HEALTH AND SAFETY MANAGEMENT SYSTEM FORMS		Form	F017
1872 PRIFYSGOL	Genetically Modified	Issue	1
ABERYSTWYTH	Organisms	Date	June 2022
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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 <u>sian.porter@aber.ac.uk</u>

Part A Application to generate and use genetically modified organisms

Proposer					
Job Title					
Faculty					
Department					
Project Title					
Location/Facility f	or intend work				
New Equipment r	equired				
Workers involved	(inc email addresses)	Last date of GN	IO Training		
Summary of Prope	osal				
Recipient Organis	m(s)				
Vector(s)					
Insert(s)					
Scale of Operation	ו	< 100ml □	< 1 L 🗆	< 10 L□	Up to 20 L 🗆
Details of the mos	t hazardous GMO	-			
In covering this point, hazards to both human health and the environments should be considered. Details should 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				of whether the tshould also	
consequences.					
More information	can be found in the parts 2	and 3 of the <u>SAC</u>	<u>GM Compendi</u>	um of Guidance.	
Hazard(s) to human health:					
Disabling mutation(s):					
Is the inserted genetic material likely to confer harmful properties to the organism?					
Likelihood of escape: Hazard(s) to the					
environment:	Consequences of escape:				

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Risks associated wit escape:	h			
Classification of the GMO(s)				
		safe, inserted genes that are non-harmf	ul to hum	ans and
the environment and a vector that ha	as a safe history of	use and is non-mobilisable?		
Recipient organism(s):				
Inserted gene(s):				
Vector(s) / Insert(s):				

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)	

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.

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.

Proposer signature:	Date:

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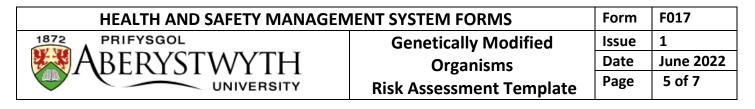
Part A approval – Completed following Teams workflow

GM Risk Assessment Number	GMF	XA 00	000
Stage 1 - Infrastructure	Senior Research Officer, Department of Life Sciences		
Additional equipment required?			
Changes to infrastructure required?			
Stage 2 – Management System	Health, Safety & Environment Team		
HSE Notification required?			
Are changes to AU Public Register required?			
Additional Training Needs required?			
Stage 3 – Technical Peer Review	GMSC Risk Assessment Panel		
Any additional risk control measures?			
Any additional technical improvements identified?			
Does the panel agree with the risk category?			
Part B required?	Yes		
	No		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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<u>Part B – Risk Assessment</u> 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	
Hazards associated with the recipient	
organism (e.g. bacterial host, viral	
vector, mammalian cell).	
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.	
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).	
cloning of a toxin gene of oncogene).	
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.	
Hazards arising from the alteration of	
existing pathogenic traits (e.g. alteration of host range or tissue	
tropism.	
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.	
The potential hazards of sequences	
within the GMO being transferred to	
related organisms.	
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.	



Hazards to the Environment

Hazards associated with the recipient organism (e.g. bacterial host, viral vector, mammalian cell).
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, & Rural Affairs.
Hazards arising due to the inserted
gene conferring the GMO with novel or
additional harmful properties.
Hazards arising from the alteration of
existing pathogenic traits (e.g.
alteration of host range or tissue
tropism).

Considerations and review of control measures

Are any of the work procedures likely to generate aerosols? If so, should the work be undertaken in a safety cabinet or isolator?	
How will waste materials be disposed of?	
Will it be necessary to use sharps?	
If the work involves the experimental	
infection of animals is it known	
whether the animal will excrete the	
GMO?	
If the work involves the experimental	
infection of plants what is known about	
the likely route of transmission of the	
GMO?	
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.	
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?	
e.g. the propagation of the infective stages of	
parasites or the release of spores from fungi?	

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Have any disinfectants been validated under the actual conditions of use?				
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?	
Does the nature of this work preclude it from being undertaken by any workers who have a serious skin condition?	
(e.g. eczema) or other health problems that might make them more susceptible to infection (e.g. some kind of immunological defect)?	

Additional control measures

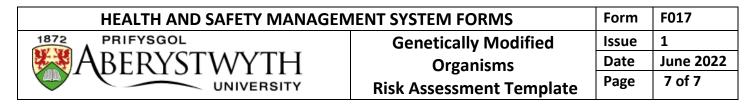
Additional control measures to protect the environment	
Additional safeguards for work procedures	

Assignment of containment measures and activity class

What is the starting point? Is the organism hazard group 1, 2 or 3?	HG 1	HG 2	HG 3	
Control measures usually applied:	HG 1	HG 2	HG 3	
Additional control measures required: Summarise from the above sections				
Final activity class	Class 1	Class 2	Class 3	

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)	



<u>Part C – Review</u>

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 <u>Sian.porter@aber.ac.uk</u>

GMRA 00000	
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	