
	<h1>Frequently Asked Question</h1>				
Ref: FAQ 001:03	RE: Biological Agents				
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Author(s):	NH&SF – Information & Advisory Team.				
Note:	<i>This information/advice has been issued in response to frequently asked questions around a specific topic and may not cover all issues arising, should you require more specific advice please contact the Health & Safety Help Desk. The management of any occupational safety and health issue(s) remains the responsibility of local management.</i>				

What is a 'biological agent'?

A biological agent is a micro-organism, including those that have been genetically modified, a cell culture and a human endoparasite, which may be able to provoke any infection, allergy or toxicity.

Agents are classified into 4 risk groups according to their level of risk of infection and can relate to bacteria, fungi, virus, parasites etc. These groups are:

- A "group 1 biological agent", means one that is unlikely to cause human disease to employees
- 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

What are the health effects associated with exposure to biological agents?

Biological agents can cause certain types of infections e.g. viruses, bacteria or parasites.

Does the employer have to carry out a Risk Assessment?

Yes, it is the duty of every employer, under Section 19 of the Safety, Health and Welfare at Work Act 2005 to carry out a [risk assessment](#). In addition to this requirement, the Safety, Health and Welfare at Work (Biological Agents) Regulations, 2013 require that the employer assesses any risk to the safety and health of employees resulting from any activity at their place of work likely to involve a risk of exposure to a biological agent.

It is the employer's duty to determine the nature, degree and duration of any employee's exposure to a biological agent and determine the control measures to be taken to ensure the safety and health of such employees. In the case of activities involving exposure to several groups of a biological agent, the risks should be assessed on the basis of the danger presented by all hazardous biological agents present.

The risk assessment must be in a written form, reviewed regularly, and whenever there is a change in conditions at the place of work, that may affect any employee's exposure to a biological agent.

The risk assessment should be conducted on the basis of all available information, including:

- The classification of a biological agent which is or may be a hazard to human health
- Information on diseases which may be contracted as a result of the work of the employees
- Potential allergenic or toxigenic effects as a result of the work of the employees
- Knowledge of a disease from which an employee is found to be suffering and which has a direct connection with his work
- Any recommendations which may be made by the Authority indicating that a particular biological agent should be controlled in order to protect employees' health where employees are or may be exposed to a biological agent as a result of their work

What measures should be put in place if it is not technically possible to prevent exposure to biological agents?

Where it is not technically possible to prevent exposure to biological agents, measures to be taken so as to reduce the risk of exposure and to ensure the control of any remaining risk so as to protect the worker should include:

1. Keep the number of employees exposed or likely to be exposed to a biological agent as low as possible
2. Work processes and engineering control measures should be designed so as to avoid or minimise the release of a biological agent into the place of work
3. Use both collective protection measures and individual protection measures where exposure cannot be avoided by other means
4. Use hygiene measures compatible with the aim of preventing or reducing the accidental transfer or release of a biological agent from the workplace
5. Use the bio-hazard sign (depicted in the Third Schedule of the 2013 Biological Agents Regulations), and other relevant warning signs
6. Draw up plans to deal with accidents involving a biological agent
7. Test, where it is necessary and technically possible, for the presence, outside the primary physical confinement, of a biological agent used at work
8. Use means for safe collection, storage and disposal of waste by employees, including the use of secure and identifiable containers
9. Make arrangements for the safe collection, storage and disposal of waste by employees within the workplace

What hygiene and individual protection measures should be taken when working with biological agents?

In the case of any activity in relation to which there is a risk to the safety or health of employees caused by working with a biological agent, the employer must take appropriate measures to ensure that:

- Employees do not eat or drink in any location within a place of work where there is a risk of contamination by a biological agent
- Employees are provided with suitable washing and toilet facilities, which may include eye washes and skin antiseptics (or both)
- Employees are provided with suitable personal protective equipment (PPE)
- Any necessary PPE is:
 - i. properly stored in a designated place
 - ii. checked and cleaned if possible, before, and in any case after each use
 - iii. repaired, where defective, or replaced, before further use
- Procedures are specified for taking, handling and processing samples of human origin
- Working clothes and PPE, which may be contaminated by a biological agent, are removed on leaving the working area and, before taking measures for cleaning, decontaminating and/or disposal, kept separately from other clothing
- The working clothes and PPE are decontaminated and cleaned or, if necessary, disposed of

What additional provisions must be in place for those who work in a health care setting?

Particular measures that must be implemented to protect the safety and health of employees working in health care include:

- Specifying appropriate decontamination and disinfection procedures
- Implementing procedures enabling contaminated waste to be handled and disposed of without risk

In addition, when carrying out the risk assessment in a health care setting, the employer must pay particular attention to:

- The risks posed by the nature of the work
- The uncertainties about the presence of a biological agent in patients and the materials and specimens taken from them
- The hazard represented by a biological agent known or suspected to be present in patients and the materials and specimens taken from them
- The containment measures specified in Schedule 2 of the relevant Code of Practice

Should employees receive any specific training or information regarding working with biological agents?

