Working with Biological Agents - Frequently asked Questions

1. **I want to start a project involving the use of biological material. What are my first steps?**
   If you are commencing a new project involving biological material, for example:

   - Biological samples
   - Clinical samples,
   - Viruses,
   - Prions,
   - Animal models,
   - Bacterial strains (genetically-modified or wild-type)
   - Mammalian cells/cell lines (genetically-modified or wild-type)

   Your first two steps are to (i) download the **Biological Agent Classification Flow Chart**, which is decomposed into three **Process Flow Charts** (A,B and C) and (ii) to download the **Biological Agent Risk Assessment**.

2. **Where can I download the forms?**
   These forms can be accessed at this link
   http://www.dcu.ie/science_and_health/safety_info.shtml.

3. **What information is contained in Process Flow Charts A, B and C?**
   Process flow chart A identifies the steps to be taken in identifying whether your research falls into Hazard Group 1 or Hazard Group 2 (and above). If your work falls into Hazard Group 1, you are advised to proceed to **Flow Chart B**. If your work falls into Hazard Group 2, 3 or 4, you are advised to proceed to **Flow Chart C**.

4. **What is a Biological Agent, and where does the definition of Hazard Group arise from?**
   In accordance with the **Biological Agents Regulations (2013)**, Biological Agent means micro-organisms (including those which have been genetically modified), cell cultures and human endoparasites, which may be able to provoke any infection, allergy or toxicity. To stratify their risk to individuals working with this material (both directly and indirectly) and also the environment, these agents are classified into 4 risk groups according to their level of risk of infection, specifically Hazard Group 1, 2, 3 and 4.

5. **What biological agents fall into Hazard Groups 1,2,3 and 4?**

   Hazard Group (HG) 1: Biological agents that are unlikely to cause human disease to employees.
   Hazard Group (HG) 2: A biological agent that can cause human disease and might be a hazard to employees.

Hazard Group (HG) 3: A biological agent that can cause severe human disease and presents a serious hazard to employees and which may present a risk of spreading to the community.

Hazard Group (HG) 4: A biological agent that causes severe human disease and is a serious hazard to employees and which may present a high risk of spreading to the community.

6. What is the basis for this classification?

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).

7. How do I know what hazard group my work falls into?

With reference to Process Flow Chart A, the first key action is to complete a **Biological Agent Risk Assessment**, which allows the individual to determine the biological risk of working with this material. The researcher is also advised to review **Schedule 1** of the **Biological Agents Regulations (2013) Code of Practice**, which can be downloaded here:

http://www.hsa.ie/eng/Publications_and_Forms/Publications/Codes_of_Practice/2013_Code_Of_Practice_for_Biological_Agents.html

This document (pages 11-29) contains a list of hazard group ratings for a panel of biological agents in the following categories: (1) bacteria, (2) fungi, (3) helminths, (4) prions, (5) protozoa and (6) viruses.

8. What is the first key action identified in Process Flow Chart A?

Complete the **Biological Agent Risk Assessment**.

9. Why do I conduct a risk assessment?

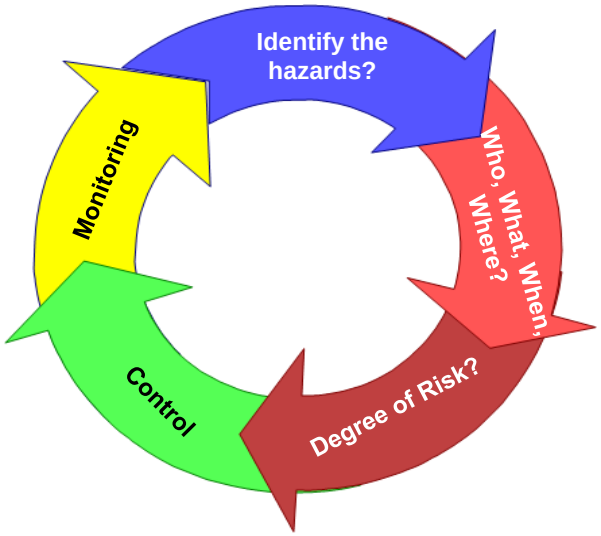
A risk assessment allows you to assess the risk(s) associated with a specific set of activities or tasks. It also assists the individual in correctly identifying the severity of the Hazard and its potential outcomes, when considered in conjunction with other factors. The **Safety, Health and Welfare at Work (General Applications) Regulations, 2007** (Statutory Instrument (S.I.) no. 299 of 2007, Regulation 2(3) states that: *"it is a requirement of employers to identify many significant hazards of the workplace and conduct proper risk assessments."*

10. What is the difference between a risk and a hazard?

A Hazard is a potential source of harm or adverse health effect on a person or persons.

A Risk is the likelihood that a person may be harmed or suffers adverse health effects if exposed to a hazard.

11. **In completing a risk assessment, what are the key things that I need to consider?**
    There are five key steps here, specifically:



    A link to a useful video outlining these steps (albeit not in a biosafety environment) is shown here: http://hsa.ie/eng/Small_Business/Risk_Assessment_Made_Easy/

12. **In identifying the hazards when completing the Biological Agent Risk Assessment, what are the key things I need to consider?**
    For work with biological agents or material containing biological agents, the key considerations are as follows: (i) *What will I be handling?*, (ii) *How much do I know about this material?, (iii) What factors could affect the hazard level of this material / activity?, (iv)* Is the work absolutely necessary, or can an alternative method / material be used? and (v) Can I use a less-hazardous material?

