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THE USE OF GENETICALLY MODIFIED ORGANISMS

Who should read this document?

If you are working with, or are proposing to work with **Genetically Modified Organisms** (GMOs) then you will need to comply with **The Genetically Modified Organisms (Contained Use) Regulations 2000**.

If you are working with **naked oncogenic DNA** then this is covered by COSHH and GMO regulations. This work should still be discussed with your Departmental Biological Safety Officer and reported to Safety Services.

You may also need to comply with other health & safety issues which are not covered by these regulations. See the Safety Services web page for details - http://cms.shef.ac.uk/safety/index.html.

The regulations are administered locally by the University of Sheffield Local Genetic Modification Safety Committee who return information to the Health & Safety Executive. If you have any general questions then you can contact the University Biological Safety Advisor in Safety Services.

It is the responsibility of the Proposer to ensure that all work is performed in compliance with current UK regulations.

Is your work covered by the regulations?

If you are unsure whether your work is covered by The Genetically Modified Organisms (Contained Use) Regulations 2000 then you should refer to the relevant section of the regulations.

The full text of these regulations is available on the HMSO website at: http://www.opsi.gov.uk/si/si2000/20002831.htm but the relevant sections (Schedule 2, Parts I-III) describing what areas of work are covered are available here: http://www.opsi.gov.uk/si/si2000/20002831.htm#sch2

The Scientific Advisory Committee on Genetic Modification (SACGM) has produced an advisory document - http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/index.htm which contains a wealth of information on working with Genetically Modified Organisms.

If you work is covered by the regulations, or you are still unsure, contact your Departmental Biological Safety Officer.

If you do not have a BSO then contact the University Biological Safety Advisor (ext. 26200).

What do I do now?

Before work can commence using Genetically Modified Organisms authorisation must be given by the appropriate regulatory bodies. See below for details of the application procedure.

In order to obtain permission to work with GMOs you need:
a) To prepare a GM Risk Assessment
b) Medical assessment of all workers involved, by University Staff Occupational Health Service
c) Inspection of laboratories, rooms etc. to be used (unless already authorised for GM work) by the University Biological Safety Advisor

The Proposer

The Proposer has overall responsibility for the work with the GMOs/GMMs. This individual must be a permanent member of staff (i.e. not a postdoctoral researcher or postgraduate student).

They will prepare the GM Risk Assessment and ensure that changes in information and personnel are reported to the Local Genetic Modification Safety Committee (LGMSC).

The Departmental Biological Safety Officer, if necessary, will help in the preparation of the GM Risk Assessment, but ultimately it is the responsibility of the Proposer to ensure that the regulations are complied with. Additional assistance may also be sought from members of the LGMSC, or colleagues with experience in preparing GM Risk Assessments.

OBTAINING AUTHORISATION

Prepare a GM Risk Assessment:

This will include information about the work which you are proposing, the vectors and organisms involved and the potential risk to (i) human health and (ii) the environment. The University's GM Risk Assessment Form (rev7 04/2008) should be used for preliminary assessment of all GM proposals and for local approval of Class 1 activities.

What is contained in the GM Risk Assessment?

The Scientific Advisory Committee on Genetic Modification (SACGM) has provided a Compendium of Guidance - http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/index.htm for help in preparing the GM Risk Assessment. This is an excellent document and has lots of examples.

There are two sorts of work:

CONTAINED USE which encompasses work in laboratories, small scale fermentation facilities and other growth facilities (glasshouses etc) and, as its name implies, is designed to prevent release of the GMO into the environment. All the work in the University falls under this heading.

DELIBERATE RELEASE is used for field trials etc. The University is not engaged in any work of this kind at present. As the regulations governing deliberate release are considerably more involved, and take a long time for approval, please contact the University Biological Safety Adviser if you are contemplating any work of this kind.

All subsequent information on these pages refers to **CONTAINED USE** of GMOs.

