University Occupational Health and Safety

Form

RISK ASSESSMENT FOR GENETICALLY MODIFIED ANIMALS

In completing this risk assessment form additional guidance can be obtained from:

1. [Guidance Note – Risk Assessment for Genetically Modified Animals](https://www.strath.ac.uk/media/ps/safetyservices/campusonly/standards/geneticmodification/Guidance_Note_-_RA_for_Genetically_Modified_Animals.pdf);
2. The University Genetic Modification Safety Committee (GMSC);
3. The Scientific Advisory Committee on [Genetic Modification (SACGM) Compendium of Guidance](http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/).

SACGM Compendium of Guidance – Brief Summary

GM animals (also known as larger GMOs or LGMOs) are those where their genetic material has been altered using a method that does not occur naturally, but excludes chemical or physical mutagenesis. In its broadest sense this includes both vertebrates and invertebrates. The legislation covers the breeding on of a genetically modified animal. Even when a GM animal is crossed with a non-GM animal the progeny will be considered to be GMOs.

All activities involving GM animals must be risk assessed in relation to human health and safety as well as the environment and records require to be kept for 10 years.

The recommended procedure for risk assessment of GM animals is reflected in the SCAGM guidance. Outlined this is as follows:

1. Risk assessment for environmental protection (including hazard identification, assessment of likelihood and consequences; determination of risk; assignment of risk management measures to protect the environment).
2. Risk assessment for human health.
3. Review of procedures and control measures.
4. Assignment of the final containment and control requirements.
5. Determination of HSE notification requirements.

As part of the consideration under (ii) it is important to determine whether the GM animal is more likely to cause harm to humans than the non-modified parental organism. This is so you can determine whether the activity has to be notified.

The hazards that need to be considered will usually be:

(i) Capacity to survive, establish, disseminate, compete with and / or displace other animals;

(ii) (Direct) adverse effects on animals and plants;

(iii) Potential for transfer of genetic material between the GMO and other organisms;

(iv) Products of gene expression, particularly if they are toxic or otherwise biologically active;

(v) Phenotypic and genetic stability; and

(vi) Other negative effects on organisms.

The risk assessment should consider the modified organism, the nature of the activity, or process, and the nature of any product. In some cases the level of containment and control may be dictated by the risk posed by the product or process rather than by the GMO itself.

Where it is proposed to inoculate animals with viable GMMs, animal containment corresponding to that used in the laboratory for the micro-organisms concerned, modified by the requirements specific to animal houses, should be used (see Part 3.4 of the Compendium of Guidance).

**Notification to the Health and Safety Executive**

Using the following guidelines, you will need to assess whether your GM animal requires notification to HSE or not.

Notification to HSE is NOT required for GM animals which where the risk to both human health and the environment have been assessed as being LOW of EFFECTIVELY ZERO and where they exhibit any of the following traits or properties:

* They are incapable of surviving in the environment in the UK; or,
* They have limited ability to transfer genetic material to UK animal species; or,
* The genetic modification does not increase the risk to human health or the environment above that of the non-modified parental organism; and
* The GM animals have either not been inoculated or have been inoculated with Class 1 GM material or other pathogens.

Notification to HSE IS required for GM animals which have any of the following characteristics:

* The animals could cause harm to humans or the environment if they escaped from the containment facility, and they have the ability to transfer novel genetic material to UK animal species; or,
* The animals could establish outside the facility; or,
* The GM increases the level of risk to human health or the environment above that of the non-modified parental organism; or
* The animals have been inoculated with a GM material or other pathogen that is above Class 1.

Only activities generating a GMO with a greater potential to cause harm to human health compared to the unmodified organism require notification

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| **Proposer Details** | |
| **Project Title** |  |
| **Principle Investigator** |  |
| **Location(s)** |  |
| **Contact Telephone** |  |
| **Contact E-mail** |  |

This project is in scope of the Nagoya Protocol and I have undertaken a due diligence check.

This project is out of scope of the Nagoya Protocol.

For further information on the Nagoya protocol please see Section 6.2.4 of the [OHS GM Standard](https://www.strath.ac.uk/media/ps/safetyservices/campusonly/standards/geneticmodification/OHS_Standard_-_Genetic_Modification.pdf).

Risk Assessment for Containment of an Individual Strain of Genetically Modified Animal (GMO)

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| **Scientific goals of project** |
| *This information provides a useful background and puts the work in context. The scientific goals need not be disclosed if presenting the information presents problems in relation to intellectual property rights or commercial sensitivity.* |
| 1. **Species, GM name and strain/background of GM animal** |
| (ii) Description of the genetic modification *to include: The origin and activity of the inserted material, and, where known, levels of expression, the location of the material on plasmids or on chromosomes. Key references, where appropriate and where known, should be included.* |
| 1. **Assessment of the hazards posed to human health by the GMO in comparison to the non-modified host** *e.g. increased allergenic or toxic effects, acting as a human vector, adverse effects to humans from altered behaviour or physical factors* |
| 1. **Assessment of the hazards posed to the environment by the GMO in comparison to the non-modified host** *e.g. Does the modification alter the capacity of the organism to survive?* |
| 1. **Assessment** **of the consequences of the GMO escaping from containment in terms of risk to the health of the human population and to the environment** *To include the potential of transfer of genetic material to other populations.* |

Following completion of this risk assessment, please indicate if the proposed project is notifiable to the HSE.

If the risk assessment determines that this project is NOTFIABLE to the HSE, you will be required to complete a separate risk assessment for the University Genetic Modification Safety Committee which has to be approved by the Health and Safety Executive.

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| **Part 3 Final assignment** | | |
| **Proposed Class** | **Non-Notifiable** | **Notifiable** |
| **Signature of PI** |  | |
| **Date Signed** |  | |
| **Date of Next Review** |  | |

###### Laboratory Staff working on this project should sign a hard copy of the risk assessment before commencing work. This should be held in the laboratory for reference. All staff should be appropriately trained by the PI or other nominated person(s) before commencing work.

**All staff working on this project must have completed the** [**BP1 and/or BP2 form**](https://ben.mis.strath.ac.uk/login/) **as appropriate.** These forms can be accessed through Pegasus under the Human Resources tab. Further information including training requirements for working with biological and GM material can be found in the [OHS Biological Safety Standard](https://www.strath.ac.uk/safetyservices/documentationforms/ohsoperationalcontrolstandards/biologicalsafety/) and the [OHS GM Standard](https://www.strath.ac.uk/media/ps/safetyservices/campusonly/standards/geneticmodification/OHS_Standard_-_Genetic_Modification.pdf).

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