

University Occupational Health and Safety

Form

RISK ASSESSMENT FOR GENETICALLY MODIFIED MICROORGANISMS – Part 1

In completing this risk assessment form additional guidance can be obtained from:

1. [Guidance Note – Risk Assessment for Genetically Modified Microorganisms](https://www.strath.ac.uk/media/ps/safetyservices/campusonly/standards/geneticmodification/Guidance_Note_-_RA_for_Genetically_Modified_Microorganisms.pdf);
2. The University Genetic Modification Safety Committee (GMSC);
3. The [Scientific Advisory Committee on Genetic Modification (SACGM) Compendium of Guidance](http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/).

**Work should not be commenced until this form has been reviewed by the GMSC**.

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| **Part 1 (a)** | |
| **Project Title** |  |
| **Principle Investigator** |  |
| **Location(s)** |  |
| **Contact Telephone** |  |
| **Contact E-mail** |  |

This project is in scope of the Nagoya Protocol and I have undertaken a due diligence check.

This project is out of scope of the Nagoya Protocol.

For further information on the Nagoya protocol please see Section 6.2.4 of the [OHS GM Standard](https://www.strath.ac.uk/media/ps/safetyservices/campusonly/standards/geneticmodification/OHS_Standard_-_Genetic_Modification.pdf).

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| **Part 1 (b) Scientific goals of project** |
| *This information provides a useful background and puts the work in context. The scientific goals need not be disclosed if presenting the information presents problems in relation to intellectual property rights or commercial sensitivity.* |
| **Part 1 (c) An overview of the different types of GMM that will be constructed** |
| *1 or 2 paragraphs, outlining the scope of the project and setting the boundaries of exactly what work will be done.* |
| 1. **List of recipient strain(s)** *Cover the name of the strain, the name of the wild-type organism from which it is derived referring to its* [*ACDP hazard group*](http://www.hse.gov.uk/pubns/misc208.pdf) *and the extent to which it is disabled.* |
| 1. List of vector(s) *Cover names and any disabling mutations.* |
| 1. **List of function of inserted gene(s)** *Genes should be identified in such a way that an outside reviewer will have a general idea of their function i.e. providing a three-letter name may not be sufficient. Where the function of a gene is unknown, provide details of any known homologues. Consideration should be given to genes encoding proteins with potentially harmful biological activity (see Part 2).* |
| **Part 1 (d) Identify the hazards associated with the GMM** |
| *This will be the most hazardous combination of recipient strain, vector and inserted material from the lists made under part (c). With some projects it will not be clear that any one GMM will be any more hazardous than any of the others (e.g. if all the work is Class 1). If this is the case this should be stated. Consider risk to human health and the environment.* |

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| **Part 1 (e)** **Are you confident that for all of the GMMs covered by this assessment there are no harmful properties associated with the recipient strain, the vector, or the inserted material? (No or negligible risk)** | |
| **YES** | **NO** |

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| **Part 1 (f)** **Are you confident that none of the final GMMs could be hazardous to humans or the environment? (No or negligible risk)** | |
| **YES** | **NO** |
| *If ‘No’ or you are unsure, Part 2 of this form should also be completed in conjunction with the rest of this form.*  *If the GMM meets BOTH of the above criteria, you may have sufficient information at this stage to propose* ***CLASS 1****, as defined in The Genetically Modified Organisms (Contained Use) Regulations 2014. 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 of* ***NO OR NEGLIGIBLE RISK*** *to human health or the environment.* | |
| **Part 1 (g) Consideration of the nature of the work to be undertaken and a detailed review of the control measures** | |
| **(i) Are any of the work procedures likely to generate aerosols?** *Consider the likelihood of the work activity generating infectious aerosols. Where aerosols are generated, work should be undertaken in an appropriate mechanically ventilated environment such as a Microbiological Safety Cabinet or where animal work may be involved an isolator.* | |
| **(ii) Will it be necessary to use sharps?** *Does work involve glass Pasteur pipettes, needles? If so, could they be substituted with safer alternatives?* | |
| **(iii) How will waste materials be disposed of?** *Include both solid and liquid laboratory waste and waste from experiments with infected animals.* | |
| **(iv) 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?* | |
| **(v) If the work involves the experimental infection of animals is it known whether the animal will shed the GMM?** | |
| **(vi) Does the organism’s multiplication involve a complex life-cycle where the work involves the propagation of organisms that are in stages in that life-cycle that are particularly hazardous?** *Examples include the propagation of the infective stages of parasites or the release of spores from fungi. Consider all potential routes of transmission including those that might not be used naturally.* | |
| **(vii) Occupational Health** *Does the nature of this work preclude it 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? Will workers require to receive any vaccinations or health surveillance?* | |
| **(viii) What personal protective equipment is required?** | |
| **(ix) Are there contingency arrangements should a spillage occur? Please specify what procedures are in place.** *Detail how a liquid spill would be decontaminated and any affected surfaces cleaned. Include information on procedures should a user be affected by a spillage.* | |

If you are assigning the work to **Class 1**, sign the form below and e-mail it to [gmcommittee@strath.ac.uk](mailto:gmcommittee@strath.ac.uk). The risk assessment will be considered by the Genetic Modification Safety Committee (GMSC). You should expect a response within 4 weeks.

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| **I confirm that the final assignment of containment measures and risk class of this project are assigned to class 1** | |
| **Signature of PI** |  |
| **Date Signed** |  |
| **Date of Next Review** |  |

If you have any uncertainty as to whether the proposal meets the above criteria you should obtain a continuation form (Part 2) and undertake a more detailed risk assessment.

###### Laboratory Staff working on this project should sign a hard copy of the risk assessment before commencing work. This should be held in the laboratory for reference. All staff should be appropriately trained by the PI or other nominated person(s) before commencing work.

**All staff working on this project must have completed the** [**BP1 and/or BP2 form**](https://ben.mis.strath.ac.uk/login/) **as appropriate.** These forms can be accessed through Pegasus under the Human Resources tab. Further information including training requirements for working with biological and GM material can be found in the [OHS Biological Safety Standard](https://www.strath.ac.uk/safetyservices/documentationforms/ohsoperationalcontrolstandards/biologicalsafety/) and the [OHS GM Standard](https://www.strath.ac.uk/media/ps/safetyservices/campusonly/standards/geneticmodification/OHS_Standard_-_Genetic_Modification.pdf).

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