

**Risk Assessment for The Contained Use of Genetically Modified Organisms**

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| This risk assessment form should be used to assist in the assessment of risks from an activity involving deliberate work with genetically modified organisms. The aim of the assessment is to identify those at risk from infection or other harm and the measures required to eliminate or control the risks to human health and the environment to an acceptable level. |

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| **Section 1: General Information** | | | |
| **1.1 Principal Investigator/ Academic Supervisor:** | | | |
| Name | | Faculty | |
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| Email | | Date | |
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| **1.2 Premises where this work will be carried out:** | | | |
| Building | Laboratories | | Containment level |
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| **Section 2: Project Information** | | |
| 2.1 Person undertaking this risk assessment (if different from above): | | |
| Name | Faculty | |
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| 2.2 GM Project Number (Biological Hazards and GM Sub-committee to allocate): | | |
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| 2.3 List Biological Risk Assessment(s) associated with this project: | | |
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| 2.4 Project title: | | |
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| **2.5 Is this proposal an extension of a previously approved project?** | | |
| Previously approved?  If yes, please complete the form emphasising the connection between the original project and this application. | | Yes  No |
| Previous reference number: | |  |
| **2.6 Brief overview of the work** (in layman’s terms)**:** | | |
| Please describe the project, detailing aims and objectives, significance, and outcomes, indicating how the GMOs will help to achieve the objectives of the project. This description should contain enough detail to help a non-specialist to understand the project. | | |
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| **2.7 Is this GMO going to form part of an undergraduate practical class?** | | Yes  No |
| **2.8 Faculty Contacts:** | | |
| Health, Safety and Resilience Advisor: | |  |
| GM Officer: | |  |

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| **Section 3: Hazards and Risks** |
| **Please complete:**   * **Part A - for Genetically modified microorganisms (GMM) and/or** * **Part B - for Genetically modified higher organisms (GMHO)** |

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| **Part A - Genetically Modified Microorganisms (GMM)** |

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| **A.1 Identification of Hazards** | |
| Give details on the identity, source organism and function of each sequence of genetic material to be inserted/modified. |  |
| Is the Donor organism(s) Pathogenic?  If yes, what harm does it cause? | Yes  No |
| Is any microorganism or nucleic acid derived from a microorganism which is listed under Schedule 5 of the Anti-terrorism crime and security act 2001 as amended?  If yes, please provide details. | Yes  No |
| If the donor organism(s) has pathological or harmful characteristics, are the donated sequences implicated in them.  If yes, please give details. | Yes  No |
| Will the sequences cause harm if expressed in humans after accidental transfer?  If yes, what harm would occur and how severe would it be? | Yes  No |
| Give details on the identity of the vector(s), and nature of any potential harmful properties (to humans and/or the environment). Include in your description their ability to mobilise and the presence of active promoters of expression.  **Note:** Disabled viruses used as a vector should be treated as recipient organisms. |  |
| If using a disabled viral vector, state its origin and the mechanisms of attenuation. |  |
| State identity [Species, strain(s)] and ACDP/SAPO hazard category of all recipient microorganisms. |  |
| Are the intended recipient organisms capable of independent survival in the environment, or will infect or transfer to other hosts?  If yes, please give details. | Yes  No |
| Give details of natural host(s) (if any) of recipient organism(s) and routes of transmission/ infection (if known). | Inhalation  Oral/ ingestion  Mucocutaneous  Percutaneous  Via vector (e.g., insect)  Allergen |
| What effect will the modification have on the intended recipient organisms? Include in your description any changes to pathogenicity or toxicity to humans. |  |
| Will the modification alter the recipient organism’s ability to survive in the environment, compete with other organisms or transfer to them the inserted sequences?  If yes, please give details | Yes  No |
| Are animals to be infected with these GMMs?  If yes, please give details. | Yes  No |

