



<b>HEALTH AND SAFETY MANAGEMENT SYSTEM FORMS</b>		<b>Form</b>	<b>F017</b>	
 <b>PRIFYSGOL</b> <b>ABERYSTWYTH</b> UNIVERSITY	<b>Genetically Modified Organisms Risk Assessment Template</b>		<b>Issue</b>	<b>1</b>
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This template is to be used for all applications or changes to the GMO activity. Once part A is completed please email to GMSC Secretary [sian.porter@aber.ac.uk](mailto:sian.porter@aber.ac.uk)

Part A      Application to generate and use genetically modified organisms

Proposer	
Job Title	
Faculty	
Department	
Project Title	
Location/Facility for intend work	
New Equipment required	
Workers involved (inc email addresses)	Last date of GMO Training
Summary of Proposal	
Recipient Organism(s)	
Vector(s)	
Insert(s)	
Scale of Operation	< 100ml <input type="checkbox"/> < 1 L <input type="checkbox"/> < 10 L <input type="checkbox"/> Up to 20 L <input type="checkbox"/>
<b>Details of the most hazardous GMO</b>  In covering this point, hazards to both human health and the environments should be considered. Details should be provided of any disabling mutations in the recipient organism and there should be consideration of whether the inserted gene might endow the modified organism with any harmful properties. The assessment should also consider the likely hazard if the GMO were to escape (i.e. capacity to survive, establish, disseminate) and its consequences.  More information can be found in the parts 2 and 3 of the <a href="#">SACGM Compendium of Guidance</a> .	
Hazard(s) to human health:	
Disabling mutation(s):	
Is the inserted genetic material likely to confer harmful properties to the organism?	
Hazard(s) to the environment:	Likelihood of escape:
	Consequences of escape:


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	Risks associated with escape:	
Classification of the GMO(s)		
Does the work involve recipient cells that are inherently safe, inserted genes that are non-harmful to humans and the environment and a vector that has a safe history of use and is non-mobilisable?		
<b>Recipient organism(s):</b>		
<b>Inserted gene(s):</b>		
<b>Vector(s) / Insert(s):</b>		
Categorise the risk as defined by the Contained Use Regulations 2014		
Category 1 (Little or No Risk)		This indicates to have NO or negligible risk to human health or the environment based on the preliminary risk assessment above.
Category 2 (Low Risk)		
Category 3 (Medium Risk)		
Category 4 (High Risk)		
<p>If the genetic modification meets all of the above criteria, in all likelihood there is sufficient information at this stage to classify the project to Class 1, as defined in the Contained Use Regulations. In order to do this you should be confident that even in the event of a total breach of containment the genetically modified organism would be no or negligible risk to human health or the environment.</p> <p>If you are assigning the work to Class 1 according to the above streamlined procedures submit it for review to the GMSC. If the GMSC do not agree with your assessment you may be asked to complete Part B of this risk assessment. Work cannot commence until the GMSC approves the procedure.</p>		
Proposer signature:		Date:

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Part A approval – Completed following Teams workflow


<b>GM Risk Assessment Number</b>	<b>GMRA 0000</b>		
<b>Stage 1 - Infrastructure</b>	<u>Senior Research Officer, Department of Life Sciences</u>		
Additional equipment required?			
Changes to infrastructure required?			
<b>Stage 2 – Management System</b>	<u>Health, Safety &amp; Environment Team</u>		
HSE Notification required?			
Are changes to AU Public Register required?			
Additional Training Needs required?			
<b>Stage 3 – Technical Peer Review</b>	<u>GMSC Risk Assessment Panel</u>		
Any additional risk control measures?			
Any additional technical improvements identified?			
Does the panel agree with the risk category?			
Part B required?	Yes	<input type="checkbox"/>	
	No	<input type="checkbox"/>	Please complete part C – if any changes, incidents occur or at least 12 months.
Date Approved by GMSC	Email circulation of GMRA number to GMSC		

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**Part B – Risk Assessment** Projects that have a broad scope will involve the construction of several GMOs. Part B is designed for the detailed assessment of a single GMO. Hazards to human health are given first and used as the basis for assigning provisional containment prior to addressing environmental issues.

