**Risk Assessment for Biological Activity (GM and BioCOSHH Assessment)**

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| ***To be completed by GMSMC***  **Project Reference (to be assigned by the GMSMC):**  **(HSE premises licence numbers as follows: Diamond GM972, ISIS GM975, RCaH GM 3067, RFI GM3564, DL GM588)** |

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| **A: PROJECT OVERVIEW** | |
| **Applicant:** | **Date:** |
| **Project Title:** | |
| **Name of project leader:** | **Organisation:** |
| **Contact details:** | |
| **Personnel involved in the project:** | |
| **General description of project, including the aim of the work:** | |
| **List all the locations of the proposed work:** | |
| **Is any of the material listed under the following regulations:**  SAPO (Specified Animal Pathogens Order) Yes  No  Schedule 5 (Anti-Terrorism Crime and Security Act) Yes  No    HTA (Human Tissue Act) Yes  No | |

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| **DOES THIS WORK INVOLVE** |
| 1. **Biological Non - GM activity**  Yes  No   If yes, please complete sections B and D |
| 1. **Biological GM activity only** Yes  No   If yes, please complete sections C and D |
| 1. **Both biological GM activity and Non GM activity**     Yes  No  If yes, please complete sections B, C and D |

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| **B: Project Risk Assessment involving Biological Non - GM activity** |
| **The nature of the biological material** |
| 1. **Describe the biological materials to be used in the work?** |
| 1. **Describe how and from where the materials will be obtained.** |
| 1. **Will the biological material(s) be subject to any form of pre-treatment to reduce risk?** |
| 1. **Where will the biological materials be stored and under what conditions, e.g. frozen, refrigerated, liquid nitrogen?** |
| **Risks from biological material and biological agents present in the material** |
| 1. **Are there any other biological agent(s) or toxins likely to be present in the biological material that may pose a risk of harm to human health, animals or the environment?** |
| 1. **Does the biological material or biological agent(s) present appear on the ACDP Approved List of Biological Agents and, if so, what is its hazard group under COSHH?**   **If the biological material or biological agent(s) has not been assigned a hazard group, what is its provisional classification, based on existing knowledge of its pathogenic traits.** |
| 1. **Provide information on the mode of transmission, disease caused and symptoms. If any toxins present, please provide information on its likely concentration in the material and at what level has an effect on human health.** |
| 1. **Provide information on the likely viability of the biological material and any biological agents present in it.** |
| 1. **Provide information on any risks posed to the environment, e.g., ability to survive outside the laboratory, effects on the ecosystem.** |

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| **C: PROJECT RISK ASSESSMENT INVOLVING BIOLOGICAL GM ACTIVITY ONLY** |
| **Give the details of all the recipient organisms, vectors used, modifications including altered genes etc.** |
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| **Consideration of potential properties of the GMM/GMO to determine if there are any potential mechanisms by which it could present a hazard to human health and/or the environment.** |
| **i) Hazards associated with the recipient micro-organism** (e.g. ACDP and SAPO classification, transmission, host range etc)   1. **Human:** 2. **Environmental:** |
| **ii) Hazards arising directly from the inserted genetic material** (e.g. does it code for a toxin, an oncogenic protein or anything which could cause harmful biological activity)   1. **Human:** 2. **Environmental:** |
| **iii) Hazards arising from the alteration of existing pathogenic traits** (e.g. alteration of host range or tissue tropism)   1. **Human:** 2. **Environmental:** |
| **iv) Potential hazards of sequences within the GMM/GMO being transferred to related micro-organisms** (e.g. via gene transfer or recombination, survivability in the environment)   1. **Human:** 2. **Environmental:** |
| **v) Potential hazards of the final GMM/GMO (Include consideration of the ability of the GMM to become established in the host and consideration of the probability that rare events will occur)**  **a) Human:**   1. **Environmental:** |

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| **Assignment of provisional Containment Level to protect human health.** (This is based on the information provided in all the answers given above) | Containment Level 1 (CL1) |
| Containment Level 2 (CL2) |
| Greater than CL2 |
| **Assignment of provisional Containment Level to protect against harm to the environment.** (This is based on the information provided in all the answers given above) | Containment Level 1 (CL1) |
| Containment Level 2 (CL2) |
| Greater than CL2 |
| **Assignment of the activity class** | Class 1 |
| Class 2 |
| Greater than Class 2 |

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**D: Control measures**

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| **D: Control Measures** |
| **Detail the control measures in place to protect against the risk of harm to human health and environment. Comment on each of the following where applicable.** |
| 1. **Reduction of aerosols** |
| 1. **Waste disposal procedure** |
| 1. **Disinfection procedure** |
| 1. **Spills management** |
| 1. **Transportation of material(s** |
| 1. **Any other information (e.g. COSHH assessment for chemicals involved)** |

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| **E: Documentation, Licences & Approvals** |
| 1. List and attach any supporting documentation |
| 1. Does the above proposed work require any Licences and approvals?   Yes  No  If yes, what are they? Please give details of approved Licences available or give details of any outstanding applications submitted to the concerned authority. |

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| **F: SIGNATURES AND REVIEW** | |
| **Person responsible for project** | **Signature:** |
| **Date:** | **Name:** |
| **Person completing risk assessment** (if different from above) | **Signature:** |
| **Date:** | **Name:** |
| **GMSMC chair** | **Signature:** |
| **Date:** | **Name:** |
| **BSO** | **Signature:** |
| **Date:** | **Name:** |

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| ***To be completed by the GMSMC and BSO*** | |
| **Final Assignment of biological activity level:** | |
| **GMSMC comments:** | |
| **HSE approval needed:** | **HSE approval granted:** |
| **Appendix in place:** | **Amendment in place:** |
| **Proposal Approved/Rejected** | |
| **Date:** | |

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| **REVIEW**  If the risk assessment is modified a new version must be submitted. | | | |
| **Comments** | | | |
| **Review Date:** |  | **GMSMC Chair:** |  |
| **Person responsible for the project** |  | **BSO** |  |
| **Comments** | | | |
| **Review Date:** |  | **GMSMC Chair:** |  |
| **Person responsible for the project** |  | **BSO** |  |
| **Comments** | | | |
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