Biological Agents and Risk Assessment

Dr Mary McDonnell
Safety Officer (Biological Hazards)
Biological agent

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

- Bacteria
- Fungi
- Helminths
- Prions
- Protozoa
- Viruses
Biological agent

Personnel may be harmed by:

• being infected by a biological agent,

• being exposed to toxins produced by the biological agent, or

• having an allergic reaction to the biological agent or substances it produces, for example, enzymes.
Legislation, COP & Guidelines

STATUTORY INSTRUMENTS.

S.I. No. 572 of 2013

SAFETY, HEALTH AND WELFARE AT WORK (BIOLOGICAL AGENTS) REGULATIONS 2013

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

Guidelines on Risk Assessments and Safety Statements

Trinity College Dublin
Coláiste na Trionóide, Baile Átha Cliath
The University of Dublin
Risk group - Biological agent

- **Group 1** Unlikely to cause human disease.
- **Group 2** Can cause human disease; unlikely to spread to community; treatment available.
- **Group 3** Can cause severe human disease; risk to community; treatment available.
- **Group 4** Can cause severe human disease; high risk to community; no effective treatment.

A list of biological agents and their classification and containment requirements are in the *Biological Agents Regulations (2013)* and the associated *Code Of Practice*.

UK - Advisory Committee on Dangerous Pathogens – recent amendments
Simple system for implementation

- Identify biological agents to be used or those that may be present in the materials to be handled

- Classify each into one of four Risk Groups
  - if not on the list seek evidence of pathogenicity; do not automatically in Group 1
  - if there is any uncertainty then the higher of the two possible groups should be chosen

- The number of the Risk Group indicates the level of containment under which the work must be carried out

- Identify whether any additional control measures needed
Categorisation is based on the infective hazard to healthy adult workers, it does not allow for any additional risk to individual workers caused by for example

➢ pre-existing disease
➢ the effects of medication
➢ compromised immunity
➢ pregnancy or breastfeeding
Classification and containment levels
Classification of biological agents and containment levels

Risk Group (1,2,3,4) - wild type organisms

Classes (1,2,3,4) - genetically modified microorganisms (GMMs) only

- (other genetically modified organisms are not sub-categorised they are referred to as GMOs)

Containment level: CL1, CL2, CL3 and CL4

- Refers to the appropriate work environment (not the Biosafety cabinet class) for the biological agent used – the risk group or class of agents determines the containment level to be used.

- Note there is no such classification as ‘Category’ in official use in Ireland.

Biological Safety Cabinets (BSCs) Class I, II, III

- Biological safety cabinets I and II can be used with risk group and class 2 and 3 organisms
## Second Schedule - Containment Measures and Containment Levels

<table>
<thead>
<tr>
<th>Containment Measures</th>
<th>Containment level 2</th>
<th>Containment level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The workplace is to be separated from any other activities in the same building</td>
<td>No</td>
<td>Recommended</td>
</tr>
<tr>
<td>2. Input air and extract air to the workplace are to be filtered using HEPA or likewise</td>
<td>No</td>
<td>Yes, on extract air</td>
</tr>
<tr>
<td>3. Access is to be restricted to nominated workers only</td>
<td>Recommended</td>
<td>Yes</td>
</tr>
<tr>
<td>4. The workplace is to be sealable to permit disinfection</td>
<td>No</td>
<td>Recommended</td>
</tr>
<tr>
<td>5. Specified disinfection procedures</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>6. The workplace is to be maintained at an air pressure negative to atmosphere</td>
<td>No</td>
<td>Recommended</td>
</tr>
<tr>
<td>7. Effective vector control e.g. rodents and insects</td>
<td>Recommended</td>
<td>Yes</td>
</tr>
</tbody>
</table>
## Second Schedule - Containment Measures and Containment Levels