Yes, 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 or their safety representative, or both, 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, special protective clothing and personal protective equipment
- The steps to be taken by employees in the case of incidents and to prevent incidents

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/her undertaking. The employer must also provide appropriate training and written instructions

at the place of work and, if appropriate, display notices containing the procedure to be followed in the case of:

- A serious accident or incident involving the handling of a biological agent, or
- The handling of a group 4 biological agent

Also, the employer must ensure that his/her employees or their safety representative (or both) are informed as quickly as possible 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.

Do all employees who work with biological agents need to get vaccinated?

It is the duty of the employer to ensure that effective vaccines are made available when necessary. Therefore, if the risk assessment reveals that there is a risk to the safety and health of employees due to their exposure to a biological agent for which effective vaccines exist, the employer must offer them vaccination, free of charge.

Employees should be informed of the benefits and drawbacks of both vaccination and non-vaccination. Records of vaccination and follow-up as necessary should be kept and retained. For queries on your vaccination immunity status please contact your local Occupational Health Department/Physician.

Does the employer have to provide health surveillance to all employees?

Yes, 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 reveals a risk to their safety or health. Such health surveillance, where appropriate, must be made available prior to exposure to biological agents and at regular intervals thereafter.

These health surveillance arrangements must be such that it is directly possible to implement individual and occupational hygiene measures. Additionally, after health surveillance has been undertaken, a further reassessment of the risk of exposure must be made.

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

What is involved in health surveillance?

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. As 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
- Where appropriate, biological monitoring as well as detection of early and reversible effects

Further tests may be decided upon for each employee, based on the advice from the Occupational Health Physician and/or other responsible medical practitioners.

How long should individual health records and medical records from health surveillance be kept for?

The employer and responsible medical practitioner is required to retain individual health records and individual confidential medical records respectively 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.

What must an employer do if an employee is exposed to biological agents?

If an employee is exposed to a biological agent, the employer must:

- Keep a list of the employees who may be exposed to a particular group 2 biological agent specified in the relevant Code of Practice and Group 3 or a group 4 biological agent (or both), indicating the type of work done by each employee, and, whenever possible, the biological agent to which they have been exposed, as well as records of exposures, accidents and incidents, as appropriate
- Keep the list referred to above for at least 10 years following the end of exposure
- Keep the list referred to above for an appropriately longer period not exceeding 40 years, depending on the likely duration of risk to the safety and health of employees determined during the risk assessment, following exposures which may result in an infection:
 - i. with a biological agent known to be capable of establishing persistent or latent infections
 - ii. that, in the light of present knowledge, is not diagnosable until illness later develops
 - iii. that has particularly long incubation periods before illness develops
 - iv. that result in illness that recrudesces at times over a long period despite treatment, or
 - v. that result in illness that may have serious long-term consequences
- Ensure that each employee has access to the information on the list which relates to him or her personally
- Ensure that the employees or their safety representative (or both) have access to collective information which does not identify information relating to any individual employee
- Ensure that the list is made available, on request, to the responsible medical practitioner or the Authority or a person designated under the Safety, Health and Welfare at Work Act 2005 for inspection
- Ensure that the employees or their safety representative (or both) have access, on request, to the information contained in the Notification

Does the HSA have to be notified of work involving the use of biological agents?

The Health and Safety Authority require notification 30 days prior to the commencement of work for the following activities:

- First time use of a group 2 biological agent
- First time use of a group 3 biological agent and any subsequent new group 3 biological agents, where the employer provisionally classifies that biological agent
- First time use of a group 4 biological agent and first time use of each subsequent group 4 biological agents
- Laboratories providing a diagnostic service in relation to group 4 biological agents are required only to make an initial notification

- Re-notification is required for all groups where there are changes to processes, procedures or the biological agent that are of importance to safety and health at work that result in the original notification being invalid or out of date

What information must be contained in this Notification?

Information that must be contained in the Notification include:

- The name and address of the establishment or undertaking (or both): this must relate to the place where the work is being carried out.
- The names and capabilities of the person responsible for safety and health at work: this must document the names and capabilities (e.g. experience / training etc.) of those at the local level
- The results of the risk assessment: at a minimum this should include the type of infection likely, the mode of transmission (e.g. skin contact) etc
- The species of biological agent
- The protective and preventative measures that are envisaged

Therefore for the purposes of notification an adequate risk assessment which should be site, task and agent specific, as appropriate and should be submitted together with the notification form.

However, it must be noted that notification is not an approval or licensing system.

Where do I get these forms for notifying the HSA?

There is no approved form for notification, for more information contact the Health & Safety Authority Website on www.hsa.ie.

If there are issues/concerns regarding any aspect which this FAQ relates, then these should be discussed with your line manager and documented as part of the risk assessment process as appropriate.

Additional Resource Information:

Legislation:

Safety, Health and Welfare at Work Act 2005

Safety, Health and Welfare at work (Biological Agents) Regulations 2013

Useful Contacts and References:

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

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

Local Infection Control Department

Guidelines for the Preparation for Transport of Patient Specimens and other Biological Materials