.

In addition, account must be taken of the relevant footnotes where one exists.

Attenuation or Avirulence

Where a strain is attenuated or has lost known virulence (avirulent), 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, when such a strain is to be used as a product or part of a product for prophylactic or therapeutic purposes.

5.0 Notes in Relation to Schedule 1

Occupational Exposure Lists

Regulation 15 of the Biological Agents Regulations requires the employer to maintain a list of employees exposed to specific group 2 biological agents as detailed in this code of practice and to any or all group 3 and group 4 biological agents for at least 10 years after the last known exposure.

In the case of certain biological agents with chronic health effects this list must be kept for an appropriately longer time, not exceeding 40 years, following the last known exposure of the employee concerned. Such agents are indicated by "**D**" in the notes column in Schedule 1. Along with the specified risk group 3 and 4 biological agents this also includes the following risk group 2 biological agents:

- Human gammaherpesvirus 8
- *Papillomaviridae*
- Human polyomavirus 1 (BK virus)
- Human polyomavirus 2 (JC virus)
- Hepatitis delta virus

Parasites

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 at the workplace.

Species

For genera where more than one species is known to be pathogenic to man, Schedule 1 includes those species, which are known to be most frequently responsible for diseases, together with a more general reference to the fact that other species of the same genus may affect health. When a whole genus is mentioned in Schedule 1, it is implied that the species and strains known to be non-pathogenic to humans are excluded.

Viruses

All viruses which have already been isolated in humans but which have not been assessed and classified in Part 2 of Schedule 1 must be classified as group 2 agents at a minimum, unless there is evidence that they are unlikely to cause disease in humans.

Vaccination

Certain biological agents are marked with a "**V**" annotation in Schedule 1 and this indicates that an effective vaccine, which has been registered within the European Union, is available. Where the risk assessment shows that there is a risk to the health and safety of employees due to working with or exposure to a biological agent for which an effective vaccine is available, the employer must offer vaccination, free of charge to employees. Vaccination should be offered prior to the employee commencing the work.

In offering vaccination, Schedule 4 of the Biological Agents Regulations must be adhered to with regard to advising employees of the benefits and drawbacks of both vaccination and non-vaccination and the preparation of vaccination certificates.

Vaccination should only be seen as a useful supplement to the correct use of engineering controls, safe working procedures and instruction, information and training and should not replace them. The risk assessment should consider non-responders to vaccination or employees who do not wish to avail of vaccination as additional control measures may be required. There may be instances, based on the risk assessment, that if someone is not vaccinated that they would not be regarded as safe to perform certain work tasks.

Vaccinations must be carried out by or under the supervision of a responsible medical practitioner, as they will know when vaccination is not advisable. For example, certain vaccines must not be given to pregnant women. Vaccinations must be in accordance with the *Immunisation Guidelines for Ireland* available on the Health Service Executive National Immunisation Office website at www.hse.ie.

Schedule 1- List of Biological Agents

Regulations 7 (1)(e)(i)

In line with Regulation 7(1)(e)(i) of the Biological Agents Regulations, this Schedule and the associated notes (Section 5) must be taken account of when conducting the written risk assessment as required under Regulation 7 of these Regulations.

Part 1: Bacteria and Similar Organisms

Biological Agent	Classification	Notes
Actinomadura madurae	2	
Actinomadura pelletieri	2	
Actinomyces gerencseriae	2	
Actinomyces israelii	2	
Actinomyces spp.	2	
Aggregatibacter actinomycetemcomitans (Actinobacillus actinomycetemcomitans)	2	
Anaplasma spp.	2	
Arcanobacterium haemolyticum (Corynebacterium haemolyticum)	2	
Arcobacter butzleri	2	
Bacillus anthracis	3	**T**
Bacteroides fragilis	2	
Bacteroides spp.	2	
Bartonella bacilliformis	2	
Bartonella quintana (Rochalimaea quintana)	2	
Bartonella (Rochalimaea) spp.	2	
Bordetella bronchiseptica	2	
Bordetella parapertussis	2	
Bordetella pertussis	2	**T, V**
Bordetella spp.	2	
Borrelia burgdorferi	2	
Borrelia duttonii	2	
Borrelia recurrentis	2	
Borrelia spp.	2	
Brachyspira spp.	2	
Brucella abortus	3	
Brucella canis	3	
Brucella inopinata	3	
Brucella melitensis	3	
Brucella suis	3	
Burkholderia cepacia	2	
Burkholderia mallei (Pseudomonas mallei)	3	

Part 1: Bacteria and Similar Organisms

Biological Agent	Classification	Notes
Burkholderia pseudomallei (Pseudomonas pseudomallei)	3	**D**
Campylobacter fetus subsp. *fetus*	2	
Campylobacter fetus subsp. *venerealis*	2	
Campylobacter jejuni subsp. *doylei*	2	
Campylobacter jejuni subsp. *jejuni*	2	
Campylobacter spp.	2	
Cardiobacterium hominis	2	
Cardiobacterium valvarum	2	
Chlamydia abortus (Chlamydophila abortus)	2	
Chlamydia caviae (Chlamydophila caviae)	2	
Chlamydia felis (Chlamydophila felis)	2	
Chlamydia pneumoniae (Chlamydophila pneumoniae)	2	
Chlamydia psittaci (Chlamydophila psittaci) (avian strains)	3	
Chlamydia psittaci (Chlamydophila psittaci) (other strains)	2	
Chlamydia trachomatis (Chlamydophila trachomatis)	2	
Clostridium botulinum	2	**T**
Clostridium difficile	2	**T**
Clostridium perfringens	2	**T**
Clostridium tetani	2	**T, V**
Clostridium spp.	2	
Corynebacterium diphtheriae	2	**T, V**
Corynebacterium minutissimum	2	
Corynebacterium pseudotuberculosis	2	**T**
Corynebacterium ulcerans	2	**T**
Corynebacterium spp.	2	
Coxiella burnetii	3	
Edwardsiella tarda	2	
Ehrlichia spp.	2	
Eikenella corrodens	2	
Elizabethkingia meningoseptia (Flavobacterium meningosepticum)	2	
Enterobacter aerogenes (Klebsiella mobilis)	2	

