Biological agents

Biological agents can cause infection, intoxication and/or allergies in adult healthy humans. These can be a pathogenic microorganism (bacteria, virus, parasite, fungi) or a UCTA (unconventional transmissible agent for pathological prion protein). They can also be a cell culture or a GMO.

In addition to the identity of the biological agent, assessing the biological risk of an experiment is based on determining activities as well as steps and gestures at risk. It is also based on channels of contamination and exposed persons.

Microorganisms that are pathogenic for humans and UCTAs are ranked and published in the Journal Officiel (risk classes 2 to 4). Ask your regional delegation’s prevention advisor to obtain this classification.

This classification is not pertinent in cases of pregnancy or immunodeficiency. The prevention doctor should then be consulted for a suitable risk analysis.

All creations, holdings or uses of GMOs must be reported to the Higher Council for Biotechnology (HCB) in the form of declaration for use or an approval request according to the case.

Even if it is apparently non-infectious, all human samples must be handled under level 2 confinement. If infection is suspected, confinement will correspond to the risk class of the biological agent involved.

Samples of human blood will be obtained from the EFS (Établissement Français du Sang, French Blood Center) in the form of "qualified blood" (guaranteed free of HIV, hepatitis B and C viruses). This should be done whenever possible and pertinent.

Exposure

When handling a pathogenic agent, an animal, human or animal biological sample, cell culture or GMO, a risk of contamination by a biological agent can be present in the event of:

- presence of infected aerosols;
- projection of droplets;
- ingestion;
- stings/bites, cuts or simple contact.

This pertains to experiments as well as activities concerning washing, upkeep or maintenance of premises and equipment inspection and repair.

Confined premises

Handling is done in level 2, 3, 4 confined premises (L2, L3, L4 formerly called P2, P3, P4), according to the classification of the pathogenic agents, the HCB recommendation or the risk analysis.

Physical confinement for the risk is procured by using certain pieces of equipment (of which the principle is NF-certified BSC (Biological Safety Cabinet)), the configuration of the premises and the gestures of the manipulators. Although it contributes in protecting people who are outside of the confined area, the premises do not participate in the safety of the manipulator. The latter is protected solely by the BSC and the gestures used during the work.

Access to level 2 or 3 confinement is strictly reserved for people who are:

- authorized;
- trained;
- equipped with the required PPE (always specific shoes and smock, gloves, mask, goggles or overboots according to the risk analysis);
- knowledgeable of the conduct to adopt in the event of an accident, incident or malfunction.

Do not eat, drink or store any food or drink in a confined area. And more than anywhere else, mouth pipetting is prohibited.

Rules for working in levels 2 and 3 are listed in rules of procedure and in written procedures that must be complied with. The confinement manager or your prevention assistant can provide you with all of these items.

Personal protective equipment

To protect oneself from contamination through the skin, in addition to the smock, gloves must be worn:

- regardless of the situation, select a latex or nitrile model that meets standard EN 374-2;
- if the risk analysis indicates a viral risk, the model must also meet standard ISO 16 604;
- for level 3 confinement, if only a single pair of gloves is worn, the model’s AQL must be 0.65;
- for level 2 or 3 confinement, if two pairs of gloves are worn, the AQL can only be 1.5;
• if a double pair of gloves is worn and two different materials are chosen, wear the latex glove on the outside and the nitrile glove on the inside.

A type-FFP2 filter mask must be worn to provide protection against biological agents that contaminate through airways.

**Waste management and disinfection**

Disinfection is obtained through autoclaving (121°, for 20 minutes, under water vapor saturation). Disinfection can also be obtained chemically. Special training is required to use the autoclave.

Choosing a commercial disinfecting product takes into account its activity spectrum and its method of disinfection (surface, soaking, airborne). The dilutions and contact time recommended by the supplier must be complied with. Disinfection follows a specific plan for a prion risk. Contact your prevention advisor.

Biological waste (called BMW for biomedical waste, in French, DASRI for « health care waste presenting infectious risks ») must be collected in containers that comply with standards:

- sharps waste collector: NF X 30-500;
- cardboard box doubled with plastic: NF X 30-507;
- plastic drum: NF X 30-505;
- canister: NF X 30-506.

For waste produced in level 3 confinement, disinfection is done through in situ autoclaving. Except cadavers of transgenic animals, GMO waste of all classes must be deactivated inactivated before they are collected. Waste produced in level 2 confinement must or must not be deactivated inactivated before collection, according to the risk analysis.

Waste management may present local or site particularities. Your prevention assistant should be contacted in order to know these.

**Medical follow-up**

Annual medical follow-up is required for all manipulators of level 2 and 3 confinement. It is recommended to consult the prevention doctor for any new type of activity in a confined area (for example, a change in the pathogenic agent handled). The prevention doctor will check that the vaccinations are up to date and may request where necessary that changes be made to the jobs of pregnant or lactating women, or for the immunosuppressed.

**In case of an accident**

Four « Conduct to adopt » sheets are available in the event of an accident with exposure to a biological risk:

- accident with a laboratory animal;
- accident with a primate.

They are available from your prevention assistant.