HEALTH AND SAFETY AUTHORITY

Guidelines to the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013

Our vision:

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

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

Contents

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1.0 Introduction

The Safety, Health and Welfare at Work (Biological Agents) Regulations, 2013, with their relevant Code of Practice, give legal effect to Council Directive 2000/54/EC, concerned with the protection of employees from risks related to exposure to biological agents at work. The regulations are made under the Safety, Health and Welfare at Work Act, 2005 (No. 10 of 2005) and are also linked to the requirements in the Safety, Health and Welfare at Work (General Application) Regulations, 2007 (S.I. No 299 of 2007) as amended by the Safety, Health and Welfare at Work (General Application) (Amendment) Regulations, 2007 (S.I. No 732 of 2007) and the Safety, Health and Welfare at Work (Chemical Agents) Regulations, 2001 (S.I. No 619 of 2001).

The regulations, and their Code of Practice, which came into effect on the 20th December, 2013, revoked 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 Safety, Health and Welfare at Work (Biological Agents) Regulations, 2013 set down obligations on employers regarding the determination and assessment of risk with respect to biological agents; the prevention and control of exposure to hazardous biological agents; specific protection and preventive measures; arrangements to deal with accidents, incidents and emergencies; information, training and consultation; health surveillance; record-keeping; notification requirements to the Authority; and duties for employees.

These guidelines are not intended as a legal interpretation of the Safety, Health and Welfare at Work (Biological Agents) Regulations, 2013.

The overall purpose of the guidelines is to give general guidance on the prevention of risks to safety and health related to exposure to certain biological agents in the workplace.

These guidelines emphasise, in particular, the importance of adequate and appropriate risk assessment as laid down in Regulation 7 of the regulations. The aim of these guidelines is to assist in the understanding and implementation of the requirements and responsibilities as set out in the Safety, Health and Welfare at Work (Biological Agents) Regulations, 2013.

2.0 Biological Agents

Biological agents are defined in the regulations, as micro-organisms, including those that have been genetically modified, cell cultures and human endoparasites, which may provoke any infection, allergy or toxicity. They are also defined in the regulations as microbiological entities, cellular or non-cellular, capable of replication or of transferring genetic material.

Biological agents are found virtually everywhere in the natural environment. However, certain biological agents can cause harm – either by causing disease (i.e. are pathogenic), by causing allergy or by producing toxins which are harmful. There are two modes of exposure at work to biological agents: (1) they are intentionally worked with, as in a microbiological laboratory; or (2) incidental exposure may occur as a result of the kind of work done, such as healthcare work, farming, refuse disposal or work with products of animal origin. In the second group the exposure to biological agents is incidental to the purpose of the work.

Schedule 1 – List of Biological Agents
• **Part 1: Bacteria**
• **Part 2: Fungi**
• **Part 3: Helminths**
• **Part 4: Protozoa**
• **Part 5: Prions** (which includes unconventional agents associated with the transmissible spongiform encephalopathies (TSEs);
• **Part 6: Viruses**

Biological agents have been classified by the World Health Organization and these classifications have been adopted worldwide by various bodies, including the EU. These are included in the Safety, Health and Welfare at Work (Biological Agents) Regulations, 2013 and the relevant Code of Practice.

The classification system is based on the relative risk of the biological agent causing disease in humans, the severity of the disease caused, the ease with which that disease may spread and the availability of effective treatments or prophylaxis (preventative measures) as follows:

▲ **A group 1 biological agent** or micro-organism is one that is unlikely to cause human disease (i.e. no or low individual or community risk). Other than requiring good hygienic procedures, this group is effectively outside the scope of the regulations.

▲ **A group 2 biological agent** is 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 (preventative measures) or treatment available (i.e. moderate individual risk, low community risk).

Example of a group 2 biological agent: *Legionella pneumophila*

What is it? *Legionella pneumophila* is naturally found in low concentrations, which are non-hazardous, in rivers/lakes/groundwater. The temperature required for growth of the bacteria is from 20ºC to 45ºC, and a temperature greater than 60ºC will kill viable bacteria. It can cause legionnaires' disease, a potentially fatal form of pneumonia if water aerosols or mists containing a sufficient number of the bacteria are inhaled.

Sources: Cooling systems, spa pools, hot/cold water systems (showers etc.), humidifiers, spray and sprinkler systems, systems with stagnant water.

Who is at risk: Immunosuppressed individuals, individuals older than 45 years old, and smokers.

Prevention: Carry out a risk assessment and put preventative measures in place, eliminate conditions for infection. See Schedules 2 and 3 of the Biological Agents Code of Practice for details of containment level 2.

See guidance on legionnaires' disease on Health Protection Surveillance Centre (HPSC) website (www.hpsc.ie) or HSA site (www.hsa.ie).

▲ **A group 3 biological agent** is one which can cause severe human disease, presents a serious hazard to employees and where there is a risk of spreading to the community, though there is usually effective prophylaxis or treatment available (i.e. high individual risk, low community risk).

Example of a group 3 biological agent: *Mycobacterium tuberculosis (M. tuberculosis)*

What is it? Tuberculosis is a common and deadly infectious disease caused by bacteria of the Mycobacteria spp., usually *Mycobacterium tuberculosis*. Tuberculosis commonly attacks the lungs, causing pulmonary TB, but it may also affect other parts of the body, including the glands, the bones and, in rare cases, the brain.

Prevention: Carry out a risk assessment and put preventative measures in place, such as eliminate conditions for infection and provide suitable vaccinations. See Schedules 2 & 3 of Biological Agents Code of Practice for details of containment level 3.

▲ **A group 4 biological agent** is one which causes severe human disease and is a serious hazard to employees and which may present a high risk of spreading to the community and in respect of which there is usually no effective prophylaxis or treatment available (i.e. high individual and high community risk). See Schedules 2 & 3 of Biological Agents Code of Practice for details of containment level 4.

Example of a group 4 biological agent *Ebola Virus*

What is it? This agent causes a viral haemorrhagic fever leading to rapid death in infected persons. It is usually highly infectious, and there is no specific effective treatment or prophylaxis available.

3.0 Legal Requirements

What are the legal requirements?

The main legal requirements stem from the following legislation:

- The Safety, Health and Welfare at Work Act, 2005, No. 10 of 2005
- The Safety, Health and Welfare at Work (General Applications) Regulations, 2007, S.I. No. 299 of 2007
- The Safety, Health and Welfare at Work (Biological Agents) Regulations, 2013, S.I. No. 572 of 2013 and the relevant Code of Practice
- The Safety, Health and Welfare at Work (Chemical Agents) Regulations, 2001, S.I. No. 619 of 2001
- The European Communities (Carriage of Dangerous Goods by Road and Use of Transportable Pressure Equipment) Regulations 2011, S.I. No. 349 of 2011 and the European Communities (Carriage Of Dangerous Goods By Road And Use Of Transportable Pressure Equipment) (Amendment) Regulations 2013 S.I. No. 238 of 2013

The Safety, Health and Welfare at Work Act, 2005, Number 10 of 2005, sets out the general duties of all employers to manage the safety, health and welfare of their employees in any place of employment. The principal elements of the Act (relevant to these guidelines) are:

- having in place protective and preventative measures, including hazard identification, risk assessment and control (Sections 19 and 20)
- consulting with employees (Section 26)
- provision of information to employees (Section 9)
- provision of instruction and training to employees (Section 10)

Separate guidelines on the Act and its requirements are available on the Health and Safety Authority's website: www.hsa.ie.

The Safety, Health and Welfare at Work (General Applications) Regulations, 2007, S.I. No. 299 of 2007, lay down more detailed requirements in a broad range of regulations that pertain, in general, to all workplaces. These regulations include the following topics:

- the general workplace, work equipment and its use
- personal protective equipment
- manual handling
- display-screen equipment
- electricity
- working at heights
- noise and vibration
- sensitive groups – pregnant employees, young people and shift employees
- safety signs and first aid
- explosive atmospheres at places of work

Separate guidelines on these regulations are available on the Health and Safety Authority's website. www.hsa.ie.

T**he Safety Health and Welfare at Work (Biological Agents) Regulations, 2013**, **S.I. No. 572 of 2013,** and the relevant **Code of Practice** lay down the specific requirements pertaining to the exposure to biological agents in the workplace.

The Safety, Health and Welfare at Work (Biological Agents) Regulations, 2013 are divided into 5 parts:

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

- The Safety, Health and Welfare at Work (Biological Agents) Regulations, 2013 apply to **all workplaces** where there is a potential for exposure to biological agents, either deliberate (when working with an agent in a laboratory, for example), or incidental (through work in a sewage treatment plant, for example). See Appendix 1 for a range of common occupational infections and their sources.
- In this Part of the Safety, Health and Welfare at Work (Biological Agents) Regulations, 2013, the **classification** of biological agents into four hazard groups is detailed (see Section 2.0 for further details).
- 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 Safety, Health and Welfare at Work (Biological Agents) Regulations, 2013** and the relevant provisions of the relevant Code of Practice.
- The duties include carrying out a **risk assessment** and putting in place the **appropriate measures** to protect employees' health and safety (see Section 4.1 of these guidelines for further details) 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 the Code of Practice**, e.g. for a group 2 agent, the employer must have the minimum controls listed in Schedule 2 in place.
- **Consult with, inform and train** their employees.
- **Notify the Health and Safety Authority as per Part 4 below**.

3.0 Legal Requirements cont'd

- It is the **duty of the employee** to report immediately any accident or incident of which he or she becomes aware. This duty is in addition to duties already specified in the Safety, Health and Welfare at Work, 2005 Act.

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

- The Safety, Health and Welfare at Work (Biological Agents) Regulations, 2013 require that a specific biological agents written **risk assessment** is completed and measures are put in place to protect the health and safety of employees.
- If possible, harmful biological agents **should be substituted** with less harmful biological agents. Where substitution with a less harmful biological agent is not possible, exposure should be prevented and at least reduced to as low a level as necessary to protect the health and safety of employees (see Section 5.0 of these guidelines).
- The regulations require that employees receive appropriate **training and information** on (a) potential health risks; (b) precautions to be taken; (c) hygiene requirements; (d) the wearing and use of personal protective equipment; (e) possible vaccines available; and (f) steps to be taken by employees in the **case of accidents and to prevent incidents**.
- In line with requirements in the General Application Regulations, the Biological Agents Regulations require that certain **hygiene measures** be in place. Employees may not eat or drink in any area where there is a risk of contamination. Employees must be provided with suitable washing and toilet facilities to **prevent contamination or re-contamination**. Appropriate use of skin antiseptics should be considered. Clear procedures, such as written standard operating procedures (SOPs), should be in place 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** (see Section 5.4 of these guidelines). 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 regulation also details matters on keeping individual **employee health and medical records** (see Section 6.8 of these guidelines for details on health surveillance).
- Regulation 13 requires that employers are required to **maintain emergency procedures** and plans in line with the requirements of sections 8 and 11 of the Safety, Health and Welfare at Work Act, 2005 (see Section 6.9 of these guidelines for details on emergency plans).

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**.
- Employers must provide **information to employees** on risk assessments carried out.
- Employers must inform the Authority of any **accident or incident** resulting in a release which

could cause serious infection or illness to any person. A form of notification of a dangerous occurrence should be completed in this case – forms for the notification of a dangerous occurrence or an accident can be found on the Health and Safety Authority's website: www.hsa.ie.

- Employers must **notify 30 days** in advance the first use of group 2, 3 or 4 biological agents. There are further requirements depending on the classification and work conditions and, in certain circumstances, some requirements can be dispensed with (see Section 5.1 – Risk Assessment – on dispensation measures, and Section 8.0 on notification requirements).
- An **Occupational Exposure List** must be kept of employees who may be exposed to any group 3 or 4 biological agents and limited number of group 2 agents as specified in the the Code of Practice (see Section 10.0 of these guidelines).

  The employer must deliver (1) the occupational exposure list and (2) the individual health records, as required by Regulation 14, to the Authority where the employer's undertaking is ceasing activity.
- Employees or their safety representative must have **access** to the **collective information** in the occupational exposure list, provided the information is not identifiable with 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.

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 regulations include 5 Schedules which expand on the requirements of the regulations:

(1) **Schedule 1** gives a non-exhaustive indicative **list of activities** where hazardous biological agents might be encountered, though perhaps not intentionally, for example food production, agriculture, healthcare and biotechnology.

(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, e.g. a biological safety cabinet.

(3) **Schedule 3** indicates the **biohazard sign.** This sign is required in the workplace at containment levels 2, 3 and 4.

(4) **Schedule 4** gives recommendations on **vaccination** (see Section 6.7 of these guidelines)

(5) **Schedule 5** gives recommendations for **health surveillance** (see Section 6.8 of these guidelines).

3.0 Legal Requirements cont'd

2013 Code of Practice to the Safety, Health and Welfare at Work (Biological Agents) Regulations, 2013, S.I. No. 572 of 2013

The foreword, revision, introduction, definitions and schedule 1 - introductory notes, give advice on interpreting and making correct use of the Code of Practice.

- **Schedule 1** lists the applicable biological agents (bacteria, fungi, heminths, protozoa, prions and viruses) and their classifications, including any relevant notes (e.g. T=toxin, A=allergen, V=vaccine available).
- **Schedule 2** lists the minimum containment measures and levels.
- **Schedule 3** lists the minimum containment measures and levels for industrial processes.
- **Schedule 4** lists dispensations of the minimum containment measures which may be exempted for certain group 3 biological agents where there is a limited risk of infection because the agent is not normally infectious by the airborne route. Biological Agents which may be considered are indicated by asterisk (*) in Schedule 1.

Safety, Health and Welfare at Work (Chemical Agents) Regulations, 2001, S.I. No. 619 of 2001

Employers working with biological agents are also likely to be using chemical agents (including disinfectants, cleaning agents, etc.) and so the requirements of the Chemical **Agents Regulations, 2001** will also be applicable.

See separate guidance for Chemical Agents published by the Health and Safety Authority, which are available on its website: www.hsa.ie.