Part 1: Bacteria and Similar Organisms

Biological Agent	Classification	Notes
Enterobacter cloacae subsp. *cloacae (Enterobacter 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
Fluoribacter bozemanae (Legionella)	2	
Francisella hispaniensis	2	
Francisella tularensis subsp. *holarctica*	2	
Francisella tularensis subsp. *mediasiatica*	2	
Francisella tularensis subsp. *novicida*	2	
Francisella tularensis subsp. *tularensis*	3	
Fusobacterium necrophorum subsp. *funduliforme*	2	
Fusobacterium necrophorum subsp. *necrophorum*	2	
Gardnerella vaginalis	2	
Haemophilus ducreyi	2	
Haemophilus influenzae	2	V
Haemophilus spp.	2	
Helicobacter pylori	2	
Helicobacter spp.	2	
Klebsiella oxytoca	2	
Klebsiella pneumoniae subsp. *ozaenae*	2	
Klebsiella pneumoniae subsp. *pneumoniae*	2	
Klebsiella pneumoniae subsp. *rhinoscleromatis*	2	
Klebsiella spp.	2	
Legionella pneumophila subsp. *fraseri*	2	
Legionella pneumophila subsp. *pascullei*	2	
Legionella pneumophila subsp. *pneumophila*	2	
Legionella spp.	2	
Leptospira interrogans (all serovars)	2	
Leptospira interrogans spp.	2	
Listeria monocytogenes	2	
Listeria ivanovii subsp. *ivanovii*	2	

Part 1: Bacteria and Similar Organisms

Biological Agent	Classification	Notes
Listeria ivanovii subsp. *londoniensis*	2	
Morganella morganii subsp. *morganii (Proteus morganii)*	2	
Morganella morganii subsp. *sibonii*	2	
Mycobacterium abscessus subsp. *abscessus*	2	
Mycobacterium africanum	3	V
Mycobacterium avium subsp. *avium (Mycobacterium avium)*	2	
Mycobacterium avium subsp. *paratuberculosis (Mycobacterium paratuberculosis)*	2	
Mycobacterium avium subsp. *silvaticum*	2	
Mycobacterium bovis	3	V
Mycobacterium caprae (Mycobacterium tuberculosis subsp. *caprae)*	3	
Mycobacterium chelonae	2	
Mycobacterium chimaera	2	
Mycobacterium fortuitum	2	
Mycobacterium intracellulare	2	
Mycobacterium kansasii	2	
Mycobacterium leprae	3	
Mycobacterium malmoense	2	
Mycobacterium marinum	2	
Mycobacterium microti	3(**)	
Mycobacterium pinnipedii	3	
Mycobacterium scrofulaceum	2	
Mycobacterium simiae	2	
Mycobacterium szulgai	2	
Mycobacterium tuberculosis	3	V
Mycobacterium ulcerans	3(**)	
Mycobacterium xenopi	2	
Mycoplasma hominis	2	
Mycoplasma pneumoniae	2	
Mycoplasma spp.	2	
Neisseria gonorrhoeae	2	
Neisseria meningitidis	2	V
Neorickettsia sennetsu (Rickettsia sennetsu, Ehrlichia sennetsu)	2	

Schedule 1- List of Biological Agents

Regulations 7 (1)(e)(i)

Part 1: Bacteria and Similar Organisms

Biological Agent	Classification	Notes
Nocardia asteroides	2	
Nocardia brasiliensis	2	
Nocardia farcinica	2	
Nocardia nova	2	
Nocardia otitidiscaviarum	2	
Nocardia spp.	2	
Orientia tsutsugamushi (Rickettsia tsutsugamushi)	3	
Pasteurella multocida subsp. *gallicida (Pasteurella gallicida)*	2	
Pasteurella multocida subsp. *multocida*	2	
Pasteurella multocida subsp. *septica*	2	
Pasteurella spp.	2	
Peptostreptococcus anaerobius	2	
Plesiomonas shigelloides	2	
Porphyromonas spp.	2	
Prevotella spp.	2	
Proteus mirabilis	2	
Proteus penneri	2	
Proteus vulgaris	2	
Providencia alcalifaciens (Proteus inconstans)	2	
Providencia rettgeri (Proteus rettgeri)	2	
Providencia spp.	2	
Pseudomonas aeruginosa	2	T
Rhodococcus hoagii (Corynebacterium equii)	2	
Rickettsia africae	3	
Rickettsia akari	3(**)	
Rickettsia australis	3	
Rickettsia canadensis	2	
Rickettsia conorii	3	
Rickettsia heilongjiangensis	3(**)	
Rickettsia japonica	3	
Rickettsia montanensis	2	
Rickettsia prowazekii	3	
Rickettsia rickettsii	3	
Rickettsia sibirica	3	
Rickettsia typhi	3	
Rickettsia spp.	2	