The GM Risk Assessment is probably the most important document which you will produce. It is not possible to describe exactly what should go into an assessment as this must be decided on a case-by-case basis.

The SACGM Compendium of Guidance is excellent and gives information on what should be included for different sorts of GMO. The document is split into sections and saved as PDF files.

Part 1 describes how the GMO legislation fits in with other legislation and how the GM work should be overseen at an Institutional level.

Parts 2 – 6 provide more specific information about different sorts of organism, and the containment facilities required for different sorts of work, along with a list of abbreviations.

Part 1: Introduction to the legislation and general health and safety issues - http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/part1.pdf

Part 2: Risk assessment of genetically modified microorganisms (other than those associated with plants)- http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/part2.pdf

Part 3: Containment and control of activities involving genetically modified microorganisms - http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/part3.pdf

Part 4: Genetic modification work that involves plants (including plant-associated genetically modified microorganisms) - http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/part4.pdf

Part 5: Genetic modification of animals - http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/part5.pdf

Part 6: Guidance on the use of genetically modified microorganisms in a clinical setting - http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/part6.pdf

List of abbreviations - http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/abbreviations.pdf

The University GM Risk Assessment document contains a number of main sections, including:

- details of the Proposer, and an overview of the project including the organisms involved, the host and recipient DNA
- a list identifying the personnel and the rooms involved.
- an assessment of the risk to human health
- an assessment of the risk to the environment
- assignment of final activity Class

The subheadings within these sections should help with laying out the information, but do ask for guidance if you are unsure.

The GM Risk Assessment should determine the containment measures required to control the identified risks. These containment levels decide the classification of the activity, and the classification determines the notification requirements.

You will now need to classify the work into risk classes (for Genetically Modified Micro-Organisms) or identify containment procedures (for Genetically Modified Plants or Animals).

Categorise the Project into a 'Risk Class':

Classes of Activity Involving Genetic Modification

The class into which each organism is placed depends upon the risk assessment and the containment required. This risk assessment is made on the basis of risk to human health and the environment.

These risk classes are used only for **Genetically Modified Micro-Organisms.**

Class	*Description*
1	Activities of no or negligible risk, for which containment level 1 is appropriate to protect human health and the environment.
2	Activities of low risk, for which containment level 2 is appropriate to protect human health and the environment.
3	Activities of moderate risk, for which containment level 3 is appropriate to protect human health and the environment.
4	Activities of high risk, for which containment level 4 is appropriate to protect human health and the environment.

For work involving **Genetically Modified Plants or Animals** a risk class is not used. Risk is assessed on a case-by-case basis and depends on whether the GMO represents a greater or lesser hazard to human health, or the environment, than the unmodified organism.

Determine the Containment Procedures to Use:

Part of the risk assessment process is determining which containment procedures will be required.

Containment Procedures for GMMs/GMOs/Animals

Containment procedures are described in Part 3 - http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/part3.pdf of the SACGM Compendium of Guidance, in the following sections:

Section	**Use**
3.2	Lab scale use of genetically modified micro-organisms (GMMs)
3.3	Large scale use of genetically modified micro-organisms (GMMs)
3.4	GM animals
3.8	Work with DNA encoding oncogenic sequences

For plants, containment procedures are described in Part 4 - http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/part4.pdf of the SACGM Compendium of Guidance, in the following sections:

Section	**Use**
4.3	Activities with GMMs in a plant growth facility
4.5	Activities with genetically modified plants

It is possible to modify the containment procedures based upon the risk assessment. In some circumstances, it may be reasonable to argue in the risk assessment that certain features of the containment procedures are not required. This would be scrutinised closely both by the LGMSC and the HSE.

Extra containment procedures may be added where required.

Fill in the Appropriate Forms:

Forms for Working with GMOs

You will already have prepared a Risk Assessment Document which describes the risks to human health and the environment.