The Carriage of Dangerous Goods by Road Regulations, 2010, S.I. No. 617 of 2010

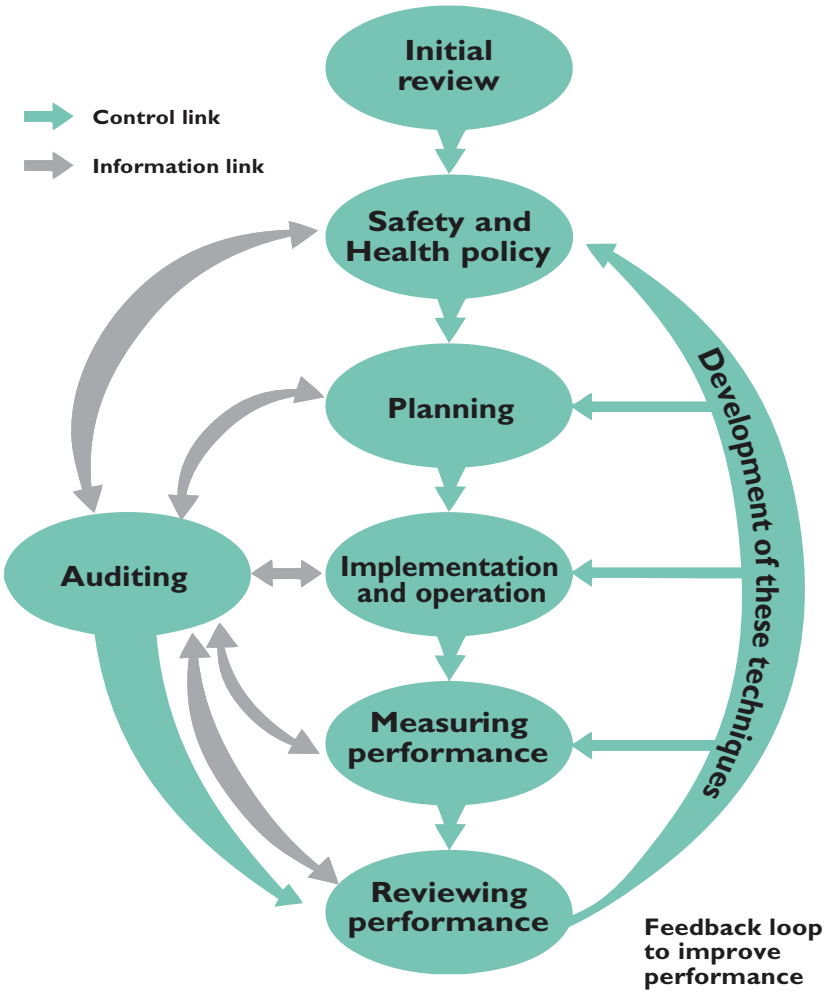
The requirements of the Dangerous Goods by Road Regulations will apply if the employer is transporting biological waste (Class 6.2 infectious substances). The employer should seek the advice of a Dangerous Goods Safety Advisor (DSGA). UN-approved packaging and labelling is required for Class 6.2 waste, and consignment documentation is also required.

For further information refer to: *Guidance on Regulations for the Transportation of Infectious Substances*, published by the World Health Organization.

For any enterprise, the key elements of a safety and health management system are:

- policy and commitment
- planning
- implementation and operation
- measuring performance
- auditing and Reviewing Performance

The Safety, Health and Welfare at Work Act, 2005, the Safety, Health and Welfare at Work (General Applications) Regulations, 2007 and the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 set out the duties of employers to manage health and safety in the workplace. The legislation also sets out the duties of employees to cooperate with the employer in health and safety matters.



Key Elements of Health and Safety Management

4.0 Health and Safety Management cont'd

The HSA publication, *Workplace Safety and Health Management*, gives guidance on general health and safety management (see publication on the HSA website: www.hsa.ie).

Health and safety management in microbiological areas would need to include:

- management responsibilities
- risk assessments
- staff selection, qualification, training and supervision
- local safety policies and standard operating procedures (SOPs)
- emergency procedures and contingency plans
- incident reporting
- health surveillance
- record-keeping

5.0 Non-intentional Exposure

This section of the guidance is aimed at employers/employees who are not deliberately working with micro-organisms (biological agents) but could, through their work, unintentionally become infected by a pathogen. The lists given below are not exhaustive, but serve to aid in the assessment and control of potential exposure. Appendices 1 and 2 show common occupational infections and their sources.

Are employees in direct contact with humans?

Besides healthcare staff (see section 7.0 of this guidance):

- carers
- minders
- hospitality staff
- beauticians
- leisure employees

Employees listed above, and those in close contact with humans, may be exposed to and become infected with a biological agent.

Are employees in direct contact with animals?

- farmers and their employees
- vets (see Section 6.6.1 on veterinary care)
- zookeepers
- employers/employees involved with bloodstock
- animal wardens
- gamekeepers or those involved in hunting etc. as an occupation
- animal trainers
- pet-shop employers/employees
- sports-grounds keepers

Employees working with animals may contact a zoonotic disease or allergy, for example the fungal infection ringworm from farm animals, or allergic alveolitis such as bird fancier's lung.

Are employees in direct contact with soil or plant materials?

- farmers (their employees and many on the animal contact list above)
- gardeners
- mushroom growers
- foresters
- construction employees

Soil can be a reservoir of many pathogens (one example: tetanus – caused by Clostridium tetani) and it can also be contaminated by the excrement and urine of various animals, both wild and domestic (rat urine – leptospirosis).

5.0 Non-intentional Exposure cont'd

Are employees in contact with water?

Water with the right conditions of temperature and some nutrient can support the growth and become the reservoir of biological agents leading to infection.

Legionella can grow in sumps or dead legs in plumbing or industrial water systems and may then be dispersed as aerosols. Inhalation of aerosols contaminated with Legionella can cause legionnaires' disease, which can be fatal in certain circumstances. For further information on legionnaires' disease (or legionellosis), see HSA factsheet at www.hsa.ie, or the Health Protection Surveillance Centre National Guidelines for the Control of Legionellosis in Ireland at www.hpsc.ie.

Occasional outbreaks of waterborne infection still arise from contamination of drinking water by soiled water (usually coliform bacteria) and protozoan parasitic contamination of water by cryptosporidium has occurred in the past.

Are employees in contact with any kind of natural or food products?

If food safety controls are not in place, there is a risk of bacterial growth which may lead to infection. For example, certain strains of E. coli can be found in raw beef (particularly minced beef) and meat products, contaminated drinking water and unpasteurised milk.

Are employees in contact with human or animal solid or liquid wastes?

Animal waste sludge and sewage is usually stabilised by digestion, which considerably reduces, but does not eliminate, the pathogen load. Raw sewage has the potential to be the reservoir of many pathogens.

The nature and concentrations of pathogens in sewage will depend on the health and the size of the population in the catchment. In a large community, a small proportion of the population is likely to be infected at any time, and consequently low levels of pathogens will be found in the sewage at all times.

The nature of sewage, and hence its sludge, is such that it may contain enteric pathogens, i.e. those which are excreted with faecal material and generally are infective by the oral route.

The levels and diversity of pathogens in sewage will be dependent upon local conditions, including the incidence of disease in the contributing community at that time.

Examples of pathogenic micro-organisms that may be found in sludge derived from faecal material (extract from Evaluation Of Sludge Treatments For Pathogen Reduction – Final Report, Study Contract No B4-3040/2001/322179/Mar/A2 for The European Commission Directorate-General Environment, September 2001):

Bacteria	Classification	Protozoa	Classification
Salmonella spp.	2 (S. typhi -3)	Giardia lambia	
Escherichia coli (enteropathogenic strains)	2	Toxoplasma gondii	2
Pseudomonas aeruginosa	2	Helminths	
Clostridium perfringens	2	Toxocara canis	2
Clostridium botulinum	2	Toxocara cati	2
Mycobacterium spp.	2 & 3	Trichuris trichiura	2
Leptospira spp.	2		
Campylobacter spp.	2	Yeast	
		Candida albicans	2
Viruses		Candida krusei	
Hepatitis A-virus	2	Cryptococcus neoformans	2
Influenza virus	2		
		Fungi	
		Aspergillus spp.	2
		Trichophyton spp.	2
		Epidermophyton spp	2

Are employees in contact with human or animal remains?

When working with corpses, blood and other bodily fluids (for example saliva, pleural fluids); waste products, such as faeces and urine; aerosols of infectious material, such as might be released when opening the body; and skin, direct contact must be considered. See Health Protection Surviellance Centre (HPSC) Guidelines for the Management of Deceased Individuals Harbouring Infectious Disease at www.hpsc.ie

All sections of this guidance, especially those on health and safety management and preventative and protective measures, apply equally to the non-intentionally exposed employee and the employee who intentionally works with biological agents.

The basic steps of risk assessment and control are (see Section 6.1):

1. Identify the hazards.
2. Consider who might be affected and how they might be harmed.
3. Evaluate the risks and take precautions.
4. Document and implement your findings.
5. Update and review.

5.0 Non-intentional Exposure cont'd

The Transmission Chain

1. **Reservoir:** the source of the infectious agent; any contaminated part of a human being or of an animal, soil, water or object.
2. **Portal of exit:** for contamination to happen, the biological agent has to get out of the reservoir or has to be accessible.
3. **Mode of transmission:** direct (inhalation or contact), semi-direct (transmitted on dirty hands); or indirect (the biological agent uses a carrier, insect, contaminated instrument etc.).
4. **Portal of entry:** respiratory tract, digestive tract, intact or damaged skin, previous injury or via a contaminated instrument or mucus.
5. **Potential host:** the employee at his/her workplace.

6.1 Risk Assessment

Whether considering chemical, physical or biological agents, there is a common general structure for completing a risk assessment. See the suggested risk-assessment checklists in Appendices 2 and 3. Appendix 2 contains a checklist for activities involving deliberate use, while Appendix 3 contains a checklist for activities involving incidental exposure to biological agents.

While the employer is responsible for carrying out a risk assessment, he or she should always involve staff and/or their safety representative in the process. Section 19 of the Safety, Health and Welfare at Work Act, 2005 deals with the requirements of hazard identification and risk assessment in general and Part 2, Chapter 1 of the Act outlines the general duties of employers (see Guide to the Safety, Health and Welfare at Work Act, 2005 on the HSA website www.hsa.ie for further advice on this topic).

The major steps in identifying and assessing the degree of risk associated with the biological hazard(s) are:

1. Identify the hazards
2. Consider who might be affected and how they might be harmed.
3. Evaluate the risks and take precautions.
4. Document and implement your findings.
5. Update and review.

(1) Identifying the hazards

The risk assessment must be completed by a competent person (as defined under the Safety, Health and Welfare at Work Act, 2005) who possesses sufficient training, experience and knowledge appropriate to the nature of the work. The technical qualifications required will vary depending on the complexity of the operation.

The first step is to identify the hazard or hazards:

- What biological agents could be or are present?
- Regarding the work sector, are there specific biological agents associated with it?
- Does the work involve deliberate or incidental exposure to biological agents?

6.0 Preventive and Protective Measures cont'd

To assess the hazards and implement controls and prevent infection, illness and death, the World Health Organization has drawn up four categories or hazard groups for workplace biological agents. These definitions have been included in major national and international authorities' guidance on biohazards, including EU Directive 2000/54/EC which has been transposed into Irish law through the Biological Agents Regulations, 2013 (see Section 2.0 on biological agents).

The hazard groups:
When considering what hazard group a biological agent should be assigned, there are four major parameters:

- Is the agent pathogenic to humans?
- Is the agent hazardous to employees?
- Is the agent transmissible to the community?
- Is effective prophylaxis (a measure taken for the prevention of a disease or condition) available?

The list of biological agents in Schedule 1 of the relevant Code of Practice classifies biological agents on their ability to cause harm to human health only (for classification see section 2.0 of these guidelines).

Certain agents listed in Schedule 1 are recognised as human allergens or are known to produce toxin(s), and these biological agents are marked with A or T in the Code of Practice. There are other notes in Schedule 1 – Introductory Notes and in 3rd column of Schedule 1 of the related Code of Practice, specific to certain biological agents, which should be borne in mind when carrying out risk assessments. Also, be aware that certain group 3 agents marked with an asterisk (*) are eligible for a certain degree of dispensation from level 3 containment requirements, due to the specific biological agent not being normally infectious via the airborne route.

(2) Consider WHO might be affected and HOW they might be harmed

An employer must determine how many employees are working with or have a potential to be exposed. Assess what training they have received and qualifications they hold. Determine the level of competence required to complete the work as planned with precautions in place and maintained to prevent harmful exposure.
There are many sources of information that employers can use to find out more about the hazardous properties of biological agents. These include:

- guidance published by the Authority or other authoritative organisations
- previous experience of using the biological agent
- technical reference sources (textbooks, scientific and technical papers, trade journals, etc.)
- professional institutions, trade associations, trade unions and specialist consultancy services
- the Internet

When assessing how employees might be harmed, it is necessary to consider:

1. the potential for generating aerosols, including splashing
2. the quantity (volume, concentration, infectious dose of the biological agent, etc.) and
3. the proposed work methods (in vitro, in vivo, aerosol challenge or environmental release)

Consider special risk groups such as pregnant employees and immune-suppressed individuals. While children are considered a special risk group, their likely exposure is more remote, indirect, but still possible (i.e. children on farms). When considering the special risk groups, consult the Safety, Health and Welfare (General Application) Regulations, 2007, Part 6, Sensitive Risk Groups, Chapter 1, Children and Young Persons, and Chapter 2, Pregnant, Post-natal and Breastfeeding Employees. The employer must also take into consideration visitors, contractors and maintenance staff. The employer should bear in mind that non-routine maintenance work is often of higher risk.

Work can be divided into two exposure types: incidental and deliberate. Incidental exposure can occur in many workplaces, where there is no intentional work with biological agents, e.g. in a mortuary. Exposures can also occur in workplaces, such as research or diagnostic processes in a laboratory, large-scale industrial processes in biotechnology, pharmaceutical or food-production plants.

(3) Evaluate the risks and take precautions

Before evaluating the risks, it is imperative to have completed a thorough list of all potential pathogens to which the employees might be exposed in the particular workplace.

If the biological agents identified are included in the lists in the associated Code of Practice, then their risk group can be identified. Leading from this, the minimum containment measures recommended for control can be referred to in Schedule 2 or 3 of the Code of Practice.

Self-classification of the agent(s) is carried out by the employer if the agent is not listed in Schedule 1 of the Code of Practice. The employer will classify that biological agent to one of the hazard groups according to the infection risk criteria, as defined in Regulation 2 of the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and restated in the relevant Code of Practice. If in doubt as to which of two groups (e.g. 2 or 3) to which to assign the agent, the employer shall assign it to the higher group. If the biological agent subsequently appears in a later edition of the Code of Practice, the classification given to it in the later edition of the Code of Practice must take priority.