Part 1: Bacteria and Similar Organisms

Biological Agent	Classification	Notes
Salmonella enterica (choleraesuis) subsp. *arizonae*	2	
Salmonella Enteritidis	2	
Salmonella Paratyphi A,B, C	2	V
Salmonella Typhi	3(**)	V
Salmonella Typhimurium	2	
Salmonella (other serovars)	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
Streptobacillus moniliformis	2	
Streptococcus agalactiae	2	
Streptococcus dysgalactiae subsp. *equisimilis*	2	
Streptococcus pneumoniae	2	T, V
Streptococcus pyogenes	2	T
Streptococcus suis	2	
Streptococcus spp.	2	
Treponema carateum	2	
Treponema pallidum	2	
Treponema pertenue	2	
Treponema spp.	2	
Trueperella pyogenes	2	
Ureaplasma parvum	2	
Ureaplasma urealyticum	2	
Vibrio cholerae (including El Tor)	2	T, V
Vibrio parahaemolyticus (Benecka parahaemolytica)	2	
Vibrio spp.	2	
Yersinia enterocolitica subsp. *enterolitica*	2	
Yersinia enterocolitica subsp. *palearctica*	2	
Yersinia pestis	3	
Yersinia pseudotuberculosis	2	
Yersinia spp.	2	

Viruses are listed according to their order (O), family (F) and genus (G).

Part 2: Viruses

Biological Agent (virus species or indicated taxonomy order)	Classification	Notes
Order: Bunyavirales		
Family: *Hantaviridae*		
Genus: Orthohantavirus		
Andes orthohantavirus (Hantavirus species causing Hantavirus Pulmonary Syndrome [HPS])	3	
Bayou orthohantavirus	3	
Black Creek Canal orthohantavirus	3	
Cano Delgadito orthohantavirus	3	
Choclo orthohantavirus	3	
Dobrava-Belgrade orthohantavirus (Hantavirus species causing Haemorrhagic Fever with Renal Syndrome [HFRS])	3	
El Moro Canyon orthohantavirus	3	
Hantaan orthohantavirus (Hantavirus species causing Haemorrhagic Fever with Renal Syndrome [HFRS])	3	
Laguna Negra orthohantavirus	3	
Prospect Hill orthohantavirus	2	
Puumala orthohantavirus (Hantavirus species causing Nephropathia Epidemica [NE])	2	
Seoul orthohantavirus (Hantavirus species causing Haemorrhagic Fever with Renal Syndrome [HFRS])	3	
Sin Nombre orthohantavirus (Hantavirus species causing Hantavirus Pulmonary Syndrome [HPS])	3	
Other hantaviruses known to be pathogenic	2	
Family: *Nairoviridae*		
Genus: Orthonairovirus		
Crimean-Congo haemorrhagic fever orthonairovirus	4	
Dugbe orthonairovirus	2	
Hazara orthonairovirus	2	
Nairobi sheep disease orthonairovirus	2	
Other nairoviruses known to be pathogenic	2	
Family: *Peribunyaviridae*	2	
Genus: Orthobunyavirus	2	
Bunyamwera orthobunyavirus (Germiston virus)	2	
California encephalitis orthobunyavirus	2	
Oropouche orthobunyavirus	3	
Other orthobunyaviruses known to be pathogenic	2	

Part 2: Viruses

Biological Agent (virus species or indicated taxonomy order)	Classification	Notes
Family: *Phenuiviridae*		
Genus: Phlebovirus		
Bhanja phlebovirus	2	
Punt Toro phlebovirus	2	
Rift Valley fever phlebovirus	3	
Sandfly fever Naples phlebovirus (Toscana Virus)	2	
SFTS phlebovirus (Severe Fever with Thrombocytopenia Syndrome-Virus)	3	
Other phleboviruses known to be pathogenic	2	
Order: Herpesvirales		
Family: *Herpesviridae*		
Genus: Cytomegalovirus		
Human betaherpesvirus 5 (Cytomegalovirus)	2	
Genus: Lymphocryptovirus		
Human gammaherpesvirus 4 (Epstein-Barr virus)	2	
Genus: Rhadinovirus		
Human gammaherpesvirus 8	2	D
Genus: Roseolovirus		
Human betaherpesvirus 6A (Human B-lymphotropic virus)	2	
Human betaherpesvirus 6B	2	
Human betaherpesvirus 7	2	
Genus: Simplexvirus		
Macacine alphaherpesvirus 1 (Herpesvirus simiae, Herpes B virus)	3	
Human alphaherpesvirus 1 (Human herpesvirus 1, Herpes simplex virus type 1)	2	
Human alphaherpesvirus 2 (Human herpesvirus 2, Herpes simplex virus type 2)	2	
Genus: Varicellovirus		
Human alphaherpesvirus 3 (Herpesvirus varicella-zoster)	2	V
Order: Mononegavirales		
Family: *Filoviridae*		
Genus: Ebolavirus	4	
Genus: Marburgvirus		

Part 2: Viruses

Biological Agent (virus species or indicated taxonomy order)	Classification	Notes
Marburg marburgvirus	4	
Family: *Paramyoviridae*		
Genus: Avulavirus		
Newcastle disease virus	2	
Genus: Henipavirus		
Hendra henipavirus	4	
Nipah henipavirus	4	
Genus: Morbillivirus		
Measles morbillivirus	2	V
Genus: Respirovirus		
Human respirovirus 1 (Parainfluenza virus 1)	2	
Human respirovirus 3 (Parainfluenza virus 3)	2	
Genus: Rubulavirus		
Mumps rubulavirus	2	V
Human rubulavirus 2 (Parainfluenza virus 2)	2	
Human rubulavirus 4 (Parainfluenza virus 4)	2	
Family: *Pneumoviridae*		
Genus: Metapneumovirus		
Genus: orthopneumovirus		
Human orthopneumovirus (Respiratory syncytial virus)	2	
Family: *Rhabdoviridae*		
Genus: Lyssavirus		
Australian bat lyssavirus	3(**)	V
Duvenhage lyssavirus	3(**)	V
European bat lyssavirus 1	3(**)	V
European bat lyssavirus 2	3(**)	V
Lagos bat lyssavirus	3(**)	
Mokola lyssavirus	3	
Rabies lyssavirus	3(**)	V
Genus: Vesiculovirus		
Vesicular stomatitis virus, Alagoas vesiculovirus	2	
Vesicular stomatitis virus, Indiana vesiculovirus	2	
Vesicular stomatitis virus, New Jersey vesiculovirus	2	
Piry vesiculovirus (Piry virus)	2	
Order: Nidovirales		
Family: *Coronaviridae*		
Genus: Betacoronavirus		
Severe acute respiratory syndrome-related coronavirus (SARS-virus)	3	