Depending upon the sort of organism with which you wish to work, and the risk class you have determined, you need to fill out one of the following forms:

Genetically Modified Micro-Organisms

Class 1

These activities are reported to the LGMSC on the form you should have used to prepare your GM Risk Assessment. (Class 1)

Class 2, 3 and 4

Along with the GM Risk Assessment you will need to fill in form CU2 2000 rev 2005.

Genetically Modified Plants or Animals

You need to fill in form CU2 2000 rev 2005.

Risk Assessment form for work with Transgenic Animals.

Sign the forms and get signatures from the BSO and Head of Department. Return the information to the University BSA at Safety Services.

Safety Services will send out the forms to the Local Genetic Modification Safety Committee for consideration and comments.

Class 1 proposals can be considered and approved via email. Class 2 proposals and above have to be approved at a meeting of the LGMSC, where comments of the LGMSC members will be considered. Proposers are invited to the meeting, and will normally attend to introduce the proposal and clarify matters where appropriate.

Laboratory inspections will be made by the University BSA to ensure that the facilities comply with containment requirements.

All personnel involved will be required to register as a GMO worker with the Staff Occupational Health Service and have a health check. This is arranged via the University BSA.

Once the risk assessment has been considered by the LGMSC, and subject to its approval, authorisation will be issued for Class 1 work which can then commence. For work assigned as Class 2 (or higher) the proposal will be sent to the HSE (together with a cheque for the fee) who will consider it and give final authorisation before work can commence.

Fees Charged by for Notifications and Applications

These fees are charged by the HSE to administer the projects.
http://www.hse.gov.uk/biosafety/gmo/acgm/acgmwarn.htm.

It is the responsibility of the Proposer to fund this.

As most departments are already registered for GM work then costs are normally limited to those involving Class 2 genetically modified micro-organisms or any work involving GM plants or animals.

Additional fees are charged where other Government agencies are involved e.g. MAFF.

Once a Department has been registered then there are no additional fees associated with GM micro-organisms which fall into Class 1.

Providing other safety issues (MAFF, COSHH etc.) have been met, work can commence.

Annual Return

The Proposer will fill in an annual return, review the project if changes occur and inform the LGMSC of any changes in procedure, personnel or facilities. Lab inspections will take place at regular intervals. The HSE may also visit to do independent checks at any time.

Waste Disposal

Waste disposal must also be closely monitored. This should be done following the procedures laid out by the University's Department of Energy and Environment, in order to comply with their legal obligations associated with waste disposal. Information on this can be found in the document " The identification, segregation and disposal of biological and associated waste" - http://estatestalk.dept.shef.ac.uk/ee/WMS001.pdf

Autoclave Load Testing

There is a need to demonstrate reliable inactivation of GMO waste by validation.

Although autoclaves undergo annual performance and safety checks, autoclave cycles may be inconsistent due to the diversity of loads placed within them.

Autoclaves which have a load temperature probe and printout of cycle parameters effectively monitor the sterilisation process.

For those autoclaves which do not have these features, an **integrated indicator strip** provides assurance that the correct time and temperature conditions have been achieved. These strips are not dependent upon autoclaving parameters and can be used in all loads.

Suitable strips are made by 3M

3M Comply Thermalog Steam Chemical Integrator

For autoclaves with internal temperature probes

Test strips are not required but printed records of recorded cycle conditions should be retained.

For autoclaves without internal temperature probes

Class 1 GMO waste

A test strip should be placed in the centre of the first GMO load each month and then stapled to a dated record sheet. The record sheet - http://www.shef.ac.uk/safety/genereg/AutoclaveClass1.doc should be retained by the autoclave. If no test is present you must include one in your load and update the record sheet. If the test fails you should repeat the cycle and inform your laboratory manager.

Class 2 GMO waste

A test strip should be included in every load. This strip should be stored in your laboratory records to demonstrate that your group is ensuring safe waste disposal. Again, if the test fails, repeat the cycle with a fresh strip and inform your laboratory manager. If the repeat cycle is failed waste must be returned to your own laboratory for safe keeping.