6.0 Preventive and Protective Measures cont'd

Risk-assessment factors that should be considered, as appropriate, include:

1. Pathogenicity of the biological agent and infectious dose of the biological agent
2. Potential outcome of exposure
3. Natural route of infection
4. Other potential routes of infection, resulting from manipulations during work processes
5. Stability of the biological agent in the environment and the form of the biological agent, e.g. infectious stages or hardy spores
6. Concentration of the agent and volume of concentrated material to be manipulated during work processes
7. Presence of a suitable host (human or animal)
8. Information available from animal studies and reports of acquired infections or clinical reports.
9. Laboratory activity planned (sonication, aerosolization, centrifugation, etc.)
10. Any genetic manipulation of the biological agents that may extend the host range of the biological agent or alter the biological agent's sensitivity to known, effective treatment regimens
11. On-site availability of effective prophylaxis, antidotes/antitoxins or therapeutic interventions

Primary prophylaxis includes any measure that is taken to prevent disease before it occurs. A good example of this is vaccination, where an effective vaccine exists.

Secondary prophylaxis refers to procedures that help to prevent infection after exposure to a pathogen or to ease symptoms associated with an illness or health condition. For example, if a healthcare employee is exposed to the HIV/AIDS virus, they may, under medical supervision, be prescribed an antiretroviral drug to help prevent them from developing the disease.

See section 6.5 of these guidelines for further details on different containment levels.

Dispensations from full containment level 3

For indicated group 3 biological agents (indicated by an asterisk (*) in Schedule 1 of the Code of Practice), specific containment measures normally required at containment level 3 may be dispensed with under certain circumstances, either because of the nature of the agent being handled or the type of work being undertaken. For example, the agent may present a limited risk of infection for employees because it is not normally infectious by the airborne route.

Dispensation from some level 3 requirements does not mean that the work can be carried out at containment level 2. It means that certain physical containment measures required at containment level 3 (see Schedules 2 and 3 of the relevant Code of Practice) may be dispensed with as indicated in Schedule 4 of the related Code of Practice.

The employer will need to carry out a full risk assessment to determine the appropriateness of such dispensation.

(4) Document and implement your findings

Putting the results of your risk assessment into practice is vital to protect your employees. Writing down the results of your risk assessment, and sharing them with your employees, ensures the active participation of employees in getting things done.

The assessment must be suitable and sufficient and show that:

- a proper check was made
- those who might be affected were considered and consulted
- significant hazards were considered, taking into account the number of people who could be involved
- the precautions are reasonable, and the remaining risk is low; and
- staff or their representatives are involved in the process

If necessary, make an action plan to minimise hazards and prioritise it to deal with the most important things first. As you complete action items, update your risk-assessment records.

(5) Update and review

Over time work procedures, personnel and systems change. Change can lead to new hazards, and so regular reviews make sense. Regular formal reviews will help maintain and build on controls.

Is the risk assessment accurate?

What are the changes since the last review?

Are there any lessons to be learnt?

See References and Further Information Section 11.0 of these guidelines for more reference material in this area.

6.0 Preventive and Protective Measures cont'd

6.2 Information and Training

Where there is a risk to the safety or health of employees due to work with a biological agent, the employer must ensure that employees receive sufficient and appropriate training and information concerning:

- potential risks to health
- precautions to be taken to prevent exposure
- hygiene requirements
- the wearing and use of personal protective equipment
- the steps to be taken by employees in the case of incidents and to prevent incidents
- the hazardous properties of the biological agents handled
- the level, type and duration of exposure and the circumstances of work involving such biological agents
- appropriate precautions to safeguard themselves and other employees at the workplaces
- the effect of risk-management procedures taken or to be taken
- to whom potential health problems should be reported
- standard operating procedures (SOPs) that may include some or all of the above

Additionally, the employer must provide such information to **any employer** of other employees or **any self-employed person** who may be affected by exposure to a biological agent arising from his or her undertaking. The employer must also provide appropriate training and written instructions at the place of work and, if appropriate, display the biohazard sign and/or notices containing the procedure(s) to be followed in the case of a serious accident or incident involving a biological agent. The employer must ensure the instructions are written in a form, manner and language likely to be understood by employees.

Also, the employer must ensure that all relevant employees and other persons are informed immediately of any **accident or incident** which may have resulted in the release of a biological agent which could cause severe human infection or illness (or both), and of the causes of and measures taken in relation to any such serious accident or incident.

Employee information in particular cases:

Employees must receive information and training by written instruction containing at least the **procedure to be followed** in the event of a serious accident or incident.

Immediate information must be available in the event of any accident or incident which may result in the release of a biological agent, including the cause and the measures taken (or to be taken).

Employees must **immediately report any accident** or incident involving the handling of a biological agent. They must have access to the information contained in the list of employees exposed, i.e. information which relates to them personally and anonymous collective information.

Employees should be informed of the **risks** they face and **the preventive measures** in place to control those risks. They need to know how to work safely and how to use protective equipment where required.

Regarding **vaccines**, employees should be made aware of the effectiveness and limitations of any vaccines available to them and also the benefits and drawbacks of vaccination and non-vaccination (see Section 6.7 for further details).

6.3 Hygiene Measures

Hygiene measures aim to prevent or reduce the accidental transfer or release of biological agents from the workplace.

- Eating, smoking and drinking should be forbidden in the area of the workplace where there is a risk of contamination with biological agents.
- Hands (and forearms potentially) should be washed before eating, drinking, smoking, using the telephone, applying cosmetics or inserting contact lenses etc.
- There should be suitable facilities provided for staff to wash with warm running water and soap. Hands should still be washed even if gloves have been worn, or alcohol hand wipes/rubs can be used on physically clean hands. Alcohol is not a way of physically cleaning, but acts as a chemical sanitising agent and is effective against some biological agents where the hands have first been physically cleaned where necessary.
- Any existing cuts or grazes on an individual's hands should be first covered with waterproof dressings before commencing any work with biological agents. If any cuts or grazes occur during work, these should be washed immediately.
- Hand-to-mouth, hand-tonose or hand-to-eye contact should be avoided. Care should be taken with pens and all stationery, that these are not inserted into the mouth or taken from dirty to clean areas.
- Rest breaks and meal breaks should be taken away from the biological agent(s) work area.
- Employees should remove any personal protective equipment and contaminated clothing when leaving the work area and not enter clean areas wearing contaminated protective equipment. Hygiene measures vary according to the safety containment level required (see section 6.5 for further details on the different containment levels).

6.0 Preventive and Protective Measures cont'd

- Procedures should be in place for taking, handling and processing any samples of human or animal origin.
- Employees should be provided with suitable washing and toilet facilities, which may include eye washes and skin antiseptics (or both).

Recommended basic practice for hand washing is:

WET

SOAP

WASH THOROUGHLY

RINSE

DRY

Hand-washing technique

Preparation

- Remove hand and wrist jewellery (wedding band allowed).
- Wet hands thoroughly under warm running water.
- Apply 5mls of soap to cupped hand by pressing dispenser with heel of hand.

Hand washing

- Rub palm to palm 5 times.
- Rub right palm over the back of the left hand up to wrist level 5 times. Do the same with the other hand.
- With right hand over the back of left hand, rub the fingers 5 times. Do the same with the other hand.
- Rub palm to palm with fingers interlaced.
- Wash thumbs of each hand separately, using a rotating movement.
- Rub the tips of the fingers against the opposite palm using a circular motion.
- Rinse hands thoroughly under running water to remove all traces of soap.
- Turn off taps using elbows or foot pedal.

Dry hands completely using paper towel or air-dryer.

Discard paper towel in waste bin, opening with foot to avoid hand contamination.

6.0 Preventive and Protective Measures cont'd

6.4 Individual Protection Measures

6.4.1 Personal Protective Equipment (PPE) – General

PPE is used as a last line of defence in the control hierarchy of biological agent exposure, where exposure cannot be avoided by other means (e.g. engineering controls). It can also be used as a secondary support to and back-up of engineering control in case of unforeseen failure of engineering control.

PPE should be fit for purpose and suitable for the person using/wearing it, with donning and removing carried out appropriately each time of use.

PPE should be located close to the point of use and stored in a clean and dry storage area to ensure that it is not contaminated prior to use.

PPE should not be a source of further contamination e.g. by being removed inappropriately or left on contaminated surfaces.

PPE should be for personal use, not shared, and should be provided free of charge to the employee.

Tight-fitting negative respirators should be fit-tested.

All PPE should comply with Harmonised European Standards for PPE and carry the CE mark.

All PPE provided should be compatible with each other.

Written information and protocols for PPE use should be available in relevant languages, where appropriate.

Face or eye protection such as goggles or face shields should be considered where there is a risk of contamination of the eyes or mucosal membranes by splashes and droplets. They should be well fitting and fit for purpose. Comfortable protection is important to ensure adequate protection.

The employer shall ensure that any personal protective equipment provided (see Regulation 62 of the Safety, Health and Welfare at Work (General Application) Regulations, 2007) is maintained in good working order and in a satisfactory hygienic condition at all times by means of any necessary storage, maintenance, repair or replacement.

Wash hands immediately after the removal or disposal of face protection.

6.4.2 Gloves

All glove selection must be preceded by risk assessment. The main concerns are what glove type to wear and how to don and remove gloves safely to prevent cross contamination. Where there is a risk of exposure to potentially infectious material, disposable gloves should be worn. Non sterile vinyl/nitrile/synthetic gloves may be used or, where sterility is an issue, sterile nitrile/neoprene or other equivalent gloves may be used. Gloves must be appropriate for use, fit for purpose and well-fitting to avoid interference with dexterity. They should not cause friction, excessive sweating, finger and hand muscle fatigue or tear easily. The supply and choice of the correct size of glove is important. All gloves should be CE marked for use with biological agents. The use of gauntlet-style (long arm) gloves to cover the forearm may be necessary in certain situations and should be considered within risk-assessment procedures.

A double-gloving strategy may be considered in particularly high-risk situations. This allows for removal and replacement of the outer gloves, if contaminated, while still retaining skin protection.

Gloves should be the last piece of PPE to be donned. At containment levels 3 and 4, gloves should be pulled over the wrists of the gown rather than worn inside.

6.4.3 Protective Clothing

Personal Protective Clothing should be worn as identified through the risk assessment.

There are various types: laboratory coats, aprons/gowns, sleeve protectors or full body suits and footwear, depending on the type of protection required from the risk assessment. Protective clothing must not be worn outside the immediate work area (i.e. the laboratory).

In laboratories, the amount of protective clothing varies according to the hazard or protection levels required in the lab (1–4) identified from the risk assessment.

6.0 Preventive and Protective Measures cont'd

For biosafety level 1, laboratory coats such as Howie coats (cross over at front, closed up to neck, elasticated wrists), gowns or uniforms to prevent contamination of personal clothing should be worn. Laundering should be controlled and organised by employer so as to prevent any risk to non-involved employees.

Additionally, face or eye protection may be required when performing procedures that have the potential to create splashes.

Level 2: At this containment level, laboratory coats must have long sleeves with elastic cuffing (Howie coats). There should be no skin exposed between gloves and the sleeve, and the coats should only be worn within the laboratory area.

Level 3: Laboratory clothing should only be worn within the lab. Solid front gowns or coats must be worn for this safety level, with back closures, close-fitting cuffs and quick-release studs or Velcro fastenings to provide better protection. The coats should be autoclaved before laundering or disposal, and head covers and dedicated footwear that can be sterilised should be worn, depending on the infectious biological agents in use.

Level 4: One-piece, positive pressure-ventilated impervious suits can be worn.

6.4.4 Respiratory Protection

The biological safety cabinet is used to contain potential aerosols where there is a risk of respiratory exposure.

Bio-aerosol particle size, the airborne agent concentration and the type of biological agent are the main decision criteria when choosing respiratory protective equipment (RPE). If such information is unknown, then an air-supplied breathing apparatus would be recommended, or an FFP3 respirator should be considered prudent until data are available that allow better assessment of the risk associated with different procedures/circumstances. An FFP2 disposable particulate/filtering half-face piece respirator is the minimum level of protection needed for airborne infectious agents (if particle size is >0.3µm in diameter). However they are not effective against high concentrations of pathogens.

- Fitting a respirator correctly is critically important for it to provide proper protection.
- Every user should be fit tested and trained in the correct use of the respirator.
- A fit check should be carried out each time a respirator is worn by the individual wearer.

See Annex E of IS EN 529:2005, Respiratory Protective Devices – Recommendations for Selection, Use, Care and Maintenance.

Various respirator types:

See the HSA publication: A Guide to Respiratory Protective Equipment

6.4.5 Donning and Removing Personal Protective Equipment

Donning PPE

Wash hands (see section 6.3) before donning personal protective equipment.

Apron

Pull over head and fasten at back of waist.

Coat/gown

Fully cover torso from neck to knees, and arms to end of wrist. Tie up coat fully. Wrap gown around the back. Fasten at the back.

Respirator (surgical mask)

Secure ties correctly (middle of head and neck if appropriate). Fit test.

Eye protection (goggles/face shield)

Place over face and eyes and adjust to fit.

Gloves

Select according to hand size and fully extend to cover wrist.

6.0 Preventive and Protective Measures cont'd

Removing PPE

Gloves

Grasp the outside of the glove with the opposite gloved hand and peel off. Hold the removed glove in gloved hand and slide the fingers of the un-gloved hand under the remaining groove at the wrist. Peel the second glove off over the first glove and discard appropriately.

Wash hands (see section 6.3) before removing gloves and other personal protective equipment, as appropriate. (Additional sentence).

Apron

Apron front may be contaminated. Break or unfasten ties and handle from inside only. Fold or roll and discard appropriately.

Coat/gown

Remove coat and fold gently. Discard into waste or liner receptacle. Remove gown using a peeling motion so that gown is inside out. Roll into bundle and dispose into waste or liner receptacle.

Eye protection

Handle only by the head band or the sides. Place in designated receptacle for reprocessing or appropriate waste bin.

Respirator (surgical mask)

Unfasten at ties. Pull away from face without touching front of respirator/ mask and discard appropriately.

6.5. Containment Levels

6.5.1 Containment

Containment can be viewed as primary and secondary containment. Primary containment uses controls to isolate the hazard at the source. For example, biological safety cabinets, sealed tubes/flasks and sealed centrifuge rotors.

Secondary containment is achieved by the facility and the applicable procedures which are designed to protect the environment and people outside. The facility should be a secure, enclosed location with effective procedures to prevent micro-organisms escaping into the environment.

The Code of Practice specifies three containment levels which correspond to hazard groups 2, 3 and 4 (see Section 2.0).