Part 2: Viruses

Biological Agent (virus species or indicated taxonomy order)	Classification	Notes
Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)[1]	3	
Middle East respiratory syndrome coronavirus (MERS-virus)	3	
Other *Coronaviridae* known to be pathogenic	2	
Order: Picornavirales		
Family: *Picornaviridae*		
Genus: Cardiovirus		
Saffold virus	2	
Genus: Cosavirus		
Cosavirus A	2	
Genus: Enterovirus		
Enterovirus A	2	
Enterovirus B	2	
Enterovirus C	2	
Enterovirus D, Human Enterovirus type 70 (Acute haemorrhagic conjunctivitis virus)	2	
Rhinoviruses	2	
Poliovirus, type 1 and 3	2	V
Poliovirus, type 2[2]	3	V
Genus: Hepatovirus		
Hepatovirus A (Hepatitis A virus, Human Enterovirus type 72)	2	V
Genus: Kobuvirus		
Aichivirus A (Aichi virus 1)	2	
Genus: Parechovirus		
Parechoviruses A	2	
Parechoviruses B (Ljungan virus)	2	
Other *Picornaviridae* known to be pathogenic	2	
Order: Unassigned		
Family: *Adenoviridae*	2	
Family: *Astroviridae*	2	
Family: *Arenaviridae*		
Genus: Mammarenavirus		
Brazilian mammarenavirus	4	
Chapare mammarenavirus	4	
Flexal mammarenavirus	3	

[1] *See special dispensation Appendix 4.*

[2] *Classification according to the World Health Organization (WHO) Global Action Plan to minimise poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use.*

Part 2: Viruses

Biological Agent (virus species or indicated taxonomy order)	Classification	Notes
Guanarito mammarenavirus	4	
Junín mammarenavirus	4	
Lassa mammarenavirus	4	
Lujo mammarenavirus	4	
Lymphocytic choriomeningitis mammarenavirus, neurotropic strains	2	
Lymphocytic choriomeningitis mammarenavirus (other strains)	2	
Machupo mammarenavirus	4	
Mobala mammarenavirus	2	
Mopeia mammarenavirus	2	
Tacaribe mammarenavirus	2	
Whitewater Arroyo mammarenavirus	3	
Family: *Caliciviridae*		
Genus: Norovirus		
Norovirus (Norwalk virus)	2	
Other *Caliciviridae* known to be pathogenic	2	
Family: *Hepadnaviridae*		
Genus: Orthohepadnavirus		
Hepatitis B virus	3(**)	V, D
Family: *Hepeviridae*		
Genus: Orthohepevirus		
Orthohepevirus A (Hepatitis E virus)	2	
Family: *Flaviviridae*		
Genus: Flavivirus		
Dengue virus	3	
Japanese encephalitis virus	3	V
Kyasanur Forest disease virus	3	V
Louping ill virus	3(**)	
Murray Valley encephalitis virus (Australia encephalitis virus)	3	
Omsk haemorrhagic fever virus	3	
Powassan virus	3	
Rocio virus	3	
St.Louis encephalitis virus	3	

Part 2: Viruses

Biological Agent (virus species or indicated taxonomy order)	Classification	Notes
Tick-borne encephalitis virus		
Absettarov virus	3	
Hanzalova virus	3	
Hypr virus	3	
Kumlinge virus	3	
Negishi virus	3	
Russian spring-summer encephalitis[3]	3	V
Tick-borne encephalitis virus Central European subtype	3(**)	V
Tick-borne encephalitis virus Far Eastern subtype	3	
Tick-borne encephalitis virus Siberian subtype	3	V
Wesselsbron virus	3(**)	
West Nile fever virus	3	
Yellow fever virus	3	V
Zika virus	2	
Other flaviviruses known to be pathogenic	2	
Genus: Hepacivirus		
Hepacivirus C (Hepatitis C virus)	3(**)	D
Family: *Orthomyxoviridae*		
Genus: Gammainfluenza virus		
Influenza C virus	2	V[4]
Genus: Influenzavirus A		
Highly Pathogenic Avian Influenza Viruses HPAIV (H5), e.g. H5N1	3	
Highly Pathogenic Avian Influenza Viruses HPAIV (H7), H7N7, H7N9	3	
Influenza A virus	2	V[4]
Influenza A virus A/New York/1/18 (H1N1) (Spanish flu 1918)	3	
Influenza A virus A/Singapore/1/57 (H2N2)	3	
Low Pathogenic Avian Influenza Virus (LPAI) H7N9	3	
Genus: Influenzavirus B		
Influenza B virus	2	V[4]
Genus: Thogoto virus		
Dhori virus (Tick-borne *orthomyxoviridae:* Dhori)	2	
Thogoto virus (Tick-borne *orthomyxoviridae:* Thogoto)	2	
Family: *Papillomaviridae*	2	D[5]

