**Risk Assessment made under the**

**Genetically Modified Organisms (Contained Use) Regulations 2014**

*(Form GMM – for genetically modified micro-organisms and eukaryotic cell and tissue culture systems)*

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| --- | --- | --- | --- |
| **Department:** | **Supervisor:** | | **Ref. No:** |
| **Project Title:** | | | |
| **Title of project:** | | | |
| **Outline Description of Project:**  *(include aims and objectives)* | | | |
| **Give details of**  **Recipient/Host(s):**  *(specify if wild type or disabled)* | | **Vector(s):** | |
| **Normal/expected biological action of inserted DNA/RNA or transcribed/translated gene product:** | | | |
| **Technique used to introduce insert or vector into host:** | | | |
| **Assessed By:** | | | |
| Signature: | | Date: | |
|  | | | |
| **Risk Assessment approved by Genetic Modification Safety Committee** | | | |
|  | | | |
| Signature: | | Date: | |
| (Biological Safety Officer) | |  | |
|  | | | |
| **Permission granted by Head of Department for project to be undertaken** | | | |
|  | | | |
| Signature: | | Date | |
| (Head of Department) | | | |

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| **RISK ASSESSMENT FOR HUMAN HEALTH AND SAFETY**  **Human health hazard identification** – (Identify any potential harmful properties of:)   1. the recipient micro-organism *(for micro-organisms also give ACDP hazard group)* | | | | | ***GUIDANCE***  *Potentially harmful effects include:*  *disease to humans – consider all properties which may give rise to harm eg infection, toxins, cytokines, allergens, hormones etc*  *alteration of existing pathogenic traits – consider alteration of tissue tropism or host range, alteration in susceptibility to human defence mechanisms etc*  *adverse effects resulting from inability to treat disease or offer effective prophylaxis*  *possibilities for any disablement or attenuation to be overcome by recombination or complementation*  *adverse effects resulting from the potential for transfer of inserted genetic material to another micro-organism* | |
| 1. the inserted (donated) genetic material | | | | |
| 1. the donor micro-organisms *(where used/appropriate)* | | | | |
| 1. the vector | | | | |
| 1. the resulting genetically modified micro-organism | | | | |
| **Brenner Scheme values** (*COMPLETION OPTIONAL* *and in any case for disabled E. coli only*) | | | | |  | |
| Access | Expression | Damage | Overall | |  | |
| **Control measures –** Assign provisional containment level:  **Containment Level:**  **with Good Microbiological Practice and Good Occupational Safety and Hygiene** | | | | | *Assign a provisional containment to control the hazards identified above taking account of severity of any consequence and likelihood of harm occurring. Select from 1,2,3 or 4* | |
| **NATURE OF WORK TO BE UNDERTAKEN** | | | | | ***GUIDANCE***  *Consider any activities that may involve risks which require specific additional control measures such as:*  *inoculation of animals or plants with GMMs*  *the use of equipment or procedures likely to generate aerosols*  *large scale work* | |
| Give brief description of types of laboratory procedures including maximum culture volumes at any time (show as multiples of unit volumes) | | | | |
| Provide details of any non-standard laboratory operations | | | | |
| **Additional control measures** required for specific risks: | | | | |

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| **RISK ASSESSMENT FOR ENVIRONMENTAL HARM**  **Environmental hazard identification -** Identify any potentially harmful properties of: | ***GUIDANCE***  *Potentially harmful effects include:*  *disease to animals including allergenic and toxic effects*  *disease to animals and plants*  *adverse effects resulting from inability to treat disease or offer effective prophylaxis*  *adverse effects resulting from establishment or dissemination of the GMMs in the environment*  *adverse effects resulting from the natural transfer of inserted genetic material to other organisms* |
| 1. the recipient micro-organism |
| 1. the inserted (donated) genetic material |
| 1. the donor micro-organisms *(where used/appropriate)* |
| 1. the vector |
| 1. the resulting genetically modified micro-organism   **Where potentially harmful effects are identified estimate:** |
| 1. consequence/severity of effects | *select from:*  *Severe/Medium/Low/Negligible* |
| 1. likelihood of effects being realised *(taking containment and control measures assigned above into account)* | *Select from:*  *High/Medium/LowNegligible* |
| 1. overall risk | *Select from:*  *High/Medium/Low/Effectively zero* |
| **Additional control measures** required to reduce all risks to low/effectively zero: |  |
| **CLASSIFICATION AND ASSIGNMENT OF FINAL CONTROL MEASURES**  **Consider each item on Table 1a** indicate whether or not it is required taking account of the provisional containment level assigned to protect human health and safety and any additional control measures necessary to control specific activities and environment risks  **Consider also Tables 1b and 1c where appropriate** | ***GUIDANCE***  *Mark up table(s) by circling for each item the first correct answer reading across the table from left to right* |
| **Classification:**  **Class:** | *The highest numbered column in which a control measure is required indicates the Class of the activity – circle class on table 1a* |
| **Assign corresponding level of containment:**  **Containment Level:** | *The class number indicates the minimum containment level required* |
| specify any other control measures required |  |

**Table 1a: Containment Measures for Activities involving GMMs in Laboratories**

Where an item is listed as "may be required" this indicates the item to be an option at that particular containment level and its requirement should be determined by the risk assessment for the particular activity concerned. Delete no or yes as indicated by risk assessment.