As biological agents of hazard group 1 involve little or no hazard to employees, no special design features beyond those suitable for a well-designed and functional laboratory are required. Biological safety cabinets are not required. Work may be done on an open bench top and containment is achieved through the use of practices normally employed in a basic microbiology laboratory – Good Microbiological Practice.

Good Microbiological Practice (GMP) has three very important objectives: (1) the prevention of contamination of employees; (2) the prevention of contamination of the laboratory by organisms being handled; and (3) the prevention of contamination of the work with organisms from the environment. The principles of GMP should apply to all types of work involving micro-organisms, regardless of containment level.

Aseptic technique is based on creating a special micro-environment in which to work with the micro-organism of interest and prevent all other contact.

- All equipment must be kept sterile.
- During work, care must be taken to avoid cross-contamination.
- Minimise the risk of aerosols from pipetting, vortexing, pouring and spillages.
- The work area or laboratory should be kept clean and tidy at all times and only the equipment required should be on the bench or in the cabinet.
- The work area or laboratory should be cleaned regularly. Benches and cabinets should be wiped down with disinfectant after the use of infectious substances. Sample storage in fridges/freezers should be kept to a minimum.

6.0 Preventive and Protective Measures cont'd

- There should be designated areas for storage.
- All employees within the work area or laboratory should be fully aware of the systems so there are no misunderstandings.

Good Microbiological Practice would include:

- A work area or laboratory that is easy to clean.
- Bench surfaces impervious to water and resistant to chemicals.
- Sink for hand washing.
- Inward flow of air into laboratory to be maintained.
- Door to be closed while work is in progress.
- Laboratory coats to be worn in the lab and removed before leaving the laboratory.
- Eating, chewing, drinking, smoking, storing food, applying cosmetics and mouth pipetting are forbidden.
- Hands must be disinfected and washed as appropriate.
- Aerosol production must be minimised.
- Effective disinfectants must be available.
- Bench tops must be cleaned after use.
- Used equipment awaiting sterilisation must be stored safely. Pipettes in disinfectant must be totally immersed.
- Waste material must either be incinerated or rendered non-viable before disposal. It must be transported in robust containers without spillage.
- Accidents and incidents must be reported.

Level 2:

Biological agents of hazard group 2 may cause infectious diseases in humans.

Agents requiring containment level 2 facilities are not usually transmitted by airborne routes.

Care must be taken to avoid the generation of aerosols or splashes, as these can settle onto bench tops and become an ingestion hazard through contamination of the hands. Containment devices such as biological safety cabinets and centrifuges with sealed rotors or safety cups should be used as well as appropriate personal protective equipment. Environmental contamination must be minimised by the use of hand-washing sinks and decontamination facilities (such as autoclaves).

For specific containment measure requirements, refer to Schedules 2 and/or 3 of the Biological Agents Code of Practice.

Level 3:

Containment measures at this level are intended to prevent any escape of biological agents and any employee exposure. These biological agents may be transmitted by the airborne route, they

frequently have a low infectious dose to produce effects and can cause serious or life-threatening disease. This containment level emphasises additional primary and secondary barriers to minimise the release of infectious organisms into the laboratory and the environment. Additional features to prevent transmission of such organisms are suitable respiratory protection, high-efficiency particulate air (HEPA) filtration of exhausted laboratory air and strictly controlled laboratory access. For specific containment measures or requirements, refer to Schedules 2 and/or 3 of the Biological Agents Code of Practice.

Level 4

The containment measures at this level are intended to consistently prevent the escape of biological agents since these represent a serious hazard to employees, third parties and the environment in terms of the risk of catching a life-threatening, untreatable, infectious disease. This is the highest containment level, as these biological agents have the potential for aerosol transmission, they often have a low infectious dose and produce very serious and often fatal disease and there is generally no treatment or vaccine available. This containment level consists of an isolated unit, functionally and when necessary structurally independent of other areas. This containment level emphasises maximum containment of the infectious agent by complete sealing of the facility perimeter (with confirmation by pressure-decay testing). It can be achieved with either: variation (a) isolation of the researcher from the pathogen by containment in a positive pressure suit; or variation (b) containment of the pathogen in a class III biological safety cabinet line and decontamination of air and other effluents produced in the facility. For specific requirements regarding containment measures, refer to Schedules 2 and/or 3 of the Code of Practice.

6.5.2 Biological safety cabinets

A biological safety cabinet (BSC) is a tool in the laboratory for those who work with biological agents, including pathogenic micro-organisms (also including genetically modified micro-organisms), cell cultures and human and animal tissues and fluids. The BSC provides a primary barrier to protect the laboratory employee against the risk of hazardous aerosols if used with Good Microbiological Practice.

There are four major components that contribute to ensuring safe working with BSCs:

- the design, construction and function of the cabinet itself
- good laboratory design (specifically with respect to cabinet location and room ventilation)
- safe systems of work that incorporate good operational technique

6.0 Preventive and Protective Measures cont'd

- regular appropriate testing and maintenance

The European Standard on Microbiological Safety Cabinets defines a cabinet as a:

'Ventilated enclosure intended to offer protection to the user and the environment from the aerosols arising from the handling of potentially hazardous and hazardous micro-organisms, with air discharged to the atmosphere being filtered.'

Good Microbiological Practice should always be performed when using a Class I or II biological safety cabinet. Gloves should be changed regularly and slow controlled movements within the cabinet should be used to reduce the disruption of airflow. Use of double gloves and arm protection may be appropriate.

See Appendix 6 for further information on biological safety cabinets.

6.5.3 Autoclaves

There are several different types of hazard associated with the use of autoclaves, for example high pressures and temperatures and the loading/unloading process. Important factors that should be taken into account in the risk assessments and controls to be implemented are:

Selection

The relevant Irish standard covering the use of autoclaves in laboratories is IS EN 12347:1998 Biotechnology – Performance Criteria for Steam Sterilisers and Autoclaves. When purchasing autoclaves or arranging maintenance work, one should confirm that the autoclave complies with the Irish Standard Specifications. The requirement for any additional controls on the exhaust for autoclaves in containment level 3 areas should be determined through risk assessment. All autoclaves should be CE marked.

Safe access

For loading and unloading, is essential that the door safety devices should function to securely fasten the door shut while it is subjected to internal pressure, thereby preventing the risk of the door being violently blown open. The device should ensure that the vessel cannot be pressurised until the door is securely closed. It should not be possible to open the door until the internal pressure has been fully vented to atmospheric pressure. The door should be restrained for the first part of its travel until the

seal has been broken.

Operation

It is recommended that microbiologically contaminated materials are disinfected before disposal. It is also best practice to disinfect before autoclaving materials to make sure that there is no chance of any infectious materials escaping into the environment.

An autoclave cycle generally consists of an air-removal step-and-steam injection so that a temperature of 121oC or higher at 15 pascals can be maintained for 15–20 minutes.

Steam sterilisation is the best method for making infectious materials safe. Steam sterilisation is effected by: air removal, steam penetration, presence of moisture and heat penetration.

Air removal is important as air pockets will stop the penetration of steam into the required areas. Trapped air can occur in any closed objects and reduce the effectiveness of the autoclaving process.

Note: See Appendix 7 for autoclave checklists.

6.5.4 Centrifuges

There are several hazards associated with the use of centrifuges, e.g. rotating parts, sample imbalance causing machine movement and sample leaks. Only trained personnel should operate centrifuges. It is important never to overload centrifuges and to balance the rotor properly at all times before operating.

See I.S. EN 12547 Centrifuges – Common Safety Requirements, for further information.

Fridges, freezers incubators

Consider the need to monitor fridge, freezer and incubator temperatures. Is an audible alarm necessary? Can they be locked? Ensure contents are secure, and that there is no spillage or leakage.

6.5.5 Disinfection, Sanitisation and Fumigation

Control of biological agents can occur through physical or chemical means. Physical methods include heat (either moist heat involving pressurisation or dry heat) and radiation. Chemical methods can use liquid, gaseous or solid states and vary from disinfectants and antiseptics to sterilants. Certain agents

6.0 Preventive and Protective Measures cont'd

are more difficult to deal with due to their inherent microbial resistance or ability to form bacterial spores which protect them from harsh chemicals.

- A **germicide** is any physical or chemical agent that kills micro-organisms.
- **Disinfection** is the destruction of biological agents to levels such that any infection hazard is removed and the disinfected object is safe to handle.
- **Sterilisation** is the destruction of all viable biological agents present.
- **Sanitisation** is any cleansing technique that mechanically removes micro-organisms to reduce the number of micro-organisms, e.g. soap or detergent.

Several factors affect the germicidal activity of chemicals, the nature of the micro-organism, the nature of the material being treated, the degree of contamination, the time of exposure and the strength and chemical action of the germicide. Several different groups of chemicals are used for antimicrobial purposes, including halogens, heavy metals, alcohols, phenols, oxidisers and aldehydes. Due to varying properties, each has different uses and limitations.

It is essential to select the most suitable disinfectant and use it in accordance with the manufacturer's instructions. Information on the effectiveness, use, storage, compatibility and safe handling of a disinfectant should be obtained from the supplier (see BS 7152:1991 *Choice of Chemical Disinfectants* for further information).

Employers should carry out a risk assessment on the use of all chemical disinfectants to determine the particular precautions required for each.

The European Parliament And The Council Of The European Union have adopted REGULATION (EU) No 528/2012 concerning the making available on the market and use of biocidal products. The objective of the regulation is to improve the functioning of the internal market in biocidal products, while maintaining the high level of the environmental and human health protection.

Fumigation

Fumigation is a potentially hazardous process involving the release of toxic gases into the atmosphere to kill biological agents. Because of the potential hazardous nature of the fumigation process, strict controls, similar to a work-permit system, must be put in place and documented in a standard operating procedure (SOP) to ensure the protection of employees and the work environment. The SOP should include precise details on how the fumigation is conducted, the measures necessary to protect employees' health and safety and who is responsible for the activity.

The work area, including the room ventilation, must be capable of being sealed for the purpose of fumigation and warning signs posted.

Commonly used fumigants are: formaldehyde, hydrogen cyanide, hydrogen peroxide, methyl bromide and phosphine, for example.

Before any fumigant is released in an area ensure it is clear of people, non-target animals and plants, and ensure non-authorised personnel cannot gain access until the area has been vented and declared safe. The fumigation area is always sealed from other areas and made as gas tight as possible.

Nobody should enter during fumigation except in a major emergency.

During fumigation, one should restrict the amount of the fumigant used to the minimum necessary to effectively and safely carry out the fumigation. The fumigation area should be checked for leaks using a suitable atmospheric monitoring device. If leaks are detected, they must be dealt with by the individual in charge of the fumigation who is wearing suitable respiratory protective equipment (RPE). If it is not possible to seal the leak, the fumigation and risk area must be extended.

The fumigation and risk areas should be ventilated at the end of the fumigation period.

When all areas have been shown to be safe for reoccupation, barriers or warning signs can then be removed.

Note: See also Appendix 5 on Fumigation.

6.6 Special Measures

6.6.1 Veterinary Care

Employees in veterinary practices, or those working with research animals, are at risk of infection by a variety of zoonoses, e.g. brucellosis, leptospirosis, Q fever. Through a variety of mechanisms, such as direct skin contact, inhalation of aerosols, contact with bodily fluids, animal waste, needle-stick injuries, bites or scratches, vets and veterinary nurses are at risk.

Particular attention must be made to the provision of adequate written risk assessments (see Section 6.1 of these guidelines), identification of control measures and good hygiene practices (see Section 6.3 of these guidelines) to prevent the spread of infection. Infection-control policies, along with specified decontamination and disinfection procedures, should be implemented to enable appropriate waste disposal (see Royal College of Veterinary Surgeons (RCVS) Practice Standards Scheme Manual for guidance available from the RCVS website: http://www.rcvs.org.uk).

Where animals are suspected of being infected with a group 3 or 4 biological agent, appropriate containment measures must be applied at the place of work (see Schedule 2 and 3 of the Code of

6.0 Preventive and Protective Measures cont'd

Practice for minimum containment measures).

Employees must receive appropriate information, instruction and training about the risks and how the risks will be controlled.

6.6.2 Laboratories, Industrial Processes and Animal Rooms

Industrial processes such as fermentation systems using biological agents or laboratory animals infected with or suspected to be carriers of such biological agents will require minimum containment measures as specified in Schedules 2 and 3 of the Biological Agents Code of Practice.

Particular attention must be made to the provision of adequate written risk assessments (see Section 6.1 of these guidelines), and identification of control measure and good hygiene practices (see Section 6.3 of these guidelines) to prevent the spread of infection (see Advisory Committee on Dangerous Pathogens (ADCP) UK guidance on 'Working Safely with Research Animals' and 'Biological Agents – Managing the risks in laboratories and healthcare premises' for further information).

6.7 Vaccination

The risks of working with particular biological agents should be fully discussed with individual employees. The availability of possible vaccines or toxoids and/or therapeutic drugs (e.g. antibiotic treatments) in case of exposure should be evaluated through risk assessment before any work with such biological agents is started.

If the risk assessment reveals that there is a risk to the health and safety of employees due to their exposure to a biological agent for which effective vaccines exist, the employer should offer them vaccination. The use of vaccines may provide an increased level of personal protection e.g. hepatitis B vaccine for occupational first aiders.

The availability of a vaccine for some biological agents is indicated in the notes column of Schedule 1 of the relevant Code of Practice (V: Effective vaccine available). Approximately 30 biological agents are so indicated.

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). This publication is available to download from the RCPI website (www.rcpi.ie). It includes further detailed guidance on routes of administration, contra-indications, etc. for

different vaccines for use by medical practitioners.

Vaccinations are carried out by or under the supervision of the responsible medical practitioner in accordance with NIAC recommendations for the routine administration of vaccines, and schedules regarding the appropriate frequency, dosage, and contra-indications.

Employees should be informed of the benefits and drawbacks of both vaccination and non-vaccination. Vaccinations must be offered free of charge to employees

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

6.8 Health Surveillance

It is the employer's duty to make provisions for relevant health surveillance to be made available for those employees for whom the results of any risk assessment identifies a risk to their safety, health or welfare. Such health surveillance, where appropriate, must be made available prior to exposure to the biological agent(s) and at regular intervals thereafter.

Health surveillance is appropriate if:

- the exposure is such that an identifiable disease or adverse health effect may be related to it
- there is reasonable likelihood that the disease or effect may occur under particular conditions of work
- there are valid techniques for detecting indications of the disease or effect

Individual records of health surveillance must be kept and be made available, on request, to the employee concerned.

Where appropriate, the responsible medical practitioner carrying out health surveillance should be familiar with the exposure conditions or circumstances of each employee.

