**University Occupational Health and Safety**

Form

RISK ASSESSMENT FOR GENETICALLY MODIFIED MICROORGANISMS – Part 2

This form is a continuation of Part 1 and is designed for the detailed assessment of a GMM project where there is doubt regarding the classification or where Class 2 is being considered. In general, as long as the scope of the work has been satisfactorily outlined in Part 1, it is sufficient to complete Part 2 for the most hazardous GMMs being constructed (i.e. those proposed as Class 2 activities).

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| **Part 2 (a) Hazards to human health** |
| **(i) Hazards associated with the recipient microorganism (e.g. bacterial host or viral vector)** *Is the recipient listed in* [*ACDP hazard groups 2, 3 or 4*](http://www.hse.gov.uk/pubns/misc208.pdf)*? Consider the micro-organism’s mode of transmission, disease symptoms, host range, and tissue tropism. Are vaccines or chemotherapeutic agents available? Provide information on any disabling mutations and whether there is any possibility of any disabling mutations being complemented or reverting.* |
| **(ii) Hazards arising directly from the inserted gene product (e.g. cloning of a toxin gene or oncogene)** *Consider 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, which may result in potentially harmful biological activity. Where the function of the inserted gene is unknown, describe the function of any known homologues. Note that even a normal human gene may be harmful if over-expressed, especially if the over-expression is in tissues that do not normally express the protein.* |
| **(iii) Hazards arising from the alteration of existing traits (e.g. alteration of pathogenicity, host range, tissue tropism, mode of transmission or host immune response)** *Consider whether the inserted gene encodes a pathogenicity determinant, such as an adhesin, a penetration factor or a surface component providing resistance to host defense mechanisms. Consider 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 microorganism. Consider whether the inserted DNA (or the plasmid sequence) encodes resistance to a drug or antibiotic that might be used for the treatment of a laboratory-acquired infection.* |
| **(iv) The potential hazards of sequences within the GMM being transferred to related microorganisms** *Consider whether widespread dissemination of the inserted gene as a result, for example, of either gene transfer or recombination of the GMM with a wild-type microorganism, would be a matter of concern. If so, consider whether, in the event of a breach of containment the GMM could survive in the environment for long enough for such a gene transfer to take place.* |

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| **Part 2 (b) Assignment of a provisional containment level that is adequate to protect against hazards to human health** |
| *Consider the containment level necessary to control the risk of the recipient microorganism (i.e.* [*the ACDP Hazard Group*](http://www.hse.gov.uk/pubns/misc208.pdf) *of the recipient microorganism) and if the modification will result in a GMM, which is more hazardous, less hazardous, or about the same. Compare the GMM with the relative hazard presented by other organisms that would fall within the same ACDP Hazard Group as the GMM.* |

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| **Part 2 (c) Identification of any hazards to the environment** |
| **(i) Hazards associated with the recipient microorganism (e.g. bacterial host or viral vector)** *Consider whether the recipient microorganism is capable of infecting any plants, animals or insects in the environment and whether there is any possibility of any disabling mutations being complemented or reverting. It should be ascertained whether the recipient microorganism is a pathogen that is controlled by DEFRA.* |
| **(ii) Hazards arising directly from the inserted gene product** *Consider whether the sequence encodes an insect or animal toxin or a product which can cause silencing of a gene encoding a crucial metabolic enzyme in susceptible hosts.* |
| **(iii) Hazards arising from the alteration of existing traits (e.g. alteration of pathogenicity, host range or tissue tropism)** *Consider whether the inserted sequence encodes a pathogenicity determinant, such as an adhesin, a penetration factor or a surface component providing resistance to host defense mechanisms. Consider 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 microorganism.* |
| **(iv) The potential hazards of sequences within the GMM being transferred to related microorganisms** *Consider whether widespread dissemination of the inserted gene as a result, for example, of either gene transfer or recombination of the GMM with a wild-type microorganism, would be a matter of concern. If so, consider whether, in the event of a breach of containment the GMM could survive in the environment for long enough for such a gene transfer to take place.* |

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| **Part 2 (d) Consideration of whether there is a need to assign additional measures over and above the provisional level of containment.** |
| *It should be noted that the containment measures set out in Schedule 8 of The Genetically Modified Organisms (Contained Use) Regulations 2014 will include some measures that are required where and to the extent that the risk assessment shows they are required*  *Additional measures may be necessary in any of the following circumstances:*  *(i) to take full account of any properties of the GMM that may be hazardous to human health.*  *(ii) to protect the environment.*  *(iii) to provide additional safeguards for particular work procedures.* |

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| **Part 3 Final assignment of containment measures and risk class** | | |
| **Proposed Class** | **1** | **2** |
| **Signature of PI** |  | |
| **Date Signed** |  | |
| **Date of Next Review** |  | |

###### 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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