GM Risk Assessment Form 4: Genetically Modified Plants

A GM risk assessment is required for any work involving the possession or use of genetically modified plants 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: Host organisms

2.3: Vector systems

2.4: 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: What are the novel hazards to human safety (eg toxicity, allergenicity, behavioural, human disease reservoir) posed by the GM plant

3.1.2: Describe the GM plant's potential to be more toxic to humans than the parent plant

3.1.3: Describe the GM plant's potential to be more allergenic to humans than the parent plant

3.1.4: Describe the GM plant's potential to exhibit any other potential hazards to humans when compared with the parent plant

3.1.5: Does the GM plant pose a greater risk to humans than the unmodified equivalent	Yes / No

Note: If a greater risk is posed then the project must be notified to HSE following provisional approval by GMBSC

3.1.6: Does this GM plant work involve the use of any non-GM microorganism or pathogen. If so, is it hazardous to humans	Yes / No
3.1.7: Does this GM plant work involve the use of any GM microorganism or GM pathogen. If so, is it hazardous to humans	Yes / No
3.1.8: 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

3.1.9: 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 plant to survive, establish, disseminate with and or displace other plants or have adverse effects on animals or plants

3.2.2: What is the potential for transfer of genetic material between the GM plant and other organisms
3.2.3: What is the potential for harmful effects from the products of gene expression
3.2.4: What is the potential for harmful effects from phenotypic or genetic instability
3.2.5: What is the potential for harmful effects from the plants acting as novel plant disease vectors
3.2.6: Will the insert be integrated into the host chromosome in a heritable manner
3.2.7: What is its ability to cause harm to animals
3.2.8: What is its ability to cause harm to plants
3.2.9: What is its ability to cause harm to microorganisms
3.2.10: Does the proposed procedure produce a potential hazard from cloning plant pest or pathogen genes into transgenic plants such as transcapsidation, recombination, virulence or mutability
3.2.11: Does the proposed procedure involve transfer of genes highly novel to plants. If so, what if any hazards are posed

3.2.12: Does this GM plant work involve the use of any non-GM microorganism or pathogen. If so, is it hazardous to the environment	Yes / No
3.2.13: Does this GM plant work involve the use of any GM microorganism or GM pathogen. If so, is it hazardous to the environment	Yes / No
3.2.14: 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 plants	
3.3.1 Assign the risk class to human health (Select one)	Harmful / Non-Harmful
3.3.2 Assign the risk class to environment (Select one)	Harmful / Non-Harmful

3.4 Risk classification for GM microorganisms (Only required if work involves GMM)	
3.4.1 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

Disinfection
Please give details of disinfectant(s), method and validation including concentration of disinfectant and contact time (eg supplier's instructions or local validation).

Autoclaving
Please give details of autoclave method and validation.

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.

Or

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).

Other
(Please give details of method and validation).

4.11: Waste disposal routes

4.12: Immunisations (if applicable)

4.13: Instructions, training and supervision

4.14: HSE notification (if applicable)

4.15: Plant Health Order (PHO) licence (if applicable)

4.16: 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: Emergency plan required in case of serious accidental release 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

	Likelihood of hazard

Consequence 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