<table>
<thead>
<tr>
<th></th>
<th>8. Surfaces impervious to water and easy to clean</th>
<th>Yes, for bench</th>
<th>Yes, for bench and floor</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>9. Surfaces resistant to acids, alkalis, solvents, disinfectants</td>
<td>Recommended</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>10. Safe storage of a biological agent</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>11. An observation window, or alternative, is to be present, so that occupants can be seen</td>
<td>Recommended</td>
<td>Recommended</td>
</tr>
<tr>
<td></td>
<td>12. A laboratory is to contain own equipment</td>
<td>No</td>
<td>Recommended</td>
</tr>
<tr>
<td></td>
<td>13. Infected material including any animal is to be handled in a safety cabinet or isolator or other suitable containment</td>
<td>Where appropriate</td>
<td>Yes, where infection is by airborne route</td>
</tr>
<tr>
<td></td>
<td>14. Incinerator for disposal of animal carcases</td>
<td>Recommended</td>
<td>Yes (available)</td>
</tr>
</tbody>
</table>
Laboratory-acquired infections (LAIs)

In 2009, Malcolm Casadaban, a University of Chicago scientist with an underlying medical condition, died from an infection with a weakened strain of plague bacteria. In 2012, 25-year-old researcher Richard Din died after being infected during vaccine research involving Neisseria meningitides bacteria at a lab inside San Francisco's VA medical center. Both of their deaths involved research in containment level 2 labs, where pathogens are considered to be less dangerous than those worked with in high-containment labs.
Table 1
Cross-tabulation Between Type of Entity and Incident Reporting (1976-2010)

<table>
<thead>
<tr>
<th>Entity Type</th>
<th>Total Reports</th>
<th>Risk Group of Agent</th>
<th>BSL²</th>
<th>ABSL²</th>
<th>Incident Type³</th>
<th>Compliance with NIH Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1 2 3</td>
<td>Unk¹</td>
<td>1 2 3</td>
<td>1 2 3</td>
<td>A B D E U N</td>
</tr>
<tr>
<td>Academic</td>
<td>170</td>
<td>14</td>
<td>121</td>
<td>34 1</td>
<td>0 74 21</td>
<td>5 57 10</td>
</tr>
<tr>
<td>Government</td>
<td>6</td>
<td>1</td>
<td>5</td>
<td>0</td>
<td>0 5 0 0</td>
<td>0 0 0 0</td>
</tr>
<tr>
<td>Hospital</td>
<td>15</td>
<td>4</td>
<td>9</td>
<td>2</td>
<td>0 6 1 1</td>
<td>6 0 0</td>
</tr>
<tr>
<td>Private</td>
<td>6</td>
<td>1</td>
<td>4</td>
<td>1</td>
<td>0 3 1 0</td>
<td>1 0 0</td>
</tr>
<tr>
<td>Total</td>
<td>197</td>
<td>20</td>
<td>139</td>
<td>37 1</td>
<td>1 88 23</td>
<td>6 64 10</td>
</tr>
</tbody>
</table>

¹ Unk: Unknown
² Animal/Biosafety Levels (ABSL/BSL)
³ Incident Type Key: A) Autoinoculation (needle and syringe or straight pin, broken glass other than pipette, abrasion, glass pipette); B) Bite from animal or ectoparasite; D) Disregard for safety; E) Environmental release (aerosol, animal escape, droplet, fomite transfer); U) Unauthorized work; and N) Not identified.
<table>
<thead>
<tr>
<th>Type of Incident</th>
<th>Agent(^1)</th>
<th>Administrative Controls</th>
<th>Engineering Controls</th>
<th>Safe Work Practices</th>
<th>PPE Use</th>
<th>Vaccinated</th>
<th>Laboratory-acquired Infection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fomite transfer (Touched eye and ear with contaminated gloved hand)</td>
<td>Vaccinia virus</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Y</td>
</tr>
<tr>
<td>Needlestick</td>
<td>Vaccinia virus</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Y</td>
</tr>
<tr>
<td>Needlestick</td>
<td>Vaccinia virus</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Y</td>
</tr>
<tr>
<td>Needlestick</td>
<td>Vaccinia virus</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Y</td>
</tr>
<tr>
<td>Not identified</td>
<td><em>Shigella flexneri</em></td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Not Available</td>
<td>Y</td>
</tr>
<tr>
<td>Not identified</td>
<td><em>Escherichia coli</em> 0157:H7</td>
<td>Yes</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Not Available</td>
<td>Y</td>
</tr>
<tr>
<td>Needlestick</td>
<td>Vaccinia virus</td>
<td>Unknown</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Y</td>
</tr>
<tr>
<td>Fomite transfer (Improper disposal of contaminated gloves)</td>
<td><em>N. meningitides</em></td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Y</td>
</tr>
<tr>
<td>Broken glass</td>
<td>Vaccinia virus</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Y</td>
</tr>
<tr>
<td>Droplet or splash</td>
<td>Vaccinia virus</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Y</td>
</tr>
<tr>
<td>Needlestick</td>
<td>Vaccinia virus</td>
<td>No</td>
<td>Unknown</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Y</td>
</tr>
<tr>
<td>Not identified</td>
<td>Adenovirus, Type 5, and; Adeno-associated virus</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
<td>No</td>
<td>Y</td>
</tr>
<tr>
<td>Needlestick</td>
<td>Vaccinia virus</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Y</td>
</tr>
<tr>
<td>Needlestick</td>
<td>Vaccinia virus</td>
<td>No</td>
<td>Unknown</td>
<td>No</td>
<td>Unknown</td>
<td>No</td>
<td>Y</td>
</tr>
</tbody>
</table>

