GM RA Number

**SGUL RISK ASSESSMENT FOR GENETICALLY MODIFIED MICROORGANISMS**

**Part 1**

**a – Title of the project.**

**b – Purpose of the contained use.** (This information should provide background and put the work into context. The purpose of the contained use needs not to be disclosed if this information presents problems in the context of intellectual property rights or commercial activity.)

**c – Characteristics of the GMM(s):**

Unless you are making a request for non-disclosure in relation to intellectual property rights this section must be completed in detail, otherwise, you must include at least general characteristics of the GMM(s).

**c1 – Overview of the GMM(s) that will be constructed/used.** (This overview should consist of 1 or 2 paragraphs outlining the general characteristics/use of the GMM(s) involved in the intended contained use together with the scope and boundaries of exactly what work will be done.)

c2 – **List of recipient or parental organisms**. (include name and strain of the organism(s), the names of parental strain(s), and the degree to which they are disabled.)

**c3 – List of vectors.** (cover names, mobilisation regions, and any disabling mutations.)

**c4 – Origin and function of the genetic material involved.** (Preferably a list of genes should be included. Genes must be identified in a way that an outside reviewer will have a general idea of their function. A three letter name may not be sufficient. When the function of the gene is unknown, providing the function of any know homologues may help.)

**d – Describe the most hazardous GMM that will be created/used during the activities\***. (Considering both human health and the environment, the most hazardous GMM that will be constructed/used in this work should be identified. For some project it will not be clear that any one GMM will be any more hazardous than any others. If this is the case, this should be stated.)

**e – Are all the non-GM risks in this activity adequately covered by up-to-date COSHH risk assessment(s)?**

**Yes** [ ]

**No** [ ]

**f – Are you confident that for the GMMs covered by this assessment there are no harmful properties associated with the recipient strain, the vector or the inserted material?** (Consider this question CAREFULLY. If the answer to this question is ‘No’ or you are in anyway unsure, Part 2 of this form needs to be completed.)

**Yes** [ ]

**No** [ ]

**g – Are you confident that none of the final GMMs could be hazardous to humans or the environment? (**Consider this question CAREFULLY. If the answer to this question is ‘No’ or you are in anyway unsure, Part 2 of this form needs to be completed.)

**Yes** [ ]

**No** [ ]

h – If your answer to the previous two questions was ‘Yes’, then you may be confident that the proposed activity can be categorised as ‘Class 1’ as defined in the Genetically Modified Organisms (Contained Use) Regulations 2014. In order to do this you must be confident that even in the event of a total breach of containment, the consequences to human health and environment will be negligible. Note that intentional release of GMMs into the environment is an offence under the GMO (Deliberate Release) Regulations 2003.

**Are the proposed activities class 1 as defined in Contained Use Regulations 2014?**

**Yes** [ ]

**No** [ ]

If you are assigning your GM activity to class 1, you do not need to complete Part 2 of this form. Complete Part 3 and email the form to the Biological Safety Officer for Genetic Modification (BSO-GM@sgul.ac.uk). The application will be considered by the Genetic Modification Safety Committee (GMSC). Work on the activity cannot commence until the GMSC has reviewed and approved the activity. The GMSC aims to review all assessments within 14 days.

If you are unsure whether the proposed GM activities can be assigned to class 1 work, you must complete Part 2 of this form before submitting it to the BSO-GM for consideration by the GMSC.

**SGUL RISK ASSESSMENT OF GENETICALLY MODIFIED MICROORGANISMS**

Part 2

Use this form where a more detailed risk assessment is required. Please bear in mind that the regulator (the HSE) does not accept simple statements such as ‘it is not anticipated’ without proper justification and supporting evidence.

This form is designed to assess the hazards presented by the most hazardous GMM identified in Part 1 section d. In cases where there are 2 or more hazardous GMMs with quite different properties, 2 or more copies of part 2 may need to be completed.

**Evaluation of foreseeable effects**

**a – Hazards to human health**

**a1 – Hazards associated with the recipient microorganism.** (Factors to be considered are classification of the microorganism by Advisory Committee on Dangerous Pathogens (ACDP), and the microorganism’s mode of transmission, dissemination, range of host, and tissue tropism. Consider also whether vaccines or any prophylaxis are available. Information must also be provided on any disabling mutation and whether there is any possibility of the disabling mutation being complemented or reverting.)

**a2 – Hazards arising directly from the gene products.** (Consideration must be given to 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. When the function of the inserted gene is unknown, it may help to describe the function of any known homologues. Please note that any human gene may be harmful if overexpressed, especially if the overexpression is in tissues that do not normally express the protein.)

**a3 – Hazards arising from the alteration of existing traits.** (Consider whether the inserted sequence carries a pathogenicity determinant, such as a receptor, a penetration factor or a surface component providing resistance to host defence mechanisms. Also consider whether the sequence carries a protein that may allow a different range of hosts for the microorganism. Consideration may also be given to whether the sequence (or its vector) carries a resistance to a drug or antibiotic that may be used for the treatment of laboratory-acquired infection.)

**a4 – Hazards arising from the transfer of the inserted sequence to other organisms.** (Factors to consider include whether the dissemination of the inserted sequence as a result, for example, of either gene transfer or recombination of the GMM with a wild-type organism, would be a matter for concern. Note that the likelihood of gene transfer will increase with the ability of the GMM to persist in the environment even if it cannot prosper there.)