Health surveillance of employees must be carried out in accordance with the principles and practices of occupational medicine. At a minimum, it must include at least the following measures:

- the keeping of records of an employee's medical and occupational history
- a personalised assessment of the employee's state of health

6.0 Preventive and Protective Measures cont'd

- where appropriate, biological monitoring in order to detect early and reversible effects

Further tests may be decided upon for each employee, when he or she is the subject of health surveillance, in light of the most recent knowledge available to occupational medicine, on the advice of the responsible registered medical practitioner.

The employer is required to retain individual health records for an 'appropriate' time, usually between 10 to 40 years, depending on the length of time of exposure and/or the likely duration of risk to the safety and health of the employee due to exposure.

It may take several years for the results of exposure to some biological agents to develop and an individual can remain asymptomatic during that time. Health surveillance is not a substitute for adequately controlling exposure, and health surveillance for certain biological risks may not be appropriate, e.g. it is not usually required for group 2 biological agents.

An example of health surveillance specifically for biological employees is the testing of immunity following vaccination, which could provide an indication of their fitness to work with that particular agent. Other testing or taking of samples may not be necessary for surveillance except in the event of an accident or if there is an indication that infection may have occurred, for example following a needle-stick injury.

Ideally, health surveillance will measure the outcomes of abnormal exposures before any real risk of ill-health occurs. Sometimes however, health surveillance can only identify problems after they have occurred (e.g. allergic sensitisation) but before complications arise or intensify (e.g. occupational asthma). The level of health surveillance should be related to the degree of risk as determined in the risk assessment.

6.9 Emergency Plans

Preparing for and practising appropriate responses for possible emergencies are critical for effectively dealing with such an event.

When completing the site risk assessment, possible emergency scenarios must be identified and then appropriate plans put in place to prevent or mitigate the potential of such emergencies. The site's emergency plan is a product of the risk assessment and the biological agent emergency plan must be an element of the site's overall emergency plan.

In preparing the biological agents emergency plan, the following steps should be considered:

Steps	Stages
1. Identify potential emergency situations.	Risk-assessment stage
2. Establish prevention and mitigation measures.	
3. Establish an emergency-response procedure.	Emergency planning and response stage
4. Review and test the emergency preparedness and response plan.	

Identify potential emergency situations

- What events might lead to an emergency?

  Potential exposures include exposure through containment or barrier failure:

  - aerosol release
  - needle-stick/sharps injury
  - spills
  - biological safety cabinet failure
  - ventilation failure
  - loss of services (power, water etc.)
  - other emergencies (such as fire, severe weather etc.)
- What activities, operations and equipment might be affected?
- What would be the likely health effects to employees and other persons?

6.0 Preventive and Protective Measures cont'd

Establish prevention and mitigation measures

- How could the emergency be prevented or the probability of occurrence reduced?
- How can the impacts of the emergency be mitigated?
    - Is an antidote, prophylaxis or effective treatment available that can be administered in a timely way?
    - Can infection be contained?
    - Have emergency treatment measures been developed and available?

Establish an emergency-response procedure

- The Safety, Health and Welfare at Work Act, 2005 sets down, in section 11, explicit requirements for dealing with all emergencies and serious and imminent dangers. It provides for the measures to be taken in emergencies, and, in the case of serious and imminent danger, in support of the general duties on employers in section 8 of the Act. The measures must be appropriate to the place of work and cover:
    - ▲ first aid
    - ▲ fire-fighting
    - ▲ the evacuation of employees and others present in the workplace
    - ▲ contact with the appropriate emergency services with regard to first aid, emergency medical care, fire-fighting and rescue arrangements
    - ▲ the designation of employees to implement the emergency plan, emergency procedures or necessary measures, and
    - ▲ the number of those designated employees, the training provided to them and the appropriate equipment available to them

- When an emergency or serious and imminent danger occurs:
    - ▲ The employer must, as soon as possible, inform all employees about the risk and the protective measures to be taken.
    - ▲ Other than to implement the emergency plan or procedures, or to instigate necessary measures to be taken, employees should not be required to continue or resume work while the serious and imminent danger continues.
    - ▲ Employees must be made aware of the circumstances in which they are expected to

stop work and move to a place of safety.

- ▲ Employees must be able to take appropriate steps to avoid the consequences of the danger in the absence of appropriate guidance or instruction and where their immediate superiors cannot be contacted. These steps should be based on their own knowledge and on the technical means at their disposal.
- ▲ Particular consideration needs to be given to ensuring that the necessary arrangements are in place for contacting the appropriate emergency services outside of normal working hours (e.g. during shift- and night-time work).
- ▲ The employer must take action and instruct employees so that they can stop work and/or immediately leave the place of work and go to a safe place. An employee may not be penalised for taking such action.

- Where there is a serious specific danger present in part of the place of work, the employer must ensure that only employees who have been given appropriate instructions have access to that area. A danger area may be taken to mean a location at the place of work where an unacceptable level of risk would be present if special precautions were not taken (for example, giving permits to work to competent employees or the wearing of breathing apparatuses).

- To comply with the legal requirements and ensure the specific biological agent safety requirements are met, a written plan should be prepared which can include instructions for dealing with specific biological agent safety scenarios for the particular workplace and relevant mitigation and recovery measures (e.g. equipment – plan failure control to contain and prevent exposure. Consider safe emergency shut-down and make available appropriate medical surveillance or clinical management of exposed persons).

- Procedures for post-incident continuation of operations should be prepared.
- Train employees at the commencement of employment and at appropriate regular intervals in the proper responses to credible scenarios.

6.0 Preventive and Protective Measures cont'd

Review and test the emergency preparedness and response plan

- Test the plan by holding regular drills and simulations.
- Review and revise the plan to reflect: (1) changing situations; and (2) lessons learned during drills and simulations.
- Review and take appropriate action following any near-miss incidents.

For further guidance see:

Emergency planning on the Health and Safety Authority's website, www.hsa.ie

and the Laboratory Biosafety Manual, published by the World Health Organization.

Healthcare work activities

Exposure to biological agents may be intentional as a result of working with the biological agent itself (e.g. in a microbiology laboratory) or unintentional (e.g. in healthcare activities where the exposure does not result from the work itself but is incidental to the work activity). Healthcare employees may come into contact with a number of sources of infection, either through direct contact with patients or with contaminated materials, including waste, laundry, contaminated surfaces, etc. Sources of infection may include blood and bodily fluids and body parts; excreta – faeces, urine and vomit; respiratory secretions and excretions.

Particular attention must be given to the provision of adequate written risk assessments (see Section 6.1 of these guidelines) and identification and implementation of control measures.

Exposure controls are often reflected in infection-control policies. Infection-control policies may include protocols on hand washing, patient isolation, aseptic procedures, disinfection and decontamination, including domestic cleaning and waste-disposal procedures. Their aim is to prevent the spread of infection and the measures protect the patient and the employee. The process of risk assessment is an integral part of managing the control of infection and the control measures required by health and safety legislation should already largely be in place as part of infection-control or related policies.

Standard precautions

Standard precautions are evidence-based clinical work practices published by the Centre of Disease Control (CDC) in 1996 and updated in 2007 that prevent transmission of infectious agents in healthcare settings.

Within a healthcare setting, both patients and healthcare staff are at risk of acquiring an infection. The purpose of the implementation of standard precautions is to minimise the transmission of infection within the healthcare environment for all who may be at risk.

Standard precautions require all healthcare employees to:

(a) Assume that every person is potentially infected or colonised with an organism that could be transmitted in the healthcare setting.

(b) Apply a set of work practices to blood, all bodily fluids except sweat, mucous membranes and non-intact skin. These work practices should include:

- hand hygiene

7.0 Biological Agents in the Healthcare Sector cont'd

- use of personal protective equipment
- management of spillages of blood and bodily fluids
- appropriate patient placement
- management of sharps
- safe injection practices
- respiratory hygiene and cough etiquette
- management of needle-stick injuries
- management of waste
- management of laundry
- decontamination of reusable medical equipment
- decontamination of the environment

For further information relating to standard precautions, refer to the Health Protection Surveillance Centre website, www.hpsc.ie

Vaccination

see also Section 6.7 Vaccination

The Immunisation Guidelines for Ireland issued by the National Immunisation Advisory Committee of the Royal College of Physicians in Ireland refers specifically to the immunisation of healthcare employees and others in at-risk occupations.

A risk assessment should be carried out to determine which, if any, vaccinations are recommended for employees. Decisions about vaccinations recommended should be based on the duties of the individual rather than on the job title alone.

Healthcare waste

see also Section 8 Waste Management

The Department of Health and Children's Guidelines for Segregation, Packaging and Storage of Healthcare Risk Waste, 2010 offers guidance for a uniform system for the segregation and packaging of clinical/healthcare risk waste generated in the provision of patient care in the Republic of Ireland.

It attempts to bring together good practice principles and the various regulatory requirements relating to waste generation and management, but it does not purport to be a legal interpretation of such regulations.

This guideline is intended to encompass the vast majority of waste generated in the provision of patient care. Wastes contaminated with high-risk biological agents – risk group 4 – are outside the scope of the guidelines. Expert advice should be sought from specialists in clinical microbiology and/or infection control in the rare event of having to deal with such material.

Healthcare waste is the solid or liquid waste arising from healthcare. The first level of segregation of the waste is into healthcare risk waste (HCRW) and healthcare non-risk waste.

The second level of segregation is between fractions within the healthcare risk waste stream (HCRW) which have distinctly different properties. Segregation of healthcare risk waste in the first instance should be based on the packaging requirements appropriate to safe containment of the waste and thereafter the packaging can be distinguished by different means, e.g. colour-coding which allows streaming of the waste in accordance with the intended disposal method.

See the Department of Health and Children's website (www.dohc.ie) publications section to view the full document.

8.0 Waste Management

Not only must care be taken when working with biological agents, but also when managing the resulting waste. The waste must be collected in appropriate containers and treated before disposal. How the waste is treated depends upon the characteristics of the waste (i.e. solid, liquid, mix) and the associated risk of the biological agent. The means of treatment for decontamination may involve chemical agents (e.g. bleach, ethanol) or physical means (e.g. autoclaving, incineration). Attention must be applied to ensure personal safety and that of others, as once treated this material will be directed into the public domain. The legislation regarding the transport of dangerous goods by road (ADR) will be applicable if road transport of biological waste is involved. Consequently, there are other bodies which are concerned and regulate or set requirements regarding this waste (e.g. the Environmental Protection Agency and Local Authorities).

Decontamination of biological waste most commonly occurs through the use of pressure-steam sterilisers (autoclaves) or the use of chemical disinfectants (e.g. alcohols, iodine or chlorine solutions). Chemical disinfectants have a range of properties and no single disinfectant is effective in all situations. Micro-organisms vary in their resistance to chemical disinfectants. To choose an appropriate chemical disinfectant, one should bear in mind the identity and concentration of micro-organisms present and the degree of inactivation required. Spores and prions tend to be very resistant to chemical disinfection.

Biological waste should be clearly labelled with a biohazard label so as to enable safe collection and disposal (see figure 1), There are strict requirements in place for the transportation of such waste through the ADR legislation.

Figure 1: Biohazard sign

The use or exposure to sharps (i.e. items capable of cutting or piercing the skin) is common in a variety of workplaces for different reasons. An object may be defined as a sharp due to its design (i.e. needles, scalpel blades) or as a result of damage (i.e., broken test tubes or microscope slides). Sharps in any form should be considered potentially dangerous and must be handled and disposed of with caution. Additional risk may be present should the object be contaminated with an infectious agent or other hazardous material.

Biologically contaminated needle and blade waste should be collected for disposal in a suitable needle and blade waste container, see figure 2 below for some examples.

Figure 2 – Examples of Sharps Disposal Containers

These filled, closed containers can be autoclaved along with other biological waste. Steam sterilisation is generally not recommended for waste contaminated with or containing a combination or mixture of viable biological agents and significant amounts of hazardous chemical or radioactive materials. These situations should be handled on a case-by-case basis.

9.0 Notification and Information to the Authority

9.1 Notification and Information Required by the Authority

Notifications under points 9.1.1 to 9.1.4 can be made electronically on the Health and Safety Authority's website using the format outlined in Appendix 4. (See Publications and Forms on the website at www.hsa.ie).

All notifications should be submitted to the Health and Safety Authority at least 30 working days prior to commencing work. If the form is completed online, it can be sent by email to the Health and Safety Authority.

Note that the definition of a biological agent includes those which have been genetically modified and, while the use of genetically modified micro-organisms (GMMs) is within the remit of the Environmental Protection Agency (EPA), the Biological Agents Regulations and related Code of Practice apply to genetically modified micro-organisms.

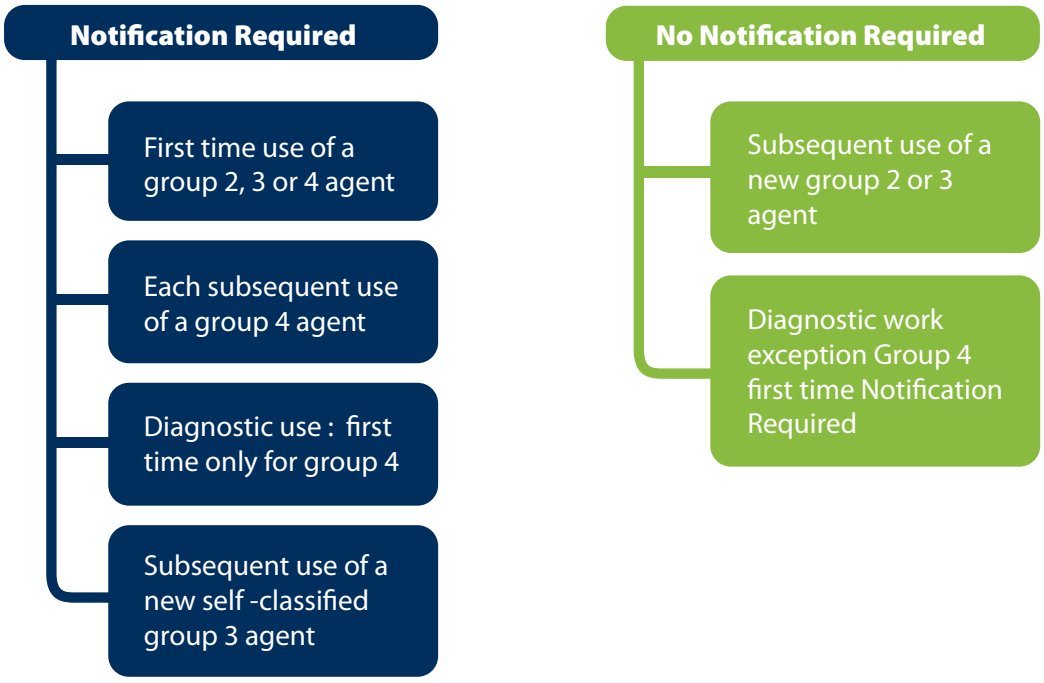


Figure 1: The Notification Process

9.1.1 First use

Notification is required for the first use of any biological agents classified as groups 2, 3 or 4 biological agents (as listed in Schedule 1 of the Code of Practice) at particular premises. This means the first time that deliberate work with a particular group 2, 3 or 4 biological agent has ever been carried out at the place of work.