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| **A.2 Risk Assessment for Genetically Modified Microorganisms** | |
| Summarise all potentially hazardous properties of each GMM in relation to human safety.  Do not forget hazardous properties of the parental organism.  Consider ALL properties of the host, vector, insert, and of the final GMM |  |
| Identify persons who could be exposed to the hazard.  e.g., Laboratory workers, co-workers, and other staff such as cleaners and students accessing laboratories, contractors. |  |

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| A.3 Estimation of Risk Magnitude – To Human Health and Safety | | | | |
| Based on the likelihood of exposure to GMM (before any controls) and the severity of the consequence of exposure, please select an estimation of risk magnitude from the matrix below. | | | | |
| Consequence | **Likelihood** | | | |
|  | Probable | Possible | Unlikely | Highly improbable |
| Severe | High | High | Medium | Effectively 0 |
| Moderate | High | Medium | Medium/low | Effectively 0 |
| Minor | Medium/Low | Low | Low | Effectively 0 |
| Negligible | Effectively 0 | Effectively 0 | Effectively 0 | Effectively 0 |

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| A.4 Estimation of Risk Magnitude – To the Environment | | | | |
| Based on the likelihood of release of GMM (before any controls) and the severity of the consequence of release, please select an estimation of risk magnitude from the matrix below. | | | | |
| Consequence | **Likelihood** | | | |
|  | Probable | Possible | Unlikely | Highly improbable |
| Severe | High | High | Medium | Effectively 0 |
| Moderate | High | Medium | Medium/low | Effectively 0 |
| Minor | Medium/Low | Low | Low | Effectively 0 |
| Negligible | Effectively 0 | Effectively 0 | Effectively 0 | Effectively 0 |

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| **A.5 GM Experimental Procedures** | | | |
| **A.5.1 Description of experimental procedures:**  Brief details, also indicate any non-standard laboratory operations and any procedures that might require specific control measures e.g., use of sharps, generation of aerosols, in vivo work. | | | |
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| **A.5.2 Quantities used and frequency of use:**  This information will enable you to determine the likelihood of exposure and therefore the risks from this activity. Please indicate maximum culture volumes at any time shown as multiples of flask volumes to give an idea of scale. | | | |
| Max. volume per culture/ sample |  | Max. volume per experiment |  |
| Frequency of experiments: | |  | |

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| **A.6 Measures to Prevent or Control Exposure** | |
| **A.6.1 Preventing Exposure** | |
| 1. Could a less hazardous substance (or form of the substance) be used instead?   If it can, then it should be used, or justification be given here why it is not being used. COSHH requires substitution with less hazardous materials wherever possible, but there may be good reasons for not using them. | |
| If no, please provide details. |  |

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| **A.6.2 Controlling Exposure** | | | |
| 1. Containment Level - what containment level is required for this work with regard to COSHH/ SAPO? | | | |
| 1 | 2 | | 3 |
| 1. CL3 only – application for derogation from the following controls (list if relevant and justify): | |  | |
| 1. Will the work be segregated from others not involved in the work and if not, how will they be informed of the hazards? | |  | |

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| **A.7 Engineering Controls – Containment and Ventilation** | |
| 1. Is a microbial safety cabinet (or isolator for in vivo work) required? These must be used for activities generating potentially infectious aerosols or splashes. | Yes  No |
| If yes, please state which class and describe underneath what processes will use it? | Class:  I  II  III |
| If required, what processes require its use? |  |
| 1. Specify other local ventilation control measures considered appropriate (e.g., downdraft table, isolator): |  |
| 1. Specify other local ventilation control measures considered appropriate (e.g., downdraft table, isolator): |  |
| 1. Will centrifugation be used? | Yes  No |
| If yes, will buckets and rotors be sealed? |  |
| If yes, where will buckets or rotors be opened? |  |
| If yes, how will spillages in the centrifuge be dealt with? |  |
| 1. Will incubators be used? | Yes  No |
| If yes, what type (e.g., shaking)? |  |
| If yes, how will spillages in the incubator be dealt with? |  |
| 1. Will sharps be used: | Yes  No |
| If yes, list and justify their use: |  |
| 1. Please give details of the control measures for sharps use: |  |
| 1. Will animals be deliberately infected with these biological agents? | Yes  No |
| 1. Do you require a licence/ permit?   <https://staff.swansea.ac.uk/media/tgn002-abps-and-import-permits.pdf> | Yes  No |
| 1. If yes, describe the procedure, control measures and whether shedding of infectious agents by animals is expected? |  |