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| **Containment Measures** | **Containment Levels** | | | |
|  | **1** | **2** | **3** | **4** |
| Isolated laboratory suite | not required | not required | required | required |
| Laboratory sealable for fumigation | not required | not required | required | required |
| Surfaces impervious, resistant and easy to clean | required for bench | required for bench | required for bench and floor | required for bench, floor, ceiling and walls |
| Entry to lab via airlock | not required | not required | may be required  no / yes | required |
| Negative pressure relative to the pressure of the immediate surroundings | not required | may be required  no / yes | required | required |
| HEPA filtered extract and input air | not required | not required | required for extract | required for input and extract |
| Microbiological safety cabinet/enclosure | not required | may be required  no / yes | required | required  (class 3) |
| Autoclave | required on site | required in the building | required in the lab suite | required in lab (double ended) |
| Access restricted to authorised personnel | not required | required | required | required |
| Specified measures to control aerosol dissemination | not required | required so as to minimise | required so as to prevent | required so as to prevent |
| Shower | not required | not required | may be required  no / yes | required |
| Protective clothing | suitable protective clothing required | suitable protective clothing required | suitable protective clothing required | complete change of clothing and footwear |
| Gloves | not required | may be required  no / yes | required | required |
| Control of disease vectors (eg rodents, insects) which could disseminate GMMs | may be required  no / yes | required | required | required |
| Specified disinfection procedures in place | may be required  no / yes | required | required | required |
| Inactivation of GMMs in effluent from handwashing sinks, showers etc | not required | not required | may be required  no / yes | required |
| Inactivation of GMMs in contaminated material and waste | required by validated means | required by validated means | required by validated means, with waste inactivated in the laboratory suite | required by validated means, with waste inactivated within the laboratory |
| Laboratory to contain its own equipment | not required | not required | required | required |
| An observation window or alternative so that occupants can be seen | may be required  no / yes | may be required  no / yes | required | required |
| Safe storage of GMMs | may be required  no / yes | required | required | secure storage required |
| Written records of staff training | not required | may be required  no / yes | required | required |
|  |  |  |  |  |
| **CLASSIFICATION** | **CLASS 1** | **CLASS 2** | **CLASS 3** | **CLASS 4** |

**Table 1c: Containment Measures for Activities involving GMMs in Animal Units** - TABLE 1a TO BE COMPLETED WITH THE FOLLOWING ADDITIONS/MODIFICATIONS:

Where an item is listed as "may be required" this indicates the item to be an option at that particular containment level and its requirement should be determined by the risk assessment for the particular activity concerned. Delete no or yes as indicated by risk assessment.

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| **Containment Measures** | **Containment Levels** | | | | **Addition/**  **modification** |
|  | **1** | **2** | **3** | **4** |  |
| Isolation of animal unit (note 1) | may be required  no / yes | required | required | required | modification |
| Animal facilities (note 2) separated by lockable doors | may be required  no / yes | required | required | required | addition |
| Animal facilities (cages etc) designed to facilitate decontamination (waterproof and easily washable material) | may be required  no / yes | may be required  no / yes | required | required | addition |
| Floor and/or walls and ceiling easily washable | may be required  no / yes | required for floor | required for floor and walls | required for floor, walls and ceiling | modification |
| Appropriate filters on isolators or isolated rooms (note 3) | not required | may be required  no / yes | required | required | addition |
| Incinerator for disposal of animal carcasses | required to be accessible | required to be accessible | required to be accessible | required to be on site | addition |
| Appropriate barriers at the room exit, and at drains and ventilation duct work | required | required | required | required | addition |
| Animals kept in appropriate containment facilities, such as cages, pens, tanks or isolator | may be required  no / yes | may be required  no / yes | may be required  no / yes | may be required  no / yes | addition |
|  |  |  |  |  |  |
| **CLASSIFICATION** | **CLASS 1** | **CLASS 2** | **CLASS 3** | **CLASS 4** |  |

**Notes**

1. "Animal unit" means a building, or separate area within a building, containing an animal facility and other areas such as changing rooms, showers, autoclaves, food storage areas etc.

2. "Animal facility" means a facility normally used to house stock, breeding or experimental animals or one which is used for the performance of minor surgical procedures on animals.

3. "Isolators" means transparent boxes where small animals are contained within or outside a cage; for large animals, isolated rooms may be more appropriate.