**a5 – Assignment of a provisional containment level that is adequate to minimise the risks to human health.** (The default containment level will be that assigned by the ACDP to the recipient organism. You should evaluate whether the GMM will represent a greater, lesser, or about the same hazard as its parental organism.)

**Containment Level 1** [ ]

**Containment Level 2** [ ]

**Containment Level 3** [ ]

**b – Hazards to the environment.**

**b1 – Hazards associated with the recipient microorganism**. (Factors to be considered are whether the recipient microorganism is capable of infecting plants or animals and whether there is any possibility of any disabling mutations being complemented or reverted. In particular, it must be asserted whether the microorganism is regulated under SAPO.)

**b2 – Hazards arising directly from the inserted product.** (Factors to be considered are whether the inserted sequence encodes a plant or animal toxin or a product which inhibits crucial metabolic enzymes in susceptible hosts.)

**b3 – Hazards arising from the alteration of existing traits.** (Consider whether the inserted sequence carries a pathogenicity determinant, such as a receptor, a penetration factor or a surface component providing resistance to host defence mechanisms. Also consider whether the sequence carries a protein that may allow a different range of hosts for the microorganism. Consideration may also be given to whether the sequence (or its vector) carries a resistance to antibiotics.)

**b4 – Hazards arising from the transfer of the inserted sequence to other organisms.** (Factors to consider include whether the dissemination of the inserted sequence as a result, for example, of either gene transfer or recombination of the GMM with a wild-type organism, would be a matter for concern. Note that the likelihood of gene transfer will increase with the ability of the GMM to persist in the environment even if it cannot prosper there.)

**c – Consideration of the nature of the work to be undertaken and a detailed review of control measures.**

**c1 – Are any of the work procedures likely to generate aerosols?** (If work will involve liquid cultures, it is likely that aerosols will be generated. Please describe what control measures will be applied.)

**c2 – Estimate maximum culture volume (Class 2) or specify the culture volume (class 3)**

**c3 – Will any sharps be used?**

**c4 – If the work involves the experimental infection of plants or animals, are they expected to shed GMMs?**

**c5 – If the work involves the experimental infection of plants, what is known about the likely route of transmission of the GMM?** (Consider for example whether the microorganism is insect-borne or can be carried in run-off water. These are important considerations regarding the type of greenhouse used.)

**c6 – In the case of microorganism with a complex life cycle, will the work involve the propagation of organisms that are in stages in that cycle that are particularly hazardous?** (Examples include the propagation of infective stages of parasites or the release of fungal spores. Consideration should be given to all potential routes of transmission including those that might not occur naturally.)

**d – Consideration whether there is a need to assign additional measures over and above the provisional level of containment assigned in Part 2 section a5.**

Additional control measures may be necessary:

1 – To protect human health

2 – To protect the environment

3 – To provide additional safeguards to particular work procedures

e – Is there an emergency plan required under regulation 21 of CU 2014?\*\*

**Yes** [ ]

**No** [ ]

If yes, please describe:

**SGUL RISK ASSESSMENT OF GENETICALLY MODIFIED MICROORGANISMS**

Part 3

**Describe the waste management measures which you will apply** (Describe how solid and liquid waste material will be treated and disposed.)

**Have your disinfectants being validated under actual conditions of work?** (e.g. are the disinfectants effective under the high levels of protein common in TC conditions?)

**Does the nature of this work precludes it from being undertaken by any workers who have a serious skin condition or other health problems?**

**Does the nature of this work precludes it from being undertaken by any worker who is pregnant or intends to become pregnant?**

**Final assignment of containment measures and activity class**

* **The following aspects of this project are assigned to Containment Level 1 and will be undertaken in room(s)** (Provide room numbers.)
* **The following aspects of this project are assigned to Containment Level 2 and will be undertaken in room(s)** (Provide room numbers.)
* **The following aspects of this project are assigned to Containment Level 3 and will be undertaken in room(s)** (Provide room numbers.)

**The activity class for this work is** (Following CU regulation the minimum activity class should be numerically equivalent to -at least- the maximum Containment Level deemed necessary by risk assessment.)

**Class 1** [ ]

**Class 2** [ ]

**Class 3** [ ]

**Has the principal investigator notified this activity to the head of the relevant institute and received approval to carry out the work?**

**Yes** [ ]

**No** [ ]

Name of the head of the institute:

**Name and email address of the Principal Investigator.** (All the communication regarding this GM activity will be via de PI named here.)

**Name, email address, and level of competency of each worker involved in the activity (1 = fully competent, 2 = needs supervisor’s advice and approval before work, 3 = requires direct supervision)**

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| --- | --- | --- |
| Name | Email address | Competency level |
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Notes:

\* It is not appropriate to consider non-disabled pathogens of plants, humans, animals or insects as inherently safe recipient microorganism. Examples of inherently safe recipient microorganisms which –depending on the nature of the insert- would in most cases be expected to form the basis of extremely safe GMMs are:

1 E coli K12 and its derived strains.

2 Replication defective retroviruses produced with the aid of helper genes that are located in two or more separated blocks of DNA (thus eliminating the possibility of reversion by a single recombination event).

3 E1-deleted adenoviruses.

\*\* An emergency plan is required under regulation 21 when -as a result of a reasonably foreseeable accident- the health or safety of persons outside the premises in which the contained use is undertaken is liable to be seriously affected; or there is a risk of serious damage to the environment from the contained use,