[3] *Tick-borne encephalitis*
[4] *Only for types A and B*
[5] *Recommended for work involving direct contact with these agents.*

Part 2: Viruses

Biological Agent (virus species or indicated taxonomy order)	Classification	Notes
Family: *Parvoviridae*		
Genus: Erythroparvovirus		
Primate erythroparvovirus 1 (Human parvovirus, B 19 virus)	2	
Family: *Polyomaviridae*		
Genus: Betapolyomavirus		
Human polyomavirus 1 (BK virus)	2	D[5]
Human polyomavirus 2 (JC virus)	2	D[5]
Family: *Poxviridae*		
Genus: Molluscipoxvirus		
Molluscum contagiosum virus	2	
Genus: Orthopoxvirus		
Cowpox virus	2	
Monkeypox virus	3	V
Vaccinia virus (incl. Buffalopox virus[6], Elephantpoxvirus[7], Rabbitpox virus[8])	2	
Variola (major and minor) virus	4	V
Genus: Parapoxvirus		
Orf virus	2	
Pseudocowpox virus (Milkers' node virus, parapoxvirus bovis)	2	
Genus: Yatapoxvirus		
Tanapox virus	2	
Yaba monkey tumour virus	2	
Family: *Reoviridae*		
Genus: Seadornavirus		
Banna virus	2	
Genus: Coltivirus	2	
Genus: Rotavirus	2	
Genus: Orbivirus	2	
Family: *Retroviridae*		
Genus: Deltaretrovirus		
Primate T-lymphotropic virus 1 (Human T-cell lymphotropic virus, type 1)	3(**)	D
Primate T-lymphotropic virus 2 (Human T-cell lymphotropic virus, type 2)	3(**)	D

[5] *Recommended for work involving direct contact with these agents.*
[6] *Two viruses are identified: one a buffalopox type and the other a variant of the Vaccinia virus.*
[7] *Variant of cowpox virus.*
[8] *Variant of Vaccinia.*

Part 2: Viruses

Biological Agent (virus species or indicated taxonomy order)	Classification	Notes
Genus: Lentivirus		
Human immunodeficiency virus 1	3(**)	D
Human immunodeficiency virus 2	3(**)	D
Simian immunodeficiency virus (SIV)[9]	2	
Family: *Togaviridae*		
Genus: Alphavirus		
Cabassouvirus	3	
Eastern equine encephalomyelitis virus	3	V
Bebaru virus	2	
Chikungunya virus	3(**)	
Everglades virus	3(**)	
Mayaro virus	3	
Mucambo virus	3(**)	
Ndumu virus	3(**)	
O'nyong-nyong virus	2	
Ross River virus	2	
Semliki Forest virus	2	
Sindbis virus	2	
Tonate virus	3(**)	
Venezuelan equine encephalomyelitis virus	3	V
Western equine encephalomyelitis virus	3	V
Other alphaviruses known to be pathogenic	2	
Genus: Rubivirus		
Rubella virus	2	V
Family: *Unassigned*		
Genus: Deltavirus		
Hepatitis delta virus[10]	2	V, D

[9] *At present, there is no evidence of disease in humans caused by the other retroviruses of simian origin. As a precaution, containment level 3 is recommended for work with them.*

[10] *Hepatitis delta virus is pathogenic in workers only in the presence of simultaneous or secondary infection caused by hepatitis B virus. Vaccination against hepatitis B virus will therefore protect workers who are not affected by hepatitis B virus against hepatitis delta virus.*

Part 3: Prion Disease Agents

Biological Agent	Classification	Notes
Agent of Creutzfeldt-Jakob disease	3(**)	D[11]
Variant Agent of Creutzfeldt-Jakob disease	3(**)	D[11]
Agent of Bovine Spongiform Encephalopathy (BSE) and other related animal TSEs	3(**)	D[11]
Agent of Gerstmann-Sträussler-Scheinker syndrome	3(**)	D[11]
Agent of Kuru	3(**)	D[11]
Agent of Scrapie	2	

[11] *Recommended for work involving direct contact with these agents.*

This part relates to endoparasites only and consists of helminths and protozoa.

Part 4: Parasites

Biological Agent	Classification	Notes
Acanthamoeba castellani	2	
Ancylostoma duodenale	2	
Angiostrongylus cantonensis	2	
Angiostrongylus costaricensis	2	
Anisakis simplex	2	A
Ascaris lumbricoides	2	A
Ascaris suum	2	A
Babesia divergens	2	
Babesia microti	2	
Balamuthia mandrillaris	3	
Balantidium coli	2	
Brugia malayi	2	
Brugia pahangi	2	
Brugia timori	2	
Capillaria philippinensis	2	
Capillaria spp.	2	
Clonorchis sinensis (Opisthorchis sinensis)	2	
Clonorchis viverrini (Opisthorchis viverrini)	2	
Cryptosporidium hominis	2	
Cryptosporidium parvum	2	
Cyclospora cayetanensis	2	
Dicrocoelium dendriticum	2	
Dipetalonema streptocerca	2	
Diphyllobothrium latum	2	
Dracunculus medinensis	2	
Echinococcus granulosus	3(**)	
Echinococcus multilocularis	3(**)	
Echinococcus oligarthrus	3(**)	
Echinococcus vogeli	3(**)	
Entamoeba histolytica	2	
Enterobius vermicularis	2	
Enterocytozoon bieneusi	2	
Fasciola gigantica	2	
Fasciola hepatica	2	
Fasciolopsis buski	2	
Giardia lamblia (Giardia duodenalis, Giardia intestinalis)	2	
Heterophyes spp.	2	