\(^1\)Vaccinia virus: A total of 19 documented exposures reported under the NIH Guidelines since January 1, 1976.
Routes of infection

- Inhalation Of The Agent
- Subcutaneous Entry / Needlestick
- Physical Contamination
- Ingestion Of The Agent
- Entry Via Mucosal Membranes
- Entry Via Damaged Skin
- Transplacental
Routes of infection; most common in a lab setting

- Inhalation
- Needle stick injury / animal bite
- Direct contact (skin or mucous membrane)
- Ingestion

*Biological Risks and Laboratory Acquired Infections – A reality that cannot be ignored in health biotechnology.* Front. In Bioeng. & Biotechnol. 3(56) 2015. 
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4412124/
WHY we need to do Risk Assessment?

- **Protect Ourselves**
  - RA is key to prevention of accident
  - Everyone deserve to go home safely at the end of the day

- **Elevate safety awareness & ownership**
  - Aware of hazards, risks and controls and practicing safe science

- **University Policy/Procedures**

- **Compliance with Legislation/Regulations**
Risk assessment flow chart – Biological Agents

1. **RESEARCH** information.  
   **WHAT:** Is the pathogen bacterial, virus, fungi, parasite or prion?

2. **WHERE:** Reservoir or geographic location for pathogen?  
   **WHEN:** Incubation period and; **HOW** infection is disseminated, transmitted, or acquired?

3. **HOW:** How are workers at risk?  
   **IDENTIFY** at-risk objects, equipment, tasks, environments in your workplace and ascertain **HOW** often risk occurs?

4. **CLASSIFY RISK** Likelihood x Severity—Low, Intermediate, or High-Risk?  
   **ASSESS** level of contact with hazardous material during work?

5. **WHAT:** Select exposure control measures that will provide required protections.  
   **USE** hierarchy of controls.

6. **WHAT:** Site specific exposure control plan  
   **WHEN:** Implementation plan  
   **HOW:** Hazard communication and post-exposure procedures.

7. **CONTINUED TRAINING:** Awareness, operations, and/or hands-on training.
**TCD Biological Agents Risk Assessment Process**

**PI/Supervisor/Manager**
- Complete Biological Agent Project Risk Assessment form & SOPs
- Consult College Health Service if applicable
- Register and submit for review with School Safety Officer
- Submit to University Biological Hazards Safety Officer for review by University Biological Safety Committee
- Notification to Health and Safety Authority 30 days prior to commencement of work

**Laboratory Personnel**
- Read completed Biological Project Risk Assessment
- Complete Training:
  - Local Lab Induction Training
  - Online Health and Safety Module
  - Attend University Biological Safety Workshop
  - Personnel Biological Training Record
- Review and register with School Safety Officer
Biological Agents Project Risk Assessment

This form must be completed to comply with the provisions of; The Safety Health and Welfare at Work (Biological Agents) Regulations 2013. If you are using any chemicals, a separate chemical Risk Assessment must be completed.