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| **A.8 Personal Protective Equipment (PPE):** | | | |
| Lab coat | Gloves | Eye or face (specify) | Other |
| Yes | Yes  No | Yes  No | Yes  No |
| Details: | Details: | Details: | Details: |
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| **A.9 Transportation** | |
| 1. How will viable material be transported within the laboratory? |  |
| 1. How will viable material be transported locally outside the laboratory? |  |
| 1. Will viable material be shipped anywhere (off campus)? | Yes  No |
| 1. If yes, what will be shipped? |  |
| 1. If yes, how will this be shipped (e.g., Category A, Category B, Exempt, Non-hazardous)? |  |

| **A.10 Waste Disposal Procedures**  Disinfectants, concentrations, exposure times, autoclaving procedures, incinerator procedures, include any animal related wastes. | | |
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| **Waste** | **Decontamination method (include details on efficacy)** | **Disposal route**  **e.g. drain/ incineration/ landfill** |
| 1. Liquid waste |  |  |
| 1. Solid waste |  |  |
| 1. Sharp waste |  |  |

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| **A.11 Emergency Procedures**  Spillages   * If covered by local rules/ standard operating procedure, please attach. * If not covered by local rules/ standard operating procedure) Remember to take into account route of exposure. | |
| 1. Inside primary containment (if relevant e.g., MSC, isolator): |  |
| 1. Outside primary containment but within the laboratory (secondary containment): |  |
| 1. Outside secondary containment (if relevant): |  |
| 1. Other procedures (e.g., first aid following any accidental exposure, needle stick, etc.): |  |

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| A.12 Estimation of Risk Magnitude – To Human Health and Safety | | | | |
| Based on the likelihood of exposure to GMM (following the procedures described above) and the severity of the consequence of exposure, please select an estimation of risk magnitude from the matrix below. | | | | |
| Consequence | **Likelihood** | | | |
|  | Probable | Possible | Unlikely | Highly improbable |
| Severe | High | High | Medium | Effectively 0 |
| Moderate | High | Medium | Medium/low | Effectively 0 |
| Minor | Medium/Low | Low | Low | Effectively 0 |
| Negligible | Effectively 0 | Effectively 0 | Effectively 0 | Effectively 0 |
| If not “effectively 0” please describe the additional measures required to control the risk. | | | | |
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| A.13 Estimation of Risk Magnitude – To the Environment | | | | | |
| Based on the likelihood of release of GMM (following the procedures described above) and the severity of the consequence of release, please select an estimation of risk magnitude from the matrix below. | | | | | |
| Consequence | **Likelihood** | | | | |
|  | | Probable | Possible | Unlikely | Highly improbable |
| Severe | | High | High | Medium | Effectively 0 |
| Moderate | | High | Medium | Medium/low | Effectively 0 |
| Minor | | Medium/Low | Low | Low | Effectively 0 |
| Negligible | | Effectively 0 | Effectively 0 | Effectively 0 | Effectively 0 |
| If not “effectively 0” please describe the additional measures required to control the risk. | | | | | |
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| **A.14 Classification** | |
| Please state the proposed class of GM activity: | Class 1  Class 2  Class 3 |

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| **Part B - Genetically Modified Higher Organisms (GMHO)** |