Part 4: Parasites

Biological Agent	Classification	Notes
Hymenolepis diminuta	2	
Hymenolepis nana	2	
Leishmania aethiopica	2	
Leishmania braziliensis	3(**)	
Leishmania donovani	3(**)	
Leishmania guyanensis (Viannia guyanensis)	3(**)	
Leishmania infantum (Leishmania chagasi)	3(**)	
Leishmania major	2	
Leishmania mexicana	2	
Leishmania panamensis (Viannia panamensis)	3(**)	
Leishmania peruviana	2	
Leishmania tropica	2	
Leishmania spp.	2	
Loa loa	2	
Mansonella ozzardi	2	
Mansonella perstans	2	
Mansonella streptocerca	2	
Metagonimus spp.	2	
Naegleria fowleri	3	
Necator americanus	2	
Onchocerca volvulus	2	
Opisthorchis felineus	2	
Opisthorchis spp.	2	
Paragonimus westermani	2	
Paragonimus spp.	2	
Plasmodium falciparum	3(**)	
Plasmodium knowlesi	3(**)	
Plasmodium spp. (human and simian)	2	
Sarcocystis suihominis	2	
Schistosoma haematobium	2	
Schistosoma intercalatum	2	
Schistosoma japonicum	2	
Schistosoma mansoni	2	
Schistosoma mekongi	2	
Strongyloides stercoralis	2	
Strongyloides spp.	2	
Taenia saginata	2	
Taenia solium	3(**)	
Toxocara canis	2	

Part 4: Parasites

Biological Agent	Classification	Notes
Toxocara cati	2	
Toxoplasma gondii	2	
Trichinella nativa	2	
Trichinella nelsoni	2	
Trichinella pseudospiralis	2	
Trichinella spiralis	2	
Trichomonas vaginalis	2	
Trichostrongylus orientalis	2	
Trichostrongylus spp.	2	
Trichuris trichiura	2	
Trypanosoma brucei brucei	2	
Trypanosoma brucei gambiense	2	
Trypanosoma brucei rhodesiense	3(**)	
Trypanosoma cruzi	3(**)	
Wuchereria bancrofti	2	

Part 5: Fungi

Biological Agent	Classification	Notes
Aspergillus flavus	2	A
Aspergillus fumigatus	2	A
Aspergillus spp.	2	
Blastomyces dermatitidis (Ajellomyces dermatitidis)	3	
Blastomyces gilchristii	3	
Candida albicans	2	A
Candida dubliniensis	2	
Candida glabrata	2	
Candida parapsilosis	2	
Candida tropicalis	2	
Cladophialophora bantiana (Xylohypha bantiana, Cladosporium bantianum, trichoides)	3	
Cladophialophora modesta	3	
Cladophialophora spp.	2	
Coccidioides immitis	3	A
Coccidioides posadasii	3	A
Cryptococcus gattii (Filobasidiella neoformans var. *bacillispora)*	2	A
Cryptococcus neoformans (Filobasidiella neoformans var. *neoformans)*	2	A
Emmonsia parva var. *parva*	2	
Emmonsia parva var. *crescens*	2	
Epidermophyton floccosum	2	A
Epidermophyton spp.	2	
Fonsecaea pedrosoi	2	
Histoplasma capsulatum	3	
Histoplasma capsulatum var. *farciminosum*	3	
Histoplasma duboisii	3	
Madurella grisea	2	
Madurella mycetomatis	2	
Microsporum spp.	2	A
Nannizzia spp.	2	
Neotestudina rosatii	2	
Paracoccidioides brasiliensis	3	A
Paracoccidioides lutzii	3	
Paraphyton spp.	2	
Rhinocladiella mackenziei	3	
Scedosporium apiospermum	2	
Scedosporium prolificans (inflatum)	2	
Sporothrix schenckii	2	

Part 5: Fungi

Biological Agent	Classification	Notes
Talaromyces marneffei (Penicillium marneffei)	2	A
Trichophyton rubrum	2	A
Trichophyton tonsurans	2	A
Trichophyton spp.	2	

Schedule 2: Containment Measures and Containment Levels for Laboratories, Isolation Facilities and Animal Rooms

Regulations 16 (c) & 17 (2)

Application

This Schedule specifically applies to:

- Laboratories, including diagnostic laboratories;
- Isolation facilities where there are human patients or animals which are infected or suspected of being infected with a group 3 or 4 biological agent, and
- Rooms for laboratory animals where the animals have been deliberately infected with or are suspected to be carriers of a group 2, 3 or 4 biological agent.

In accordance with Regulations 16(c) and 17(2) of the Biological Agents Regulations, the measures contained in this Schedule must be applied according to the nature of the activities, the assessment of risk to employees and the nature of the biological agent concerned. Dispensations from minimum containment measures for laboratories and animal rooms are as detailed in Schedule 4.

Note in Relation to this Table

In the table "Recommended" means that the measures must be applied, unless the results of the risk assessment as required under Regulation 7 of the Biological Agents Regulations prove otherwise.