### Hazards to Human Health

<p><b>Hazards associated with the recipient organism (e.g. bacterial host, viral vector, mammalian cell).</b></p> <p><i>Factors to consider include whether the recipient organism is listed in ACDP hazard groups 2, 3 or 4 or whether there is any possibility of any disabling mutations being complemented or reverting.</i></p>	
<p><b>Hazards arising due to the inserted gene conferring the GMO with a novel or additional harmful property (e.g. cloning of a toxin gene or oncogene).</b></p> <p><i>Consideration should be given to whether the inserted DNA encodes a toxin, an oncogenic protein, an allergen, a modulator of growth or differentiation (hormone or cytokine) or any other protein with a potentially harmful biological activity.</i></p>	
<p><b>Hazards arising from the alteration of existing pathogenic traits (e.g. alteration of host range or tissue tropism).</b></p> <p><i>One factor to consider is whether the inserted gene encodes a pathogenicity determinant, such as an adhesion, a penetration factor or a surface component providing resistance to host defence mechanisms. Another important consideration is whether the inserted gene encodes a surface component, envelope protein or capsid protein that might bind to a different receptor to that used by the recipient organism. Consideration should also be given to whether the inserted DNA encodes resistance to a drug or antibiotic that might be used for the treatment of a laboratory-acquired infection.</i></p>	
<p><b>The potential hazards of sequences within the GMO being transferred to related organisms.</b></p> <p><i>Factors to consider include whether the nature of the inserted gene is such that its widespread dissemination as a result, for example, of either gene transfer or recombination of the GMO with wild-type organisms would be a matter of concern. If this is the case an important consideration will be whether, in the event of a breach of containment the GMO could survive in the environment for a long enough time for such a gene transfer to take place.</i></p>	


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### Hazards to the Environment

<b>Hazards associated with the recipient organism (e.g. bacterial host, viral vector, mammalian cell).</b>  <i>Factors to consider include whether the recipient organism is capable of infecting any plants or animals in the environment and whether there is any possibility of any disabling mutations being complemented or reverting. In particular it should be ascertained whether the recipient organism is a pathogen that is controlled by The Department for Environment, Food, &amp; Rural Affairs.</i>	
<b>Hazards arising due to the inserted gene conferring the GMO with novel or additional harmful properties.</b>	
<b>Hazards arising from the alteration of existing pathogenic traits (e.g. alteration of host range or tissue tropism).</b>	

### Considerations and review of control measures

<b>Are any of the work procedures likely to generate aerosols? If so, should the work be undertaken in a safety cabinet or isolator?</b>	
<b>How will waste materials be disposed of?</b>	
<b>Will it be necessary to use sharps?</b>	
<b>If the work involves the experimental infection of animals is it known whether the animal will excrete the GMO?</b>	
<b>If the work involves the experimental infection of plants what is known about the likely route of transmission of the GMO?</b>  <i>For example, is the organism insect-borne or carried in run-off water as this will have important implications for the type of glasshouse used.</i>	
<b>In the case of organisms whose multiplication involves a complex life-cycle, will work involve the propagation of organisms that are in stages in that life cycle that are particularly hazardous?</b>  <i>e.g. the propagation of the infective stages of parasites or the release of spores from fungi?</i>	

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<b>Have any disinfectants been validated under the actual conditions of use?</b>  <i>For example, if disinfectant is being used for the treatment of virus in tissue culture medium, is it known that the disinfectant is effective in the presence of high levels of protein?</i>	
<b>Does the nature of this work preclude it from being undertaken by any workers who have a serious skin condition?</b>  <i>(e.g. eczema) or other health problems that might make them more susceptible to infection (e.g. some kind of immunological defect)?</i>	

### Additional control measures


Additional control measures to protect the environment	
Additional safeguards for work procedures	

### Assignment of containment measures and activity class

What is the starting point? Is the organism hazard group 1, 2 or 3?	HG 1	<input type="checkbox"/>	HG 2	<input type="checkbox"/>	HG 3	<input type="checkbox"/>
Control measures usually applied:	HG 1	<input type="checkbox"/>	HG 2	<input type="checkbox"/>	HG 3	<input type="checkbox"/>
Additional control measures required: <i>Summarise from the above sections</i>						
Final activity class	Class 1	<input type="checkbox"/>	Class 2	<input type="checkbox"/>	Class 3	<input type="checkbox"/>

### Part B approval – to be completed following the Team’s workflow

Date reviewed by GMRA Panel	
Date approved by GMSC	
Application submitted to HSE (if required)	

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Part C – Review

You should review your risk assessment prior to any changes such as moving location, new staff, and change of disinfectant for example. If an incident occurs, you should review your risk assessments to identify any further risk control improvements and send your review document to GMSC

[Sian.porter@aber.ac.uk](mailto:Sian.porter@aber.ac.uk)

<b>GMRA 00000</b>	
Reviewed by	
Review date	
Any changes to procedure?	
Any changes to materials?	
Changes to your location?	
Any new staff requiring training?	
Have any incidents occurred during the last 12 months?	
Do you have any infrastructure concerns? When was your last infrastructure inspection?	
Any other information to share with the GMSC	