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| **B.1 Identification of Hazards** | |
| List the identity of all recipient organism(s):  Give common and scientific names and where relevant strain, cultivar, or subspecies designations |  |
| Give details on the identity of the host/vector system or the method used for genetic modification. |  |
| Give details on the nature and identity of any toxic, allergenic, or other potentially harmful effects attributed to the recipient organism, or its metabolic products. |  |
| Origin and intended function of inserted genetic material. Identify any harmful effects attributable to the inserted sequences. |  |
| Do these GMHO pose greater risk to humans than the unmodified parental organism.  If yes, please give details. | Yes  No |
| Describe the likely routes of release of the GMHO. |  |
| Identify all potentially hazardous properties of the GMHO’s to the environment  e.g., Ability to transfer genes to other organisms, colonise new ecosystems, improved survival, etc. |  |

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| **B.2 Risk Assessment for Working with Genetically Modified Higher Organisms** | |
| Identify all potentially hazardous properties of the GMHOs to **human** health and safety  Take into account any toxic or allergenic effects, new reservoir for pathogens, etc. |  |
| Identify persons who could be exposed to the hazard.  e.g., Laboratory workers, co-workers, and other staff such as cleaners and students accessing laboratories, contractors |  |

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| B.3 Estimation of Risk Magnitude – To Human Health and Safety | | | | |
| Based on the likelihood of release of GMHO (before controls) and the severity of the consequence of release please select an estimation of risk magnitude from the matrix below. | | | | |
| Consequence | **Likelihood** | | | |
|  | Probable | Possible | Unlikely | Highly improbable |
| Severe | High | High | Medium | Effectively 0 |
| Moderate | High | Medium | Medium/low | Effectively 0 |
| Minor | Medium/Low | Low | Low | Effectively 0 |
| Negligible | Effectively 0 | Effectively 0 | Effectively 0 | Effectively 0 |

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| B.4 Estimation of Risk Magnitude – To the Environment | | | | |
| Based on the likelihood of release of GMHO (before controls) and the severity of the consequence of release please select an estimation of risk magnitude from the matrix below. | | | | |
| Consequence | **Likelihood** | | | |
|  | Probable | Possible | Unlikely | Highly improbable |
| Severe | High | High | Medium | Effectively 0 |
| Moderate | High | Medium | Medium/low | Effectively 0 |
| Minor | Medium/Low | Low | Low | Effectively 0 |
| Negligible | Effectively 0 | Effectively 0 | Effectively 0 | Effectively 0 |

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| **B.5 Controlling Exposure** | |
| 1. What are the measures put in place to prevent or control the risk? |  |
| 1. Describe the physical control measures that will be in place to minimise or prevent such release and identify control measures required to manage the risks. |  |
| 1. Will the work be segregated from others not involved in the work and if not, how will they be informed of the hazards? |  |

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| **B.6 Personal Protective Equipment (PPE):** | | | |
| Lab coat | Gloves | Eye or face (specify) | Other |
| Yes | Yes  No | Yes  No | Yes  No |
| Details: | Details: | Details: | Details: |
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| **B.7 Transportation** | |
| 1. How will viable material be transported within the laboratory? |  |
| 1. How will viable material be transported locally outside the laboratory? |  |
| 1. Will viable material be shipped anywhere (off campus)? | Yes  No |
| 1. If yes, what will be shipped? |  |
| 1. If yes, how will this be shipped (e.g., Category A, Category B, Exempt, Non-hazardous)? |  |

| **B.8 Waste Disposal Procedures**  Disinfectants, concentrations, exposure times, autoclaving procedures, incinerator procedures, include any animal related wastes. | | |
| --- | --- | --- |
| **Waste** | **Decontamination method (include details on efficacy)** | **Disposal route**  **e.g., drain/ incineration/ landfill** |
| 1. Liquid waste |  |  |
| 1. Solid waste |  |  |
| 1. Sharp waste |  |  |