13. **In determining who, what, when and where when completing the Biological Agent Risk Assessment, what are the key things I need to consider?**
    For work with biological agents or material containing biological agents, the key considerations are as follows: (i) Who will do the work?, (ii) What will the work involve?, (iii) When will the work be performed?, (iv) Where do they intend to do this? And (v) Who could be affected by this work? Here, one should also consider other individuals who may be affected by this work, such as co-workers in the laboratory and cleaning staff, especially where overnight procedures are to be undertaken.

14. **In evaluating the risk when completing the Biological Agent Risk Assessment, what are the key things I need to consider?**
    This is the process of estimating the likelihood of an event occurring (e.g. exposure to a biohazard) and identifying the likely consequence of exposure. This can be represented as a Risk Matrix generating a Risk Rank / Factor. Here, one estimates the potential severity of harm versus likelihood of the event happening (or consequence vs probability), and determining a risk rating.

15. What does the risk matrix look like, and how does it work?

The risk matrix is shown below. Here, severity (of an incident resulting from a risk) is decomposed into three classifications, (i) slightly harmful, (ii) harmful and (iii) very harmful. Likelihood (or the risk resulting in an incident) is determined as being unlikely, likely or very likely.

Severity → ↓ Likelihood	Slightly Harmful	Harmful	Very Harmful
Unlikely	Trivial	Acceptable	Medium
Likely	Acceptable	Medium	Substantial
Very Likely	Medium	Substantial	Intolerable

The grid works as follows: the individual (through their risk assessment) determines the severity (slightly harmful, harmful or very harmful) of the risk, and then the likelihood (unlikely, likely or very likely) and then extrapolates to determine the **Risk Rating**. For example, if it is **Unlikely** and **Very Harmful** the risk is ***Medium***. If it is **Very Likely** and **Very Harmful**, the risk is ***Intolerable***.

- Low risk activities are identified as being *Trivial or Acceptable (Green)*.
- Medium risk activities are identified as being *Medium (Orange).*
- High risk activities are identified as being *Substantial or Intolerable (Red)*.

16. After determining the risk of the activity, what happens next?

- If the **Risk Rating** is **Intolerable or Substantial:**
  Cease/do not commence activity until further controls are implemented.
- If the **Risk Rating** is **Medium:**
  Consult Biological Safety Advisor.
- If ALL risk ratings are **Trivial / Acceptable:**
  No further controls required.

For **Medium / Intolerable or Substantial Risks:** further control measures are to be implemented to reduce the residual risk.

17. My work involves genetic modification. What do I do here?

Contact the Biological Safety Advisor (BSA), who can be contacted at the following address: bio.safety@dcu.ie. There is a legal requirement to notify the **Environmental Protection Agency** (EPA) of your intention to undertake this work, and individuals who intent to genetically-modify organisms or microorganisms require an EPA licence. In accordance with the Genetically Modified Organisms (Contained Use) Regulations, 2001 (SI No. 73 of 2001):

- Micro-organism means any microbiological entity (cellular or non-cellular), capable of replication or of transferring genetic material, including viruses, viroids and animal and plant cells in culture.

- Genetically-modified micro-organism means a micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating or natural recombination, or by a combination of both.

18. **Should I make direct contact with the EPA?**
    No. All EPA engagement is to be undertaken by the Biological Safety Advisor (BSA), who can be contacted at the following address: bio.safety@dcu.ie.

19. **I am unsure how to complete these forms. Who can I contact to assist/advise me?**
    The University has appointed a Biological Safety Advisor (BSA), who can be contacted at the following address: bio.safety@dcu.ie

20. **What additional documentation is required?**
    In addition to the Biological Agent Risk Assessment, if your work is deemed to fall into Hazard Group 1 activity, you will be required to submit a **Notification Form** and a **Standard Operating Procedure (SOP) for each associated risk** to the Biological Safety Advisor. As summarised in **Process Flow Chart B**, the application is review and, if the activity is deemed not to satisfy the criteria of Hazard Group 1, you will be advised to proceed to **Process Flow Chart B** and submit a full application to the Biological Safety Committee. This is specific to Class (Hazard Group) 2 and above activity.

21. **Where can I download these forms?**
    The link is here http://www.dcu.ie/science_and_health/safety_info.shtml
    Remember, Hazard Group 1 activities require the completion of the Notification Form, while Hazard Group 2 and above require the completion of the full application form.

22. **What happens to my application once I have completed it?**
    Hazard Group 1 submissions are sent to the Biological Safety Advisor (bio.safety@dcu.ie). Full applications are submitted to grace.kelly@dcu.ie, and the documents are reviewed by the full Biological Safety Committee.

23. **What is the duration for reviewing these documents?**
    The typical turnaround time for Notifications is 1-2 weeks. For full applications, this is 4 weeks.

24. **My research project may require the use of animals. In addition to getting approval from the Biological Safety Committee, what additional approval is needed?**
    The use of animals for scientific or educational purposes is very strictly regulated at European, national and university level, and requires multiple approvals. You must first receive advice and a recommendation from DCU's Bio Resource Advisory Group (BRAG), followed then by approval from the DCU Research Ethics Committee (REC). If they approve the use of animals in your project, you will then need to get the relevant authorisations from the Health Products Regulatory Authority (HPRA), for the procedures required by the project, and for the individuals managing the project and/or carrying out the

procedures. For detailed advice on how to proceed you should contact the Chairman of the BRAG, by sending an E-mail to bru@dcu.ie

25. **My project also requires ethical approval. Can I apply for this in parallel with the Biological Safety Committee and BRAG applications?**
No. Approval from the Biological Safety Committee (BSC) and BioResearch Advisory Group (BRAG) is required prior to seeking ethical approval.

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