A key requirement of the legislation is to assess the risks associated with projects involving the use of biological agents. Biological agents include, micro-organisms; natural or genetically modified, cell cultures, endotoxins, human or animal tissues, fluids, preparations and derivatives, which may be able to cause an infection, allergy, or toxicity.

NOTES:

- This risk assessment is intended for use by individuals (usually Principal Investigators (PI) / Project Supervisors / Managers) that will undertake or supervise work, which may involve exposure to materials which may be biologically hazardous.
- Conduct/record periodic reviews and notify significant alterations using a new form.
- This form is not for assessing the risks associated with genetically modified activities.
- This form should only be completed after reading the appropriate legislation and guidance notes, available at [https://www.tcd.ie/elsewhere/facilities/health-and-safety/lab-safety/biological-safety/](https://www.tcd.ie/elsewhere/facilities/health-and-safety/lab-safety/biological-safety/)
- All biological materials should be treated as being potentially hazardous until proven otherwise.
- If the risk assessment defines the activity as Risk Group 1 or Risk Group 2, please complete this form and append a copy of the standard operating procedures (SOPs), information for workers concerning facility use and the emergency response plans.
- If the risk assessment defines the activity as Risk Group 3, please complete this form and append a copy of the SOPs, information for workers concerning the operation of the Containment Level 3 facility and the emergency response plans.
- Prior to commencement of any work this form MUST be:
  - reviewed by the School Safety Officer (SSO),
  - reviewed the College Biohazard Officer (CBO), and
  - subsequent submission to Health and Safety Authority 30 days prior to commencement of work with respect to the following:
    - First time use of a group 2 biological agent
    - First time and subsequent use of a group 3 biological agent.

GENERAL DETAILS:

<table>
<thead>
<tr>
<th>Name of PI / Supervisor / Manager:</th>
<th>Staff Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>School / Department / Centre:</td>
<td></td>
</tr>
</tbody>
</table>

Work commencement date: 
Expected completion date:

Name of Local Safety Officer (LSO):

Have you registered with your LSO Yes [ ] No [ ]

Refer to Biological Agents Project Risk Assessment form to enable completion of the following section.

HAZARD IDENTIFICATION

1) Biological agents to be used:

<table>
<thead>
<tr>
<th>Biological Agent(s)</th>
<th>Risk Group (Select from 1-3)</th>
</tr>
</thead>
</table>

Containment Level required (Specify the containment level required)

Level 2 [ ] Level 3 [ ]

Refer to Safety Health and Welfare at Work (Biological Agents) Regulations 2013.
Risk Assessment Review

Regular intervals—annually

Whenever a change in research program occurs

- Move or renovation
- New employee
- New pathogen or reagent
- New equipment
- New technique or procedure.
Control Measures
Hierarchy of Risk Control Measures

1. Eliminate / Substitute
2. Engineering Controls
3. Administrative Measures
4. PPE
What does the law say?

The Biological Agents regulations requires the employer to conduct a risk assessment:

- Assess any risk to the safety and health of employees resulting from any activity likely to involve a risk of exposure of any employee to a biological agent.
- Keep the risk assessment in written form
- Assess the risk, in the case of activities involving exposure to several groups of a biological agent, on the basis of the danger presented by all hazardous biological agents present.
- Renew the risk assessment regularly and, in any event, whenever there is a change in conditions at the place of work which may affect any employee's exposure to a biological agent.
Control Measures – Biological Agents

Eliminate
– substitution
– transfer

Minimise
– Engineering controls
– Vaccination/ Health Surveillance
– Training of all personnel, Emergency Plans
– Training of all personnel, Emergency Plans
– Safety work procedures/ Standard operating Procedure
– Personal Protective Equipment (PPE)
Engineering Controls – Biological Agents

- Negative pressure laboratory
- Biological safety cabinet
- Containment levels
- Sealed centrifuge rotors
- Pipetting devices
- Robust and leak proof containers
- Anti needle stick devices
- Puncture resistant sharps containers
Good Laboratory Practice

- Restrict access to the lab
- Hazard & Safety signs on entrance to the lab
- Prohibit eating, drinking and smoking in the laboratory
- Pipetting by mouth strictly forbidden
- Wear appropriate clothing and PPE as per risk assessment
- Remove PPE and wash hands before exiting the lab
Transport of Biological Agents

