**Section 2:**

**Detailed risk assessment for Class II Genetic Modification Projects**

**All projects that are deemed to require assessment via the more detailed risk assessment below will require approval by the University Biological Safety Adviser and/or the University Biological Hazards and GM Safety Committee, so should be completed well ahead of the planned project start date.**

**A: For projects involving Genetically Modified Microorganisms**

Hazards associated with the recipient microorganism

Guidance:
Is the recipient microorganism on the ACDP lists?
You need to consider mode of transmission, disease symptoms, host range and tissue tropisms, along with availability of vaccines or therapies.
Please detail any disabling mutations and whether there is ANY possibility of these being complemented or reverting.

Hazards associated with the inserted gene product

Guidance:
You need to consider whether the inserted DNA encodes a toxic product, oncogenic protein, an allergen, growth modulator, differentiation modulator (e.g. hormone or cytokine) or any other protein which may be hazardous. Remember that overexpression of a normal gene may produce harmful effects. If functions are unknown, please describe known homologues.

Hazards associated with the alteration of existing traits

Guidance:
You need to consider any possible changes to pathogenicity (e.g. changes to surface binding, penetration or increased resistance). Also please consider whether the inserted gene encodes a surface component that could bind to a different receptor than the one on the recipient microorganism. Can the inserted DNA sequence encode drug resistance that may affect treatment in the event of a laboratory acquired infection?

Hazards associated with the potential transfer of genetic material

Guidance:
You need to consider whether dissemination of the inserted gene could occur by either gene transfer or recombination of the GMM with wild type organisms. If this is a risk, you must consider how long the GMM could survive in the environment, and could it be long enough for such a transfer to occur.

Assign provisional containment level: 1 or 2

B: For projects involving GMMs, GMOs or both.

Environmental hazards

Guidance:
Is the microorganism controlled by DEFRA or other authorities?
You need to consider if any GMMs produced can infect any organism in the environment, and if any disabling mutations could be complemented or revert.
Can the inserted sequence encode toxic products in other organisms, or could it silence an existing gene?
Can the inserted gene affect surface tropisms, binding or affect penetration into another organism?
Could dissemination of the inserted gene occur by either gene transfer or recombination of the GMM with wild type organisms? If this is a risk, you must consider how long the GMM could survive in the environment, and could it be long enough for such a transfer to occur.

Transmission routes for infecting other organisms

Guidance:
Could the GMM be insect-borne or carried in run-off water? If so, please consider what conditions would be needed within growth facilities (chamber or greenhouse)

C: Detailed control measures (beyond those defined by final assigned Containment Level)

Could any procedures generate aerosols?

Guidance:
If so, should work be carried out within a microbiological safety cabinet or other isolator?

Do any of your waste materials require special processing?

Guidance:
Please detail any specific requirements for both liquid and solid waste, both during the project and for the final organism(s) produced.

Have any disinfectants been specifically validated under actual conditions of use?

Guidance:
For example, have they been validate to work in cell culture medium, in high protein levels etc.?

Will it be necessary to use sharps?

Guidance:
Established policy prohibits use of sharps with GM work, but if these are needed please consider hypodermic needles, scalpel blades, other blades, glass Pasteur pipettes etc.

Does this project require any additional control measures not detailed elsewhere?

Final assignment of GM Class and Containment Level:

PI signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Approval by University Biological Safety Adviser
on behalf of Biological Hazards and Genetic Modification Safety Committee

Signed \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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