Containment Measures		Containment Levels		
		2	3	4
Workplace				
(1)	The workplace is to be separated from any other activities in the same building	No	Recommended	Yes
(2)	The workplace is to be sealable to permit fumigation	No	Recommended	Yes
Facilities				
(3)	Infected material including any animal is to be handled in a safety cabinet or isolation or other suitable containment	Where appropriate	Yes, where infection is by airborne route	Yes
Equipment				
(4)	Input air and extract air to the workplace are to be filtered using HEPA filters or likewise	No	Yes, on extract air	Yes, on input and extract air

Containment Measures		Containment Levels		
Equipment Cont'd		**2**	**3**	**4**
(5)	The workplace is to be maintained at an air pressure negative to atmosphere	No	Recommended	Yes
(6)	Surfaces impervious to water and easy to clean	Yes, for bench and floor	Yes, for bench, floor and other surfaces determined by risk assessment	Yes, for bench, walls, floor and ceiling
(7)	Surfaces resistant to acids, alkalis, solvents, disinfectants	Recommended	Yes	Yes
System of Work				
(8)	Access is to be restricted to nominated workers only	Recommended	Yes	Yes, via airlock
(9)	Efficient vector control, for example rodents and insects	Recommended	Yes	Yes
(10)	Specified disinfection procedures	Yes	Yes	Yes
(11)	Safe storage of a biological agent	Yes	Yes	Yes, secure storage
(12)	Personnel should shower before leaving the contained area	No	Recommended	Recommended
Waste				
(13)	Validated inactivation process for the safe disposal of animal carcasses	Recommended	Yes, on or off site	Yes, on site
Other Measures				
(14)	A laboratory is to contain its own equipment	No	Recommended	Yes
(15)	An observation window, or, alternative, is to be present, so that occupants can be seen	Recommended	Recommended	Yes

Schedule 3: Containment Measures and Containment Levels for Industrial Processes

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

Application

This Schedule specifically applies to industrial processes as defined.

Notes in relation to this table

In the table, 'Recommended' means that the measures must be applied, unless the results of the risk assessment as required under Regulation 7 of the Biological Agents Regulations prove otherwise.

Group 1 biological agents

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

Groups 2, 3 and 4 biological agents

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

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

Containment Measures		Containment Level		
General Cont'd		2	3	4
(6)	The controlled area should be designed to contain spillage of the entire contents of the closed system	No	Recommended	Yes
(7)	The controlled area should be sealable to permit fumigation	No	Recommended	Yes
Facilities				
(8)	Decontamination and washing facilities should be provided for personnel	Yes	Yes	Yes
Equipment				
(9)	Input air and extract air to the controlled area should be HEPA filtered	No	Recommended	Yes
(10)	The controlled area should be maintained at an air pressure negative to atmosphere	No	Recommended	Yes
(11)	The controlled area should be adequately ventilated to minimise air contamination	Recommended	Recommended	Yes
System of Work				
(12)	Closed systems should be located within a controlled area	Recommended	Recommended	Yes, and purpose-built
(13)	Biohazard signs should be posted	Yes	Yes	Yes
(14)	Access should be restricted to nominated personnel only	Recommended	Yes	Yes, via an airlock
(15)	Personnel should shower before leaving the controlled area	No	Recommended	Yes
(16)	Personnel should wear protective clothing	Yes, work clothing	Yes	Yes, complete change

Containment Measures		Containment Level		
System of Work Cont'd		2	3	4
Waste				
(17)	Effluent from sinks and showers should be collected and inactivated before release	No	Recommended	Yes
(18)	Effluent treatment before final discharge	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means

Dispensation for Certain Risk Group 3 Biological Agents Annotated with **

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

As a result, some of the minimum containment measures, particularly those aimed at controlling airborne infection, may not be required subject to risk assessment.

Special Dispensation for SARS-CoV-2 (Risk Group 3)

A special dispensation (page 56) has been made for SARS-CoV-2, the causative agent of the disease COVID-19, in light of the 2020 pandemic. This special dispensation is primarily in order to ensure sufficient testing capacity and continuity of testing.

Notes in Relation to Dispensations

Dispensation does not mean that work can automatically be carried out at containment level 2. Dispensation permits certain physical containment measures to be changed or dispensed with subject to risk assessment. Containment level 3 requirements such as the maintenance of lists of exposed workers, a high level of instruction, information, training, and a high level of supervision will still be required to containment level 3 requirements.

Prior to dispensing with any of the minimum containment measures, a full risk assessment must be completed in accordance with Regulation 7 of the Biological Agents Regulations.

Biological Agents	Diagnostic Work Measures	Intentional Work Measures
Enteric bacteria: *Escherchia coli* verocytotoxigenic strains (e.g. O157:H7 or O103) *Salmonella* Typhi, *Shigella dysenteriae* (Type 1)	Points 1 to 4	All intentional work must be carried out at full containment level 3
Mycobacteria: *Mycobacterium microti, M.ulcerans*	Points 5 & 6	Points 5 & 6
Blood-borne viruses: Hepatitis B virus, Hepacivirus C, Human immunodeficiency viruses 1 and 2, Primate T-lymphotropic viruses 1 and 2, Simian immunodeficiency virus	Points 7 & 8	All intentional work must be carried out at full containment Level 3
Prion Disease Agents: Agent of Creutzfeldt-Jakob disease, variant agent of Creutzfeldt-Jakob disease, agent of Bovine Spongiform Encephalopathy (BSE) and other related animal TSEs, agent of Gerstmann-Sträussler-Scheinker syndrome, agent of Kuru	Points 9 to 11	Points 9 to 11
Parasites: *Echinococcus granulosus, E. multilocularis, E.oligarthus, E.vogeli, Leishmania braziliensis, L.donovani, L.guyanensis, L.infantum, L.panamensis, Plasmodium falciparum, P.knowlesi, Taenia solium, Trypanosoma brucei rhodesiense, T.cruzi*	Point 12	Point 13 to 19

Biological Agents	Diagnostic Work Measures	Intentional Work Measures
Other biological agents denoted with **	Point 20	Point 20
Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)	Point 21	Points 22-24

Dispensations from Containment Measures

Group 3 Enteric Biological Agents Annotated with **

1. For diagnostic work, 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:

    - The laboratory does not need to be maintained at an air pressure negative to atmosphere. In practice, negative pressure may be achieved if a safety cabinet is in use.
    - The laboratory does not need to be sealable to permit fumigation.
    - The laboratory does not need to have exhaust air extracted using HEPA filtration, although in practice this may be the case if a safety cabinet is in use. Any work that could give rise to an aerosol of infectious material must be carried out in a safety cabinet (or equivalent containment).