If moving biological agents from a site/place of work, consideration must be given to the Dangerous Goods Modal Transport Regulations -

**Classification**

Biological agents which are classed as pathogenic (as defined by ADR - see below) will be assigned to Class 6.2, infectious substance of ADR. Genetically modified microorganisms (GMMs) will generally be assigned to Class 9 if they do not meet the definition of toxic substances or of infectious substances under ADR but are capable of altering animals, plants or microbiological substances in a way not normally the result of natural reproduction.
Transport of Biological Agents

Note: Class 6.2 of ADR does not refer specifically to biological agents but instead refers to **infectious substances**. Infectious substances are defined under ADR as substances which are known or are reasonably expected to carry pathogens. Pathogens in turn are defined under ADR as microorganisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals. **It should be noted that ADR is broader in scope than the Biological Agents Regulations as it covers microorganisms which cause disease in animals also.**

**Class 6.2**
Substances of class 6.2 are subdivided as follows:
I1 Infectious substances affecting humans;
I2 Infectious substances affecting animals only;
I3 Clinical waste;
I4 Biological substances.

[https://www.hsa.ie/eng/topics/biological_agents/biological_agents_introduction/transporting_biological_agents/](https://www.hsa.ie/eng/topics/biological_agents/biological_agents_introduction/transporting_biological_agents/)
Transport of Biological Agents by air

CHECKLIST FOR SHIPPING BIO SAMPLES

Marking and Labelling on the Package

- Ensure that your account is approved to ship Dangerous Goods
- Shipper and Cnee name and address
- UN3373 label (or marking)
- Label can be either in 100mm x 100mm or 50mm x 50mm diamond format
- All labels must be sufficiently durable to withstand normal transport conditions
- Labels must not cover any other marking or label
- Label must not be folded over two sides of the package
- Labels must be located on the same surface of the package as the proper shipping name.

Required in description of Goods on the waybill

- UN3373
- Biological Substance, Category B

DHL Express Ireland 2016
Transport of Biological Agents by air

CHECKLIST FOR EXEMPTED BIO SPECIMEN

Marking and Labelling on the Package

- The DHL account must be approved for Exempt Human or Animal Specimens
- The shipment must be triple packed in a leak-proof primary receptacle
- A leak-proof Secondary receptacle and then Outer packaging of no less than 100mm X 100mm and capable of withstanding normal shipping conditions (Does not need to be UN spec)
- When shipping liquids, enough absorbent material to absorb entire contents of substance, should be placed between the first and second receptacles

Required in description of Goods on the waybill

- All that is required on the waybill is the description “Exempt Human Specimen” or “Exempt Animal Specimen”
Transport of Biological Agents by air

CHECKLIST FOR DRY ICE

Marking and Labelling on the Package

- The DHL account must be approved to ship Dry ice
- Shipper and Cnee name and address
- UN1845 Dry Ice along with the net weight
- Class 9 Miscellaneous label
- Label must be in 100 X 100mm diamond format
- Must be sufficiently durable to withstand normal transport conditions
- Must not cover any other marking or label
- Must be affixed to one face of the package only
- Labels must be located on the same surface of the package as the Proper Shipping Name

Required in description of Goods on the waybill

- UN1845
- Dry Ice
- (Class) 9
- Net weight of the Dry Ice per package
- Number of packages

DHL Express Ireland 2016
Transport of Biological Agents by air

WHERE CAN I LEARN MORE?

Mayo Clinic training Module, shipping Specimens and Biological samples:
http://www.mayomedicallaboratories.com/education/online/dangerousgoods/

Helpful YouTube videos:
http://www.youtube.com/channel/UCfXKxo5EK0JGndpJNHX9kVg?feature=watch

Dry Ice - http://dryice.ie/

Label Supplies:
Label Line - http://www.labeline.com/store_uk/

Southern Tapes & Packaging (ORK) - http://www.southerntapes.ie/

Trident Safety Group (ORK) - http://www.tridentsafety.com/

DHL Express Ireland 2016
Thank You