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| **B.9 Emergency Procedures**  Describe what procedures you have in place in case of the emergency situations described below. | |
| 1. Flood |  |
| 1. Fire |  |
| 1. Theft |  |
| 1. First Aid |  |
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| B.10 Estimation of Risk Magnitude – To Human Health and Safety | | | | |
| Based on the likelihood of exposure to GMHO (following the procedures described above) and the severity of the consequence of exposure please now select an estimation of risk magnitude from the matrix below. | | | | |
| Consequence | **Likelihood** | | | |
|  | Probable | Possible | Unlikely | Highly improbable |
| Severe | High | High | Medium | Effectively 0 |
| Moderate | High | Medium | Medium/low | Effectively 0 |
| Minor | Medium/Low | Low | Low | Effectively 0 |
| Negligible | Effectively 0 | Effectively 0 | Effectively 0 | Effectively 0 |
| If not “effectively 0” please describe the additional measures required to control the risk. | | | | |
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| B.11 Estimation of Risk Magnitude – To the Environment | | | | |
| Based on the likelihood of release of GMHO (following the procedures described above) and the severity of the consequence of release please select an estimation of risk magnitude from the matrix below. | | | | |
| Consequence | **Likelihood** | | | |
|  | Probable | Possible | Unlikely | Highly improbable |
| Severe | High | High | Medium | Effectively 0 |
| Moderate | High | Medium | Medium/low | Effectively 0 |
| Minor | Medium/Low | Low | Low | Effectively 0 |
| Negligible | Effectively 0 | Effectively 0 | Effectively 0 | Effectively 0 |
| If not “effectively 0” please describe the additional measures required to control the risk. | | | | |
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| **Section 4: Information, Instruction and Training** | |
| **4.1 Training** | |
| 1. Describe the training that will be given to all those affected (directly or indirectly) by the work activity. |  |

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| **Section 5: Declarations and Approval** | | |
| **5.1 Principal Investigator:** | | |
| I the undersigned:   * Confirm that all information contained in this assessment is correct and up to date. * Will ensure that suitable and sufficient instruction, information and supervision is provided to all individuals working on the activity. * Will ensure that no work will be carried out until this assessment has been completed and approved and that all necessary control measures are in place. * Will ensure that all information contained in this assessment will remain correct and up to date and re-submit for approval if any significant changes occur. * Work will only be undertaken in appropriate facilities. * I am submitting this application for approval at the next meeting of the Biological Hazards and Genetic Modified Organisms Sub-Committee. * I agree that work will not commence on this project until Biological Hazards and Genetic Modified Organisms Sub-Committee has given its approval. | | |
| Name | Signature | Date |
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| **5.2 Confidentiality Statement** | | | | |
| I wish to claim the information given in sections [ ] of this form as “Confidential”.  This information is given on the understanding that it is only received by persons properly authorised by the Biological Hazards and Genetic Modified Organisms Sub-Committee and who have agreed to the non-disclosure of such confidential information. | | | | |
| Name | Signature | | | Date |
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| **5.3 Approval on Behalf of the Faculty** | | | | |
| * Approval of Hazard Group 1 only. * I support the presentation of this proposal to the Biological Hazards and Genetic Modified Organisms Sub-Committee (for ACDP Hazard Group 2-4, SAPO Hazard Group 2-4 and organisms listed on schedule 5.   The person supporting this proposal must not be involved in the project being proposed. | | | | |
| Faculty GM Officer | | Name |  | |
| Signature |  | |
| Date |  | |
| University BSO | | Name |  | |
| Signature |  | |
| Date |  | |
|  |  | | |  |
| **5.4 Approval on Behalf of the University** | | | | |
| * The risk assessment has been reviewed and approved by the Biological Hazards and GMO Sub-Committee. * Approval of ACDP Hazard Group 2-4, SAPO Hazard Group 2-4 and organisms listed on schedule 5. | | | | |
| Chair Biological Hazards and GMO Sub-Committee | | Name |  | |
| Signature |  | |
| Date |  | |

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| **Section 6: List of Workers Under this Project** | | | | | | | |
| List any persons who will be working on this project. They must have access to this risk assessment and other associated risk assessments. Those listed should sign and date to confirm they have read understand the risk assessment. | | | | | | | |
| Full Name | Worker Type | | | | | Signature and date |
| Staff | PG Research | PG Taught | UG | Other |
|  |  |  |  |  | Details |  |
|  |  |  |  |  | Details |  |
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