2. The other procedural or management measures normally required at containment level 3 (above those required at containment level 2) must still be in place:

    - 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 other routine diagnostic work that may also be carried out in the laboratory.
    - An observation window (or alternative) to allow occupants to be seen should be in place. However, if it is not available, then there will need to be some means of checking on employees. Adequate supervision and lone working procedures must be in place when individuals are working alone.

3. The need for a 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 Annotated with **

5. All work (intentional and diagnostic) with *Mycobacterium microti* should be carried out at full containment level 3, as it can cause severe pulmonary disease 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 may be housed at containment level 2, with procedures such as taking blood and post-mortem examination taking place in a 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 (see end of point 12) should be used.

Group 3 Blood-Borne Viruses Annotated with **

7. Routine diagnostic work with specimens that contain or may contain blood-borne viruses can be carried out at containment level 2. However, additional measures (see end of point 12) will be required to control the risk of sharps injuries and contamination of the skin and mucous membranes. The risk assessment should reflect whether the work procedures could otherwise increase the risk of exposure by virtue of the nature of the work.

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

Group 3 Prion Disease Agents Annotated with **

9. Prion disease 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. For example, the need for a sealable laboratory to allow fumigation (these agents are not affected by normal fumigants) and the requirement for an inward airflow may not be necessary. Any decision to change the containment measures must be on the basis of a risk assessment.

10. Brain and spinal cord samples present the greatest risk of exposure to these agents 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:

    - Take care to avoid accidental inoculation or injury for example, when preparing samples for microscopy or culture.

    - Use disposable equipment wherever practicable for example, cell counting chambers.

- Destroy any items contaminated by the specimens by incinerating, autoclaving or disinfecting to the required standard;
- Minimise any residual contamination of automated equipment and ensure equipment is safe to handle before servicing;
- Clean and maintain delicate equipment such as microscopes regularly to avoid accumulation of potentially contaminated debris.

11. '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.

Group 3 Parasites Annotated with **

12. 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:

- Covering cuts or lesions with waterproof dressings.
- Wearing gloves and discarding them before handling items likely to be used by others, for example telephones.
- Avoiding the use of sharps including glassware as far as is reasonably practicable.
- Carrying out work in a designated area of the laboratory with sufficient space to work safely.
- Keeping the workspace clear of any unnecessary equipment.
- Wearing eye protection if there is a risk of splashing.

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

13. When working with certain group 3 parasites (*Echinococcus granulosus, E.multilocularis, E.oligarthrus, E.vogeli, Leishmania braziliensis, L.donovani, L.guyanensis, L.infantum, L.panamensis, Plasmodium falciparum, P.knowlesi, Taenia solium, Trypanosoma brucei rhodesiense and T.cruzi)* 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).

14. The other procedural and management measures normally required at containment level 3 (above those required at containment level 2) must still be in place:

- Separate work with parasites from the other routine work that may also be carried out in the laboratory to control potential exposure. Ideally, use a separate room. If this is not possible, carry out the work in a designated area of a larger laboratory that can be separated temporally, for example, 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, the designated area must be away from the main thoroughfare, for example, 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.

- An observation window (or alternative) to allow occupants be seen should be in place. However, if it is not available, then there will need to be some means of checking on employees. Adequate supervision and lone working procedures must be in place when individuals are working alone.

15. The need for a 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 consider the potential means of transmission of the parasite from host to host (including humans) and whether the work involves:

    - the infectious or transmissive stage of the parasite;
    - tissue culture; or
    - passaging the parasite in an intermediate host (vertebrate or invertebrate).

16. 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.

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

18. 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.

19. 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 Organization at www.who.int). A risk assessment is necessary, based on the intended nature of the work.

Other Group 3 Biological Agents Annotated with **

20. For the remaining group 3 biological agents annotated with ** (namely *Rickettsia akari, R.heilongjiangensis*, Australian bat lyssavirus, Duvenhage lyssavirus, European bat lyssavirus 1, European bat lyssavirus 2, Lagos bat virus, Rabies lyssavirus, Louping ill virus, Tick-borne encephalitis virus Central European subtype, Wesselsbron virus, Chikungunya virus, Everglades virus, Mucambo virus, Ndumu virus and Tonate virus), all deliberate work should be carried out at containment level 3. The requirement for inward airflow and HEPA filtration for extract air should be determined by risk assessment.

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)

21. Non-propagative diagnostic laboratory work (for example sequencing, nucleic acid amplification test [NAAT]), involving SARS-CoV-2 subject to written risk assessment, can be conducted at a facility using procedures equivalent to at least containment level 2. Heightened control measures may be required based on the written risk assessment. Initial sample processing (before virus inactivation) must take place in a validated safety cabinet.

22. Research or development work using non-propagative laboratory work techniques may be carried out at minimum of containment level 2 subject to written risk assessment and heightened control measures where required.

23. Handling of materials with high concentrations of the live virus or large volumes of infectious materials must be carried out at containment level 3.

24. Propagative work (for example, virus culture, isolation or neutralisation assays) involving SARS-CoV-2 must be conducted in a containment level 3 laboratory with air pressure negative to atmosphere.

Notes

Further Information and Guidance:

Visit our website at **www.hsa.ie**, telephone our contact centre on **1890 289 389** or email **wcu@hsa.ie**

Use BeSMART, our free online risk assessment tool at **www.besmart.ie**

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