Use can include carrying out activities such as propagation or concentration of a biological agent (e.g. in microbiology laboratories, if a biological agent is obtained to lodge in a culture collection, that collection will need to be maintained. Deliberate work with the biological agent would ensue (e.g. growing or culturing the biological agent to check for viability or for quality-control purposes) and so there is a notification requirement.

9.1.2 Subsequent use

Any subsequent use of any new self-classified group 3 biological agent and all new group 4 biological agents, i.e. another strain of the biological agent, or where the risk of infection is different to that expected for the biological agent previously notified, requires notification to the Authority of this biological agent.

9.1.3 Diagnostic work

Diagnostic work in laboratories will involve working with specimens that are likely to contain biological agents. Provided the work undertaken does not involve deliberate propagation or concentration of the biological agent, then there is no requirement to notify for either first use or any subsequent use of the biological agent.

However, if the employer does provide a diagnostic service for a group 4 biological agent, there is a requirement to notify the Health and Safety Authority in advance of carrying out the work for the first time.

Employers who provide a purely diagnostic service for group 2 and 3 biological agents only and, where there is no propagation of the biological agent, are exempted from the notification requirements.

9.0 Notification and Information to the Authority cont'd

9.1.4 Self-classification

If the biological agent being worked with does not appear in Schedule 1 of the Code of Practice, the employer must classify the agent themselves. The employer shall classify that biological agent in one of the groups according to its level of risk of infection as defined in the Code of Practice. If there is any doubt as to which of the two groups to assign the biological agent, he or she must assign it to the higher of the two groups. If the biological agent subsequently appears in a later edition of the Code of Practice, the classification given to it in that edition takes priority. If the agent is classified as being in either hazard group 2, 3 or 4, then work with the agent will need to be notified to the Authority. However, if notification of a group 2 agent has already occurred, then there is no requirement to notify for a subsequent self-classified group 2 agent(s).

9.1.5 Risk assessments and preventive measures sections

Sufficient information must be written in this section to demonstrate that you have identified the hazards associated with this biological agent appropriate to the work to be undertaken. The circumstances under which staff and others could potentially be exposed to a source of infection during the work should be identified and the containment facilities specified. It is not sufficient just to identify the hazard group of the organism and list the containment level used (see Section 6.1).

9.1.6 Accidents, incidents and dangerous occurrences

Where an incident, accident or dangerous occurrence has or may have resulted in the release of a biological agent which could cause severe human disease, as soon as practicable the employer must ensure that the details are reported to the Authority.

Accidents can be reported to the Health and Safety Authority in two ways, namely:

a. **by hard copy**, i.e. completing the Incident Report Form (IR1) or Dangerous Occurrence Form (IR3) and posting the completed form to the Workplace Contact Unit, Health and Safety Authority, The Metropolitan Building, James Joyce Street, Dublin 1; or

b. **online**, via the Health and Safety Authority's website, www.hsa.ie.

9.1.7 Employer ceases activity

The employer must deliver (1) the occupational exposure list and (2) the individual health records, as required by Regulation 15 of the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013, to the Authority (see section 9.0) where the undertaking is to cease activity.

Where an employer fails to deliver the above exposure list and health records, any person, who was at the time of the cessation, was a director of the undertaking or body corporate, is personally liable to ensure the records are delivered to the Authority.

9.2 Notification and Information Requested by the Authority

9.2.1 The employer must provide to the Authority, when requested, information used for carrying out any risk assessment under the Safety, Health and Welfare (Biological Agents) Regulations 2013 and also with the findings of the risk assessment.

9.2.2 Where a risk assessment reveals a risk to any employee's health or safety, the employer must provide the Authority, when requested, with appropriate information in writing relating to:

(i) the results of the risk assessment

(ii) the activities in which the employee has or may have been exposed

(iii) the number of employees exposed

(iv) the name and competencies of the persons responsible for health and safety

(v) the protective and preventative measures taken, including work procedures and methods; and

(vi) relevant emergency plans for the protection of the employees

9.2.3 The employer must provide employees or their representative (or both) at their request, with the information mentioned above in Section 9.2.2.

10.0 Occupational Exposure Lists

An employer must retain an occupational exposure list of employee(s) who may be exposed to a Group 3 or Group 4 biological agent(s). This requirement applies to the following group 2 agents: Human herpesvirus type 8 (HHV8), BK polyomavrus, JC polyomavirus,and Human papillomaviruses

An exposure record is required where there is a likelihood of exposure, not just when there has been a known incident or accident relating to a biological agent. The requirement to maintain a list for exposure to certain biological agents is specified with 'D' in the notes column of Schedule 1 of the relevant Code of Practice.

The rationale for keeping such records is to allow the management of the health and safety of exposed or potentially exposed employees. Many infections caused by group 3 or 4 biological agents will be acute and occur shortly after exposure, whereas others can cause illnesses such as cancer many years after exposure.

This list should describe the nature of the work being done by each employee and name the biological agent to which they may have been exposed. Relevant dates, duration and the amount and type of exposure (i.e. inhalation, ingestion, absorption or injection) should be recorded. Accidents and incidents should also be recorded on the list and, if necessary, also be sent on an IR1 form to the Health and Safety Authority.

The occupational exposure list for an employee(s) must be kept for at least 10 years following the employee's last exposure. However, the occupational exposure list should be kept up to 40 years if a biological agent has the potential to cause a persistent or latent infection, has a particularly long incubation period before illness develops or, in the light of present knowledge, is not diagnosable until illness later develops. Such biological agents include, for example, some hepatitis viruses, human immunodeficiency virus, human T-cell lymphotropic virus and unconventional biological agents associated with certain encephalopathies, e.g. prions.

There are currently no occupational exposure limit values (OELVs) set for biological agents, although some member states of the EU have set limits relating to the toxins which can be produced by certain biological agents, e.g. aflatoxins in the Netherlands. OELVs have not been set because one essential difference between biological agents and chemical agents is the ability of the biological agent to replicate. A small amount of a micro-organism may grow considerably in a very short time under favourable conditions and so the amount of an organism present does not remain constant.

Each employee should have access to the information on the list which relates to him or her personally. The safety representative should have access to collective information, on request, which does not identify any individual employees. The responsible medical practitioner and any inspector from the Health and Safety Authority should also have access to the list on request.

In the event of an employer ceasing to trade, an appropriate person (the employer or a former director of the undertaking (see 9.1.7) must inform the Health and Safety Authority that they are ceasing to trade and deposit the occupational exposure list and the related individual health records with the Authority.

11.0 References & Further Information

- A Review of the Regulatory Framework for Handling Animal Pathogens (O'Callaghan Report-UK DEFRA, 2007).
- Anthrax in Humans and Animals (WHO, 2008).
- Biological Agents – Managing the risks in laboratories and healthcare premises (ACDP, 2005).
- Biological Agents – The principles, design and operation of containment level 4 facilities (ACDP, HSE, 2006).
- Biorisk Management – Laboratory biosecurity guidance (WHO, 2006).
- Blood-borne Viruses in the Workplace – Guidance for employers and employees (HSE, UK).
- Brucellosis in Humans and Animals (WHO, 2006).
- BSE: Occupational Guidance (ACDP, 2007).
- Chronic Health Effects of Exposure to Biological Agents – A systemic literature review (HSE, 2002).
- Controlling the Risks of Infection at Work from Human Remains (HSE, 2005).
- Expert Forecast on Emerging Biological Risks Related to Occupational Safety and Health (EASHW, 2007).
- Guidance on Regulations for the Transportation of Infectious Substances 2007–2008 (WHO, 2007).
- Guideline for Hand Hygiene in Healthcare Settings: recommendations of the healthcare infection control practices advisory committee and the HICPAC/SHEA/APIC/IDSA hand hygiene task force. http://www.ncbi.nlm.nih.gov
- Hand Hygiene Guidelines Factsheet October 2002 (Centres for Disease Control and Prevention, USA) http://www.cdc.gov
- HSG61 – Health Surveillance at Work (HSE,1999).
- Infection at Work: Controlling the Risks – A guide for employers and the self-employed on identifying, controlling and assessing the risks of infection in the workplace. (ACDP, 2003).

- Infection Risks to New and Expectant mothers – Guide for employers (ACDP, 2005).
- Laboratory Biosafety Manual – 3rd Ed, (WHO, 2004).
- National Guidelines for the Control of Legionellosis in Ireland (HPSC, 2009).
- Personal Protective Equipment Policy & Procedure (Health Protection Scotland, 2009).
- Preparedness for the Deliberate Use of Biological Agents – A rational approach to the unthinkable (WHO, 2002).
- Preventing Asthma at Work – How to control respiratory sensitisers (HSE, 1994).
- Safe Working and the Prevention of Infection in Clinical Laboratories and Similar Facilities (HSE, 2003).
- Sealability of Microbiological Containment Level 3 and 4 Facilities (HSE, 2006).
- Technical Rules for Biological Agents (TRBA) 100 – Protective measures for specific and non-specific activities involving biological agents in laboratories (BauA, 2006).
- The Large-scale Contained Use of Biological Agents (ACDP, 1998).
- The Management, Design and Operation of Microbiological Containment Laboratories (ACDP, 2001).
- The Occupational Zoonoses (HSE, 1993).
- Working Safely with Research Animals: Management of infection risks (ACDP, 1997).
- Working Safely with Simians: Management of infection risks (ACDP, 1998).
- Working with Sewage: Health hazards – a guide for employees (INDG 197, HSE, 2004).

11.0 References & Further Information cont'd

Legal Obligations & Standards:

2013 Code of Practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations, 2013, S.I. No 572 of 2013.

British Standard EN 5726:2005 Microbiological Safety Cabinets – Information to be supplied by the purchaser to the vendor and to the installer, and siting and use of cabinets: recommendations and guidance.

Irish Standard CEN TR 15321 Guidelines on the Selection, use, care and maintenance of protective clothing.

Irish Standard E.N 12128: 1998 Biotechnology – Laboratories for Research, Development and Analysis – Containment levels of microbiology laboratories, areas of risk, localities and physical safety requirements.

Irish Standard EN 1082-1:1997 – Protective clothing – Gloves and arm guards protecting against cuts and stabs by hand knives: chain-mail gloves and arm guards.

Irish Standard EN 1231:1997 Short-term Detector Tube Measurement Systems – Requirements and test methods.

Irish Standard EN 12469:2000 Performance Criteria for Microbiological Safety Cabinets.

Irish Standard EN 12547:1999 +A1 2009 Centrifuges – Common Safety Requirements.

Irish Standard EN 14031:2003 Workplace atmospheres – Determination of airborne endotoxins.

Irish Standard EN 374-1:2003 Protective Gloves against Chemicals and Micro-organisms.

Irish Standard EN 420:2003 Protective Gloves – General requirements and test methods.

Irish Standard EN 464: 1994 Protective Clothing for Use against Liquid and Gaseous Chemicals, Including Aerosols and Solid Particles – Test Method: Determination of leak tightness of gas tight suits (Internal Pressure Test).

Irish Standard EN 529 Respiratory Protective Devices – Recommendations for selection, use, care and maintenance – guidance document.

Irish Standard EN13098:2001 Workplace Atmosphere – Guidelines for the measurement of airborne micro-organisms and endotoxin.

Irish Standard SR CWA 15793:2008 Laboratory Biorisk Management Standard.

Safety, Health and Welfare at Work (Biological Agents) Regulations, 2013, S.I. No 572 of 2013.

Safety, Health and Welfare at Work (General Application) Regulations (2007) Personal.

Safety, Health and Welfare at Work Act, 2005.

COMMON OCCUPATIONAL INFECTIONS[1]

Table 1 – Common Occupational Infections & Sources

	Source of Infection				
	Blood, bodily fluids, body parts	**Bodily waste (faeces, urine, vomit)**	**Substantial skin contact**	**Infectious aerosols (coughs, sneezes): airborne**	**Environmental micro-organisms**
People – Human Health & Work Activities	Hepatitis B & C, HIV	Haemorrhagic colitis/ haemolytic uraemic syndrome, viral gastroenteritis, shigellosis, salmonellosis, Hepatitis A	Ringworm	Tuberculosis, SARS	
Animals – Agriculture, Forestry & Fishing					Tetanus (soil) Lyme Disease (Ticks found on animals & vegetation), fungi & moulds
Horses		Salmonellosis	Ringworm		
Cattle	Bovine tuberculosis, Q fever, BSE	Leptospirosis, haemorrhagic colitis/ haemolytic uraemic syndrome, Q fever, cryptosporidiosis, salmonellosis	Ringworm	Bovine Tuberculosis	
Sheep/Goats	Chlamydiosis, Scrapie	Q fever, haemorrhagic colitis/haemolytic uraemic syndrome, salmonellosis, cryptosporidiosis, toxoplasmosis	Orf		
Cats		Toxoplasmosis	Ringworm		
Dogs		Leptospirosis, toxocariasis, rabies	Ringworm		

[1] *Taken from Infection at Work: Controlling the Risks ¬– A guide for employers and the self-employed on identifying, controlling and assessing the risk of infection in the workplace. (UK Health and Safety Executive, 2003*

Appendix 1 cont'd

COMMON OCCUPATIONAL INFECTIONS[1]

Table 1 – Common Occupational Infections & Sources continued

	Source of Infection				
	Blood, bodily fluids, body parts	**Bodily waste (faeces, urine, vomit)**	**Substantial skin contact**	**Infectious aerosols (coughs, sneezes): airborne**	**Environmental micro-organisms**
Poultry	Chlamydiosis, campylobacteriosis	Campylobacteriosis, salmonellosis		Chlamydiosis	
Pigeons & other birds	Chlamydiosis	Salmonellosis		Chlamydiosis	
Rats		Leptospirosis			
Reptiles		Salmonellosis			
Pigs	Streptococcosis		Ringworm		
Water Supply: Sewerage, Waste Management & Remediation		Leptospirosis, Hepatitis A, Hantavirus infection, gastrointestinal pathogens			Legionellosis (natural & artificial systems), fungi & moulds
Construction, Mining, Quarrying & Ceramics		Histoplasmosis			Fungi & moulds
Professional, Scientific & Technical Activities					Fungi & moulds

Table 2: Most Common Infections[2]

Bovine tuberculosis	
Biological agent (bacterium)	Mycobacterium bovis
Natural hosts	Cows, also has been found in deer & badgers
Disease in humans	Chronic, progressive disease with fever & weight loss
Transmission route	Inhaling infectious aerosols of respiratory discharges or possibly when handling meat from infected animals or drinking unpasteurised milk.
Campylobacteriosis	
Biological agent (bacterium)	*Campylobacter jejuni*
Natural hosts	Farm animals, chickens, wild birds & household pets
Disease in humans	Abdominal pain, fever and nausea
Transmission	Hand-to-mouth contact with faeces or contaminated material, handling of raw poultry during processing (contaminated with faeces).
Chlamydiosis	
Biological agent (bacterium)	Chlamydophila psittaci
Natural hosts	Birds – caged, wild exotic birds, poultry, pigeons, sheep & goats
Disease in humans	Two forms: Birds – causes ornithosis/psittacosis – flu-like illness which may lead to pneumonia and, in severe cases, endocarditis, hepatitis and death. Sheep – causes ovine chlamydiosis, may cause abortion or flu-like illness.
Transmission	Birds – inhaling infected respiratory discharges from infected birds or breathing in dust contaminate with faeces and/or respiratory discharges. Sheep – contact with products of gestation, e.g. placentae, amniotic fluid or contaminated bedding.
Cryptosporidiosis	
Biological Agent (parasite)	*Cryptosporidium parvum*
Natural hosts	Calves and lambs, goats and kids
Disease in humans	Diarrhoea and abdominal pain
Transmission	Hand-to-mouth contact with faeces or contaminated material.

