



Risk Management of Hazardous Biological Materials

Definitions for services

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What do we mean by hazardous biological material?

Hazardous biological material is any biologically-derived material or material which, either by accident or design is, or contains:

- **hazardous biological agents**
 - **hazardous multicellular organisms**
 - **any genetically modified organism**
- } These can **harm** (i.e. infection, allergy, toxicity) or otherwise create a hazard to **human** or animal health or the **environment**
} Whether or not it can cause harm to health or the environment

Hazardous multicellular organisms: microscopic infectious forms of larger parasites (e.g. the ova and infectious larval forms of helminths, tapeworm, parasitic flukes and nematodes etc.). Other multicellular organisms that can cause **harm** to **human** or animal health or the **environment** (from mosquitoes to [American bullfrogs to mink](#)).

Harm: harm can be caused in a number of ways, either directly by:

- 1) infecting and causing disease in humans, animals, or plants
- 2) colonising or displacing within the environment

or indirectly:

- 3) by acting as a reservoir/host/source for hazardous biological materials

Human: In the context of this protocol, human is taken to mean “healthy” individuals. Where an individual’s health status places them at increased risk from hazardous biological material (e.g. weakened immune response) then they will need to be assessed separately.

Health Surveillance Monitoring a person’s health where there is the potential for a significant risk to health brought about through work. In its widest sense health surveillance may cover statutory screening of employers exposed to particular hazards e.g. ionising radiation, advisory screening of those potentially or accidentally exposed to certain hazards and pre-placement health screening, along with other areas. See the [Occupational Health Service website](#) (for more information).

Environment: The environment includes the air, water, land, flora and fauna that go to make it up. Environmental damage is caused by the presence of organisms that have escaped and are capable of causing harm to any other living organisms or the environment. This includes:

- organisms likely to disturb natural ecosystems, especially derivatives of naturally-occurring species that may have a selective advantage;
- non-indigenous organisms that are able to become established and might prey upon native organisms or compete for the niche they currently occupy;
- non-indigenous organisms that might consume indigenous organisms and disrupt the ecology;
- non-indigenous organisms that express potentially harmful biologically active products, especially if they are likely to be preyed upon.

Zoonoses is any infectious disease that can be transmitted (in some instances, by a vector) from animals, both wild and domestic, to humans or from humans to animals (the latter is sometimes called reverse zoonosis). Many serious diseases fall under this category.

Human Materials these are any samples obtained from a human; including blood, urine, tissue, faeces, saliva, cerebral spinal fluid, synovial fluid, foetal tissue, amniotic fluid, placenta etc.

Sharps

These are blunt and sharp needles, scalpel blades, glass pasteur pipettes (short and long form), broken contaminated glassware, glass drug/chemical vials, surgical instruments and glass slides or any other item that may cause cuts or puncture wounds.

Categorisation of hazardous biological material into Hazard Groups:

Hazardous biological materials are classified into defined hazard groups based on the potential level of harm that they can cause to humans, animals or the environment.

Each biological agent has been categorised into one of four hazard groups, based on factors such as the severity of the disease it causes, the routes of infection, its virulence and infectivity, existence of effective therapies, immunization, the presence or absence of vectors, quantity of agent, whether the agent is indigenous and possible effects on other species, including plants and animals (see table below).

Hazard Group 1	<ul style="list-style-type: none">○ is unlikely to cause human disease; and○ in relation to susceptible animals is unlikely to produce disease or is enzootic and does not produce notifiable animal disease.
Hazard Group 2	<ul style="list-style-type: none">○ can cause human disease and may be a hazard to employees; it is unlikely to spread to the community and there is usually effective prophylaxis or treatment available; or○ in relation to susceptible animals is exotic, novel or produces notifiable diseases; and it has both of the following characteristics:<ul style="list-style-type: none">▪ is of low clinical significance; and▪ has low likelihood of spread.
Hazard Group 3	<ul style="list-style-type: none">○ can cause severe human disease and may be a serious hazard to employees; it may spread to the community, but there is usually effective prophylaxis or treatment available; or○ in relation to susceptible animals is exotic, novel or produces notifiable disease and it has one or both of the following characteristics:<ul style="list-style-type: none">▪ moderate clinical significance;▪ moderate likelihood of spread.
Hazard Group 4	<ul style="list-style-type: none">○ causes severe human disease and is a serious hazard to employees; it is likely to spread to the community and there is usually no effective prophylaxis or treatment available; or○ in relation to susceptible animals is exotic, novel or produces notifiable disease; and it has one or both of the following characteristics:<ul style="list-style-type: none">▪ the disease has serious clinical significance;▪ has a high likelihood of spread.
<ul style="list-style-type: none">● Disease this is referring to disease caused by infection● Susceptible animals are any kind of mammal except man, any kind of four-footed beast which is not a mammal and any species of bird likely to be affected by the biological agent.● Novel means a new strain of biological agent not previously seen.● Spread means the passing of the biological agent from one susceptible animal to another and assumes any necessary enzootic vector is present.	

Many hazardous biological agents have already been [categorised](#) by Advisory Committee on Dangerous Pathogens, and this classification is therefore legally recognised. When provisionally categorising biological agents, the agent should be assigned to one of the above Hazard Groups according to its level of risk of infection to humans and according to its level of risk to susceptible animals. Where the biological agent meets the definition in more than one group, the higher group should be assigned.