



GM Risk Assessment Form 1: Genetically Modified Microorganisms

A GM risk assessment is required for any work involving the possession or use of genetically modified microorganisms and related materials. Please complete this form and email it to your GM Biological Safety Officer (GMBSO) to submit it to your GM Biological Safety Committee (GMBSC). The School GMBSO provides advice to Principal Investigators on GM risk assessment and HSE notification. You should read the guidance provided on [GM risk assessment](#) and [biological safety](#) on the Biosafety Unit website. Please complete the boxes that apply to your work.

Section 1 Basic Details

Title of project	
Local reference number	
HSE reference number	
Principal investigator	
School / Institute	
Date of application	
Location of work (Building and room numbers)	

Section 2 Project

This section should describe the project, host organisms, vectors and genetic materials which should be reasonably detailed but not exhaustive.

2.1: Description of the project and activities including the methods to be used and the purpose of the genetic modification

2.2: Expected maximum titres and culture volumes

2.3: Host organisms and hazard groups

2.4: Vector systems

2.5: Genetic inserts or materials (eg origins, nature of genetic modifications and intended functions)

Section 3 Risk Assessment	
This section should describe any potential risks to humans and or the environment. It should include a clear and explicit justification of any statements made about the risks with a logical explanation and any relevant evidence or references. The level of risk is estimated using the matrix given at the end of this form and then stating the risk as either Effectively zero, Low, Low / Medium, Medium or High.	
3.1 Risks to human health	
3.1.1: Characteristics of the host and any hazards associated with it	
3.1.2: Characteristics of the vector system and any hazards associated with it	
3.1.3: Source and characteristics of the inserted gene products and any hazards arising directly from their use including an estimation of the level of expression and biological activity of the recombinant gene product (eg toxins, carcinogens, allergens, virulence or immunomodulatory products)	
3.1.4: Hazards arising from the alteration of any existing pathogenic traits, if applicable	
3.1.5: Potential hazards of sequences within the GM microorganism being transferred to related microorganisms	
3.1.6: Does this work pose a specific risk to susceptible individuals such as immunocompromised people, pregnant women, new mothers, etc. If so, please provide details below.	Yes / No
3.1.7: The overall likelihood that in the event of exposure the GM microorganism could cause harm to human health	
3.1.8: Overall assessment of risk to human health (Prior to use of controls)	
Level of risk (Select one)	Effectively zero / Low / Medium/Low / Medium / High
3.2 Risks to environment	
3.2.1: What is the capacity of the GM microorganism to survive, establish, disseminate with and or displace other organisms	
3.2.2: What is its ability to cause harm to animals	

3.2.3: What is its ability to cause harm to plants	
3.2.4: What is its ability to cause harm to any other organisms	
3.2.5: What is the potential for transfer of genetic material between the GM microorganism and other organisms	
3.2.6: Is there any hazard as a result of phenotypic or genetic instability	
3.2.7: Overall assessment of risk to environment (Prior to use of controls)	
Level of risk (Select one)	Effectively zero / Low / Medium/Low / Medium / High
3.3 Risk classification for GM microorganisms	
3.3.1 Assign the risk class (Select one)	1 / 2 / 3

Section 4 Control Measures to Eliminate or Reduce Risks of Exposure or Release	
This section should describe the types of controls which will be required to carry out the work safely. You must follow the hierarchy of risk control by choosing the most effective control measures needed to safely carry out your work and not just the easiest controls. Please do not include detailed standard operating procedures which should be specified in a separate document.	
4.1: Containment level (Select one)	1 / 2 / 3
4.2: Containment laboratories or facilities	
Select all that apply	Laboratory / Animal facility / Plant facility / Other
4.3: Microbiological safety cabinets (MSC) and isolators	
Select all that apply	Class I / Class II / Class III / Isolator / Other
4.4: Sharps controls	
4.5: Special controls	
4.6: Personal protective equipment (PPE)	

Select all that apply	Lab coat / Lab gown / Surgical scrubs / Disposable clothing / Apron / Safety spectacles / Goggles / Face shield / Gloves / Headwear / Footwear / Other
4.7: Respiratory protective equipment (RPE)	
Select all that apply	Filter mask / Half face respirator / Full face respirator / Powered respirator / Breathing apparatus / Other
4.8: Storage controls	
4.9: Transport controls	
4.10: Inactivation controls	
Select all that apply	Disinfection / Autoclave / Fumigation / Incineration / Other
<p>Disinfection Please give details of disinfectant(s), method and validation including concentration of disinfectant and contact time (eg supplier's instructions or local validation).</p> <p>Autoclaving Please give details of autoclave method and validation.</p> <p>All contaminated materials will be inactivated by autoclaving (100% kill) at 121°C or 134°C prior to disposal of waste or cleaning and recycling of reusable laboratory equipment, such as glassware. Autoclaves will be validated by annual (at least) thermocouple mapping and each run will be monitored by continuous chart or digital recording of the temperature / time profile.</p> <p>Or</p> <p>All contaminated materials will be inactivated by autoclaving (100% kill) at 121°C or 134°C prior to disposal of waste or cleaning and recycling of reusable laboratory equipment, such as glassware. Autoclaves will be validated by annual (at least) thermocouple mapping and each run will be monitored using chemical indicators (eg Browne TST indicator test strips).</p> <p>Other (Please give details of method and validation).</p>	
4.11: Waste disposal routes	
4.12: Immunisations (if applicable)	
4.13: Instructions, training and supervision	
4.14: HSE notification (if applicable)	

4.15: Specified Animal Pathogen Order (SAPO) licence (if applicable)
4.16: Plant Health Order (PHO) licence (if applicable)
4.17: Import, export or other licence (if applicable)

Section 5 Emergency Procedures		
This section should describe any emergency procedures used to deal with accidental exposure, release or spillages.		
5.1: Emergency procedures		
5.2: Emergency contacts		
Name	Position	Telephone
	Principal Investigator	

Section 6 Emergency Planning	
This section should describe any emergency plan used to deal with serious accidental release. An emergency plan is only required for high risk work.	
6.1: In case of serious accidental release is an emergency plan required to protect humans or environment	Yes / No

Section 7 Approval		
This section should be signed and dated by the assessor, principal investigator and GMBSO.		
7.1: Assessor		
Name	Signature	Date
7.2: Principal investigator		
Name	Signature	Date
As the principal investigator for this project you have a legal responsibility to ensure that all those involved or working on the project have an appropriate level of training and expertise to enable safe working. This includes ensuring that workers read and understand this risk assessment and that all the control measures are in strict accordance with those approved for the project. You should also check for compliance with the control measures.		
7.3: School GMBSO Biological Safety Adviser for GMBSC		
Name	Signature	Date

Section 8 Review

The risk assessment must be reviewed periodically, at least annually, and immediately if there are any significant changes to the work or where the risk assessment is no longer valid.

8.1: Assessor

Name	Signature	Date

8.2: Principal investigator

Name	Signature	Date

Risk Estimation Matrix

Consequence of hazard	Likelihood of hazard			
	High	Medium	Low	Negligible
Severe	High	High	Medium	Effectively zero
Modest	High	Medium	Medium / Low	Effectively zero
Minor	Medium / Low	Low	Low	Effectively zero
Negligible	Effectively zero	Effectively zero	Effectively zero	Effectively zero