[2] *Taken from Infection at Work: Controlling the Risks – A guide for employers and the self-employed on identifying, controlling and assessing the risk of infection in the workplace. (UK Health and Safety Executive, 2003)*

Appendix 1 cont'd

Fungi & Moulds	
Biological agents	Various species – likely to be found in damp areas or naturally present in soil, e.g. *Aspergillus spp.*
Natural hosts	Found widely in the environment
Disease in humans	Can cause infection and allergy (farmer's lung)
Transmission	Inhaling spores, for example in dust from mouldy hay or when carrying out construction work.
Haemorrhagic colitis/haemolytic uraemic syndrome (HUS)	
Biological agent (bacterium)	Escherchia coli O157
Natural hosts	Cattle, sheep, goats and deer
Disease in humans	Haemolytic uraemic syndrome (HUS) and haemorrhagic colitis are the most severe forms of the disease. Can cause a range of symptoms from mild diarrhoea to bloody diarrhoea (haemorrhagic colitis) and HUS. HUS is characterised by acute renal failure.
Transmission	Hand-to-mouth contact with faeces or contaminated objects.
Hepatitis A	
Biological agent (virus)	Hepatitis A virus
Natural hosts	Humans
Disease in humans	Age dependent, more severe in adults, common symptoms include fever, headache. Jaundice, loss of appetite, vomiting and abdominal pain
Transmission	Hand-to-mouth contact with faeces or contaminated matter.
Hepatitis B	
Biological agent (virus)	Hepatitis B virus
Natural hosts	Humans
Disease in humans	Infection may cause acute inflammation of the liver (hepatitis) which may be life-threatening. A person showing no symptoms may still carry the infection.
Transmission	Contact with blood (and other bodily fluids which may be contaminated with blood) via a skin-penetrating injury or via broken skin. Through splashes of blood (and other bodily fluids which may be contaminated with blood) to eyes, nose and mouth.

Hepatitis C	
Biological agent (virus)	Hepatitis C virus
Natural hosts	Humans
Disease in humans	Acute infection may be symptom free or mild. If disease progresses, most common symptom is fatigue. At least 50% of those with acute infection develop chronic hepatitis.
Transmission	Contact with blood (and other bodily fluids which may be contaminated with blood) via a skin-penetrating injury or via broken skin. Through splashes of blood (and other bodily fluids which may be contaminated with blood) to eyes, nose and mouth.
HIV (AIDS)	
Biological agent (virus)	Human immunodeficiency virus
Natural hosts	Humans
Disease in humans	Acquired immune deficiency disease and related conditions affecting the immune system
Transmission	Contact with blood (and other bodily fluids which may be contaminated with blood) via a skin-penetrating injury or via broken skin. Through splashes of blood (and other bodily fluids which may be contaminated with blood) to eyes, nose and mouth.
Legionellosis	
Biological agent (bacterium)	Legionella pneumophila
Natural host	Humans – but found naturally occurring in the aquatic environment
Disease in humans	Ranges in severity from a mild flu-like illness to the more severe pneumonic form, Legionnaires' disease
Transmission	Inhaling contaminated water droplets, e.g. from cooling towers, showers, spa baths.
Leptospirosis	
Biological agent (bacterium)	Leptospira interrogans (serovars include icterhaemorrhagiae, hardjo)
Natural hosts	Rodents (icterhaemorrhagiae); cattle (hardjo)
Disease in humans	Rodents – Weil's disease: fever, headache, vomiting, muscle pain, can lead to jaundice, meningitis and kidney failure – can be fatal. Cattle – cattle-associated leptospirosis: flu-like illness of short duration, often with headache.
Transmission	Rats – direct contact through breaks in the skin with infected urine or water contaminated with urine. Cattle – splashing of urine during milking and other close contact.

Appendix 1 cont'd

Lyme disease	
Biological agent (bacterium)	*Borrelia burgdorferi*
Natural hosts	Ticks
Disease in humans	Begins with skin rash, often associated with flu-like illness. Later cardiac, arthritic and/or neurological diseases may develop
Transmission	Via the bite of infected ticks which are often found on the tips of vegetation waiting for a host to pass.
Orf	
Biological agent (virus)	Orf virus
Natural hosts	Sheep and goats
Disease in humans	Causes ulcerative lesions on face, hands and arms
Transmission	Direct skin contact with lesions on animals or by contact with virus on infected wool, hedges/fences, etc. where it can survive almost indefinitely.
Q Fever	
Biological agent (bacterium)	Coxiella burnetii
Natural hosts	Sheep and cattle
Disease in humans	Mild illness – chills, headaches and general malaise, but rarely can progress to pneumonia, liver and heart valve damage and death.
Transmission	Usually by breathing in dust contaminated by placental tissue, amniotic fluids, urine and faeces. Also direct contact with the animal and these secreta/excreta. Micro-organism is resistant to drying and can survive for long periods in the environment.
Ringworm	
Biological agent (fungus)	Trichophyton – various species of the fungus
Natural hosts	Humans, cows (and some other farm animals, e.g. horses, pigs, sheep)
Disease in humans	Causes inflamed, swollen, crusty lesions mainly on hands, forearms, head and neck
Transmission	Direct skin contact with infected animal, spores enter through broken skin.
Salmonellosis	
Biological agent (bacterium)	Various species of Salmonella bacterium
Natural hosts	Wild and domestic animals, birds (especially poultry), reptiles, amphibians (e.g. terrapins) and occasionally humans
Disease in humans	Diarrhoea, vomiting, fever
Transmission	Hand-to-mouth contact with faeces or contaminated matter.

Shigellosis	
Biological agent (bacterium)	Various species of the Shigella bacterium
Natural hosts	Humans
Disease in humans	Bloody diarrhoea – disease severity depends on infecting species
Transmission	Hand-to-mouth contact with faeces or contaminated objects.
Streptococcosis	
Biological agent (bacterium)	Streptococcus suis
Natural hosts	Pigs
Disease in humans	May be severe and serious disease with meningitis & septicemia
Transmission	Inhaling infectious respiratory discharges, also direct contact through broken skin and contaminated meat.
Tetanus	
Biological agent (bacterium)	Clostridium tetani
Natural hosts	Humans and animals, spores of the bacterium occur widely in the environment, e.g. soil
Disease in humans	Exaggerated reflexes, muscle rigidity and uncontrolled muscle spasms – lockjaw
Transmission	Organism enters through broken skin.
Toxocariasis	
Biological agent (parasite)	Toxocara canis, Toxocara cati
Natural hosts	Dogs (canis) and cats (cati)
Disease in humans	Following ingestion of the eggs, these hatch and the larvae migrate to the liver, lungs, eyes and brain
Transmission	Hand-to-mouth contact with faeces or contaminated objects.
Toxoplasmosis	
Biological agent (parasite)	Toxoplasma gondii
Natural hosts	Cats
Disease in humans	May be without symptoms, can vary from persistent acute fever to rare infection in the brain, muscle and eye leading to death, causes abortion in pregnant women.
Transmission	Hand-to-mouth contact with faeces or contaminated objects

Appendix 1 cont'd

Tuberculosis	
Biological agent (bacterium)	*Mycobacterium tuberculosis*
Natural hosts	Humans
Disease in humans	Disease develops slowly, usually takes several months for symptoms to appear, symptoms include fever and night sweats, coughing, losing weight and blood in phlegm or spit.
Transmission	Inhaling infectious respiratory discharges
Viral gastroenteritis	
Biological agent (virus)	Most commonly small round structured viruses – Norwalk-like viruses.
Natural hosts	Humans
Disease in humans	Vomiting, diarrhoea, fever
Transmission	Hand-to-mouth contact with faeces or contaminated objects, also from inhaling aerosols of projectile vomit – this can lead to environmental contamination, especially of toilets.

Risk-assessment Checklist for Activities Involving the Deliberate Use of Biological Agents

This checklist can be used as an aid in compiling a detailed risk assessment for activities involving the deliberate use of biological agents.

The following should be included:

Preliminaries

Provide details of:

- the person responsible for the work
- the person conducting the risk assessment
- persons conducting the work
- project/ work activity being undertaken
- where the work will be carried out

Hazards and risks

- Identify and describe the most hazardous procedures.
- What biological agents are to be used deliberately, including name/strain and classification?
- What is the possibility of adventitious biological agents being present?
- Describe the hazards associated with the biological agents.
- Identify routes of infections for each biological agent (in the laboratory setting) and minimum infectious dose.
- What is concentration and volume of biological agent(s) to be used?
- Is there known or suspected drug resistance of biological agent(s) to be used?
- Are strains attenuated or do they have increased virulence in any way?
- What ability has the biological agent(s) to survive, e.g. resistance to chemical disinfection?
- Are there any pre-existing medical issues that increase the risk associated with this biological agent(s), e.g. pregnancy, immunosuppression etc.?
- Assess for non-biological hazards such as chemicals to be used, non-ionising radiation, cryogenic gases, etc.
- Details of others who may be affected by the work activity, e.g. maintenance employees, cleaners.

Appendix 2 cont'd

Control Measures

- Describe the level of containment required for the work or per biological agent, if necessary.
- Have preventative measures such as substitution with safer alternative being considered?
- How is the work segregated/ isolated from others not involved with the work activity?
- Is a biological safety cabinet to be used; if so, what type and how will it be used?
- Is there any other local exhaust ventilation required?
- Are there any particular requirements required for the work area, e.g. negative pressure, temperature control, etc?
- How will the biological agent(s) be 'transported' within the laboratory to avoid accidental splashes, spills, etc?
- How will the biological agent(s) be transported safely on site, if relevant?
- How are samples dealt with for shipment and receivers?
- How will the biological agent(s) be securely stored and what procedures are in palce to determine if samples are missing?
- If biological agents are stored in liquid nitrogen, are there safety procedures in place for loading/ unloading samples?
- Describe procedures in place if infectious agent(s) are to be centrifuged.
- Describe safety procedures in place if incubators are to be used, e.g. to avoid spillages
- If sharps are to be used, detail justification of their use and procedures for use and disposal.
- Describe procedures in place if animals or vectors are to be used.
- Describe procedures in place where bioreactors or fermentors are to be used.
- Provide details of personal protective equipment to be used, e.g. lab coats, gloves, eye protection, etc.
- Describe the hygiene measures in place.
- Describe waste-treatment procedures for both liquid and solid wastes prior to disposal and how these methods are validated as being effective.
- Provide details for autoclave sterilisation methods.
- Describe control measures in place where lone working may be involved.

Administrative controls

- Provide details of maintenance controls in place, e.g. for BSCs, autoclaves, etc.
- Describe details of training and instruction provided to all relevant staff.
- Is there a local Code of Practice to be adhered to, e.g. biosafety manual of procedures?

Emergency procedures

- Describe emergency procedures in place for spillages within the safety cabinet, in the laboratory and outside the laboratory.

Medical issues

- Is an assessment required to be undertaken by an occupational physician.
- Details of health surveillance measures.

Notification to Health and Safety Authority

- Is the work notifiable under Regulation 14 of the Safety, Health and Welfare (Biological Agents) Regulations 2013?
  - ✔ Full details of work activity.
  - ✔ Circumstances in which incidental exposure could occur.
  - ✔ List potential biological agent(s) and hazard category (e.g. present in materials used or in the environment).
  - ✔ Consider infection risk and allergenicity and/or toxicity.
  - ✔ List of all staff who could potentially be exposed.
  - ✔ How often and how much exposure?
  - ✔ How would exposure occur – routes of entry, e.g. inhalation, ingestion or absorption?

Appendix 3

Risk-assessment Checklist for Activities Involving Incidental Exposure to Biological Agent(s):

No intention to work with (i.e. isolate or concentrate) such biological agents, the hazardous biological agents may be present during work activities, e.g work with farm animals, soil, refuse-disposal work.

A. <u>Identification of possible biological agent hazard(s):</u>

- ✔ List any existing controls in place, e.g. engineering controls, PPE, procedures.

B. <u>Assessment of level of risk and review if further action needed:</u>

- ✔ How severe is any health effect likely to be (severity can be equated to hazard category of organism(s))?
- ✔ How likely is exposure (high/medium/low)?
- ✔ Calculate risk = severity hazard x probability of exposure.
- ✔ Is health surveillance required?

FORM OF NOTIFICATION FOR USE OF A GROUP 2, 3 OR 4 BIOLOGICAL AGENT*

As required under Regulation 14 (1) (e) of the Safety, Health and Welfare at Work (Biological Agents) Regulations, 2013 (S.I. No. 572 of 2013)

For Office Use Only

Employer Place of Work No. (EPOW)	*Employer No.*	*Correspondence No.*	*Date Received*
Comments:			

Section 1

For Notifier to complete

1. Name of Company/Establishment	
2. Company Registration Number (CRO No) (if applicable)	
3. Address & Telephone Number of Company/Establishment	
4. Email address	
5. Address of premises where the biological agent will be stored or used (if different to 3 above)	
6. Date of Notification	**Click here to enter a date.**
7. Type of Notification	**Choose an item.**
	(if 'other' chosen please state why or if re-notification state reasons why)

Appendix 4 cont'd

Section 2

1. Type of Biological Agent being notified	**Choose an item.** (If other please state)
2. Species of biological agent	
3. Biological agent classification group	**Choose an item.**
4. Name(s), qualifications and relevant experience of people responsible for safety and health at work	
5. Results of risk assessment (as required under Regulation 7 of the above Regulations)	
6. Protective and preventative measures envisaged	
Name of Notifier:	
Position in Company / Establishment:	
Contact Telephone Number:	
Contact Email Address:	

This form must be submitted to the Health and Safety Authority 30 days prior to the commencement of work *involving the use for the first time of a group 2 or 3 or 4 biological agent or for the first time of each subsequent group 4 biological agent and any subsequent new group 3 biological agent, where the employer himself classifies that biological agent. Forms should be sent to:*

1. **bioagents_notif@hsa.ie or**
2. **Health & Safety Authority, Occupational Hygiene Unit, 3rd Floor, Hebron House, Hebron Rd, Kilkenny**

*** Classification of Biological Agents – Groups 2, 3 & 4**

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

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, although there is usually effective prophylaxis or treatment available

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

Refer to Schedule 1 of the Code of Practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations, 2013 (S.I. No .248/1998), for current classification of biological agents.

Appendix 5

Fumigation

Fumigation is a potentially hazardous process involving the release of toxic gases into the atmosphere to kill biological agents. Strict controls, similar to a work-permit system, must be put in place and documented in an SOP to ensure the protection of employees and the work environment. The work area, including the room ventilation, must be capable of being sealed for the purpose of fumigation.

Commonly used fumigants are: formaldehyde, hydrogen cyanide, hydrogen peroxide, methyl bromide and phosphine, for example. The Safety, Health and Welfare at Work (Chemical Agents) Regulations, apply to the use of such chemicals in the workplace. Under these regulations, a risk assessment must be carried out prior to commencement of a fumigation operation.

Of the above fumigants, formaldehyde is the most common. There has been long experience of its use. It is effective for most biological agents. It is highly effective for whole room decontamination and it is easy to detect. It is toxic by inhalation, skin contact or if swallowed; a skin sensitiser and a suspect carcinogen. In some cases, formalin and paraformaldehye are used. Formalin contains 38–40% formaldehyde in solution and paraformaldehyde is a product of formaldehyde which converts with heat and moisture to formaldehyde during the fumigation process.

Before commencing any fumigation the operator will need:

- ✔ protective clothing
- ✔ sealing materials
- ✔ full face respirator (positive pressure or self-contained)
- ✔ fumigant (formalin)
- ✔ biological indicators
- ✔ boiling pots
- ✔ monitoring equipment
- ✔ warning notices
- ✔ fumigation documentation

The fumigator should be trained in the use of the equipment and understand the hazards of the materials being used. He/she should be trained in the use of the respirator and fit tested for same.

Before fumigation commences, the area is handed over to the fumigator. The fumigation should be performed by two operators. The specific procedure should be logged or documented. Biological indicators can be used to validate the effectiveness of the fumigation process.

Before any fumigant is released in an area, ensure it is clear of people, non-target animals and plants, and ensure non-authorised personnel cannot gain access until the area has been vented and declared safe.

The fumigation area is always sealed from other areas and made as gas tight as possible. Nobody should enter during fumigation except in a major emergency. Incubators, fridges, drawers, cabinets, etc. may need to be opened and notices need to be put in place. In an emergency, suitable personal protective equipment will need to be worn. The risk area comprises all adjacent spaces where it is considered that concentrations of fumigant above the occupational exposure limit value (OELV) could occur.

During fumigation, one should restrict the amount of the fumigant used to the minimum necessary to effectively carry out the fumigation safely. The fumigation area should be checked for leaks using a suitable atmospheric monitoring device. If leaks are detected, they must be dealt with by the individual in charge of the fumigation while wearing suitable respiratory protective equipment (RPE). If it is not possible to seal the leak, the fumigation and risk area must be extended. Additional areas may need to be evacuated and warning notices erected as a result.

After application of the fumigant, equipment and surplus fumigant should be removed from the area. All equipment should be ventilated and inspected for residues while wearing appropriate PPE before placing into store or loading onto transport. Remove any contaminated clothing and equipment and air it in a well-ventilated place for a minimum of two hours or until free of fumigant, whichever is the greater.

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[3] *A list of occupational exposure limits can be found in the Code or Practice for the Health, Safety and Welfare at Work (Chemical Agents), 2001 (S.I. No 619 of 2001).*

Appendix 5 cont'd

The fumigation and risk areas should be ventilated at the end of the fumigation period. If it is necessary to enter the fumigation area to effect the ventilation, e.g. open windows or doors, then suitable breathing apparatus should be used. The risk assessment should identify areas which may require forced ventilation to remove the fumigant, e.g. cellars, confined spaces, especially where heavy gases such as methyl bromide or sulfuryl fluoride are used. The individual in charge (fumigator) of the fumigation should ensure that all areas are safe for reoccupation by testing the atmosphere until the concentrations of fumigant have fallen below the OELV or other appropriate level. The fumigator should wear appropriate RPE. Take special note of materials in the fumigation area that may continue to desorb gas following the end of the fumigation operation.

When all areas have been shown to be safe for reoccupation, barriers or warning signs can then be removed.

Biological safety cabinet fumigation

Cabinets should be fumigated before any service work or removal of HEPA filters and between projects. Spills, etc. should be treated with appropriate disinfectant and cleaned up before fumigation. Fumigation is the final part of the decontamination process. An SOP for biological safety cabinet fumigation should be developed that covers all aspects of the activity from start to finish. Each fumigation should be documented and recorded.

Validation using biological indicators can be performed to determine the effective levels of fumigant.

Fumigation is completed with hazardous/toxic chemicals. It can be undertaken safely if based on the risk assessment of the activity, rules and SOP are applied and followed.

Further Information on Biological Safety Cabinets

There are three basic types of safety cabinet:

Class I cabinet

A class I cabinet is an open-fronted cabinet designed to protect the operator by continuously drawing air into the front of the cabinet. It works by drawing air into the cabinet away from the employee which is then expelled at the top of the cabinet through high-efficiency particulate air [HEPA] filters to remove any contamination. Class I cabinets can be used with risk group 2 and 3 organisms when performing procedures likely to cause an aerosol.

Class II cabinet

A class II cabinet is an open-fronted cabinet designed to protect the operator from exposure and the work from external contamination. The inward air is directed downwards into a plenum below the work surface and is HEPA filtered before being redirected into the work area as a laminar downflow of clean air. The employee is protected by the downflow curtain of filtered air.

Class II cabinets can be used with risk groups 2 and 3 organisms when performing a procedure likely to cause an aerosol and when the experimental work must also be protected from contamination. Class II cabinets offer less operator protection than Class I cabinets and additional respiratory protection may be required when working with respiratory pathogens.

Class III cabinet

A Class III cabinet is a totally enclosed cabinet in which operations are conducted through gloves attached to glove ports. Air enters the cabinet through a HEPA filter at the side or rear of the cabinet and is exhausted in a similar way to a class I cabinet. Class III cabinets are designed to completely contain the hazardous agent and are used mainly for work with group 4 biological agents or work with group 3 biological agents deemed to be at high risk, for example where highly concentrated samples are being handled. They offer the greatest protection to the employee and work place.

Appendix 6 cont'd

Irish Standard IS EN 12469 2000

The effectiveness of the microbiological safety cabinet depends on good design, suitable installation, ongoing maintenance and correct use

Performance criteria are set out in IS EN 12469:2000 Performance criteria for microbiological safety cabinets. This standard sets out minimum performance criteria for these cabinets and specifies test procedures for protection of employees, the environment, protection of product and prevention of cross-contamination. It also specifies tests for the protection of operators.

Arrangements for exhaust air

The preferred option for venting safety cabinets is to duct the exhaust air to the exterior of the building.

Positioning

Biological safety cabinets should be sited so as to minimise disturbance of the airflow at the front of the cabinet.

The key requirements are:

a) that the cabinet has sufficient clearance from walls, corners and doorways

b) that no obstacles are placed where they may interfere with the airflow

c) that sufficient room is provided for the operator to avoid interference with other employees

Proper use of safety cabinets

Preparation for work

- Appropriate protective clothing according to the level of containment and the risk assessment for the work should be worn.
- Ensure that the cabinet is switched on and running for sufficient time to allow airflow stability before starting the work.
- Do not use unless the airflow indicator is registering in the 'safe' zone.
- Prepare thoroughly for the work, e.g., number or code tubes, flasks, dishes, etc., organise media, solutions, etc. (a checklist may be useful, and/or referral to protocols, codes).
- Ensure active solutions of appropriate disinfectants (and granules or powders as required) are available according to local protocols and procedures.
- Ensure the inside of the cabinet is clean and free of clutter.
- Ensure the laboratory door is closed.
- Ensure any equipment required for the work is available and ready for use (e.g., centrifuge, microscope, etc., but note following section re use of equipment within the cabinet).
- Place work in the cabinet, ensuring clean and dirty materials are kept separate.

Appendix 6 cont'd

Use of cabinets

- Do not overcrowd the cabinet.
- For open-fronted cabinets, always work as near to the centre of the work area as possible, but at least 15cm from the front of the cabinet.
- For Class II cabinets, never obstruct the air in-flow grille or any exhaust grilles.
- Obstructions will adversely affect performance and, in particular, operator protection. Large equipment (e.g. centrifuges, especially air-cooled models) should not be used within an open-fronted cabinet unless the appropriate testing has been done to establish that containment performance is maintained.
- Do not mix sterile with infected materials and avoid passing potentially infected material over clean material.
- Dispose of equipment and contaminated material appropriately after use. Wherever practicable at containment level 2, this means disposal into appropriate containers or disinfectants within the safety cabinet. This must always be done at containment level 3.
- Never use a cabinet if its operational safety is in doubt. If the alarm sounds, make the work area secure for open-fronted cabinets place the front on the cabinet, and inform the appropriate people according to local protocols and procedures.

Clearing the cabinets after use

- Check the performance of the cabinet.
- Remove samples for incubation, etc., after wiping down flasks, containers, etc., as appropriate with disinfectant.
- Ensure that all containers for autoclaving and incineration are marked correctly and secured. Only remove contaminated materials from the cabinet as directed by local protocols and procedures. Normally, this will mean only when the material can be taken directly to the autoclave, although exceptionally it may be permitted to place containers in a holding area within the containment area.
- Wipe all surfaces with disinfectant.
- Leave fan(s) on for 5 to 10 minutes.
- Where local arrangements require, turn off cabinet and replace front of open-fronted cabinet or inward filter cover (Class III).
- Precautions should be adopted for cleaning the interior of biological safety cabinets used for work with dangerous pathogens.
- The interior of a biological safety cabinet should be wiped down with appropriate disinfectant or fumigated after use (see previous section). Normally it will not be necessary to remove the working surface grilles, and indeed this should be avoided wherever possible. If it is absolutely necessary, the following precautions should be taken:
    - Wear heavy-duty PVC or rubber gloves that can be disinfected after use over normal surgical gloves to provide adequate protection for hands and wrists.
    - Spray the appropriate disinfectant at the prescribed dilution for the pathogens in use onto all exposed surfaces and allow sufficient time before proceeding.
    - Do not attempt to lift the grilles by placing the fingers through the holes or slots, which may have sharp edges. If no handles are provided, use an implement to hook or lever the grilles up from their housing so that the edges may be grasped safely. Warning: the edges may have sharp corners or edges.
    - Spray the appropriate disinfectant at the prescribed dilution onto all newly exposed surfaces. Allow sufficient time before proceeding.
    - For cleaning use a thick wad of material to protect your gloved hand from sharp edges.
    - Disinfect the outer gloves before removal.
    - Autoclave the cleaning material before disposal.

Appendix 6 cont'd

Training and competence

No person should be allowed to work at a biological safety cabinet unless proper training has been given and the person is competent to do the work.

The requirements for competence to use a biological safety cabinet should include full instruction in the following as a minimum:

- how to work at cabinets safely
- classification of cabinets
- appropriate and inappropriate use of cabinets
- mode of operation and function of all controls and indicators
- limitations of performance
- how to decontaminate after use
- principles of airflow and operator protection tests

Maintenance and testing

All biological safety cabinets must be regularly serviced and tested to ensure their continued safe performance and thereby to satisfy legislative requirements for risk-control equipment. The recommended maintenance and testing programme below is subject to local circumstances but should normally be regarded as a minimum. However, in low-risk areas (i.e. containment level 1 or equivalent), an annual frequency for all operations may be acceptable so long as it is subject to regular risk-assessment review. The recommended frequency for maintenance and testing is set out below:

Operation	Frequency
Alarms/ indicators	Daily
Airflows: user	Monthly
Filter integrity	6-Monthly
Mechanical and electrical function	6-Monthly
Mechanical integrity (including visible ductwork)	Annual
Operator protection	Level 2 - Annual Level 3 - 6 monthly

Autoclave checklists

Apparatus checklist

a. Are safety devices, valves, gauges, controls, alarms, etc. simple to read and understand?

b. Are they easily accessible to operatives of all sizes?

c. Where machines have automatic door opening, are alarms and trip devices fitted?

d. Is there a suitable safety valve fitted?

e. Is there a correct steam-pressure gauge?

f. Is the maximum safe working pressure clearly marked?

g. Is a suitable reducing valve or similar automatic device fitted?

h. Is there an isolating valve in the inlet line for each machine?

i. For multi- and single-bolted door machines, is a device fitted to break the seal?

j. For quick-opening type doors, are the required devices provided?

Checklist for autoclave uses and procedures

a. Has the autoclave been examined according to a scheme of examination in the last 14 months?

b. Is a permit system available and used for entering vessels for any reason?

c. Are records kept of weekly checks on locks, guards, gauges and safety devices?

d. Is the autoclave checked by a competent person at specified intervals, and do the managers see the report?

e. Are operators fully instructed and properly trained in correct operating procedures, purpose and function of the controls and safety devices?

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