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# CODE OF PRACTICE

## SAFE MANAGEMENT OF WORK (CONTAINED USE) WITH GENETICALLY MODIFIED ORGANISMS (GMOS)

Document Information

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## Contents

# 1 Summary

Employers have a duty of care to assess, manage and control significant risks to their employees and anyone else who may be affected by their undertaking. The University's health and safety policy sets out its general arrangements to fulfil this duty of care.

This Code of Practice describes how the University manages the risks associated with work with Genetically Modified Organisms (GMOs) so that we can reduce risks of occupational ill health and environmental impact.

The Code of Practice is also intended to ensure that the University is managing our legal responsibilities to people using GMOs under the:

- Health and Safety at Work Act 1974
- Management of Health and Safety at Work Regulations 1999 (the "management regulations")
- Genetically Modified Organisms (Contained Use) Regulations 2014.
- HSE Guidance on Regulations L29

# 2 Scope

This Code of Practice (CoP) has been written to support:

- People who work with GMOs known as "contained use"
- People who supervise persons who work with GMOs (GMO project owners)
- Directors, Heads of Department and others who have responsibility for oversight of health and safety matters in departments, directorates, institutes and other functional units.

It applies to all users of Genetically Modified Organisms at the University of Bath. "using" includes management tasks such as storage and waste disposal as well as handling.

# 3 Introduction

This document sets out the University arrangements to ensure that all work with Genetically Modified Organisms (GMOs) is managed safely to ensure that risks to human health and the environment are assessed and controlled to a level as low as reasonably practicable.

To aid in meeting these responsibilities, a University Genetic Modification Safety Committee (GMSC) has been appointed to provide competent advice for all work with GMOs. The GMSC have reviewed this document.

Before undertaking any work with GMOs, all users should ensure that they have:

- Completed the online GM Awareness course (on Moodle)
- Approval to work with GMOs from the GMSC via the personnel registration form (see GM SharePoint site for guidance and form)
- Read and understand this Code of Practice (CoP,) and
- Ensured there is a GM risk assessment in place for their work and that they read and sign onto the GMO risk assessment (acknowledgement of understanding and record of training).

This document should be read in conjunction with other University resources including:

- GMO Policy
- GM SharePoint site
- Local department guidance/rules/risk assessments

Other recommended reference material includes:

- HSE Guidance to The Genetically Modified Organisms (Contained Use) Regulations 2014 L29
- The SACGM Compendium of guidance (see below)

This CoP only covers the safe management of GMOs to ensure compliance with legislation in that risks are assessed and controlled. It does not cover technical aspects of genetic modification, apart from basic definitions.

The main piece of legislation is the Genetically Modified Organisms (Contained Use) Regulations 2014.

This covers both human health and environmental aspects of work with genetically modified microorganisms (GMMs) but only human health aspects for larger GMOs, e.g. plants, animals and insects. Environmental considerations for the latter come under the Environmental Protection Act (EPA) 1990.

The GMO(CU) Regulations place legal duties on duty holders that includes:

- the requirement to carry out an assessment of the risks to human health and the environment (or human health for larger GMOs) and to obtain competent advice on that assessment before any contained use can start.
- the requirement to make a notification to the competent authority (the HSE) depending on categorisation of risk
- the requirement for a person who undertakes contained use to adhere to the safety principles and apply containment and control measures appropriate to that contained use to protect human health and the environment.

### 3.1.1 Guidance from the Scientific Advisory Committee on Genetic Modification

The Scientific Advisory Committee on Genetic Modification (Contained Use) (SACGM(CU)) is a non-statutory scientific advisory committee established in 2004. SACGM(CU) provides scientific advice to the competent authorities on the contained use of GMOs, particularly in respect of hazard identification and risk assessment. HSE, with advice from the SACGM(CU), has prepared a compendium of guidance on subjects related to the contained use of GMOs. The compendium provides useful advice on how to comply with the Regulations.

# 4 Definitions

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| **Micro-organism** | a microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, and includes a virus, a viroid, and an animal or plant cell in culture. |
| **Larger GMO** | an organism, which is genetically modified or is the subject of genetic modification, which is not a micro-organism. |

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| **Organism** | a biological entity capable of replication or of transferring genetic material and includes a micro-organism, but does not include a human, human embryo or human admixed embryo. |
| **Genetic Modification** | in relation to an organism means the altering of the genetic material in that organism in a way that does not occur naturally by mating or natural recombination (or both) and which has been achieved through one of the techniques set out in Part 1 of Schedule 2 (of L29). Information is also provided in the online GM Awareness Course. |
| **Contained Use** | an activity in which organisms are genetically modified or in which genetically modified organisms are cultured, stored, transported, destroyed, disposed of or used in any other way and for which physical, chemical or biological barriers, or any combination of such barriers, are used to limit their contact with, and to provide a high level of protection for, humans and the environment. |
| **Class** | Contained use is classified into one of four classes, as described in Schedule 1 of L29, based on the risk that the contained use presents to human health and the environment. These are referred to as<br>• Class 1 (no or negligible risk),<br>• Class 2 (low risk),<br>• Class 3 (moderate risk) and<br>• Class 4 (high risk).<br>The contained use class is derived from the outcome of the risk assessment and is only applicable to micro-organisms (GMMs). It is not used for larger GMOs, the assessment for these considers at increased risk to human health. |
| **Genetic Modification Safety Committee (GMSC)** | A group of technical and operational experts who provide competent advice on the adequacy of GMO risk assessments. |
| **GM Project Owner** | "Person responsible for "contained use" - a person who has control of the planning or conduct (or both) of the contained use covered in the risk assessment. This includes supervision and training of other GM users assigned to the contained use via the GM personnel registration form. |
| **GM worker or user** | A person who undertakes a contained use. They must be approved by the GMSC via the personnel registration form. |

# 5 Roles and Responsibilities

The University's health and safety policy describes the general roles and responsibilities on all employees to safeguard themselves and others in the workplace.
This CoP sets out the additional specific roles and responsibilities for managing risks related to GMO contained use.

## 5.1 Heads of Department

Heads of Department are responsible for the day-to-day implementation of this code of practice. Responsibilities include ensuring that:

- Effective and regular communication of the university arrangements is in place to enable work with GMOs to be undertaken
- GMO Risk assessments are carried out for all work activities using GMOs within area of responsibility
- Identified control measures are implemented and monitored such as provision of suitable LEV, PPE, inactivation and waste disposal

## 5.2 GM Project Owners

The GM Project Owner is responsible for ensuring that:

- GM work is not started until the required approvals have been granted
- A GM risk assessment is in place produced on the required template
- The GM Risk assessment has been reviewed and approved (signed) by the GMSC
- All GM workers under their supervision have completed the GM awareness training and a GM personnel form which has been approved by the GMSC
- All GM workers under their supervision are trained in the contained use they are to undertake including understanding the content of the GM Risk assessment. This must be recorded, preferably on the sign on sheet provided.
- The GM risk assessment is reviewed at intervals specified by the GMSC and when any changes occur such as a change in location or an incident occurs
- All records required by the GMSC are easily accessible to workers and for inspection.

## 5.3 GM Workers

Anyone who is classified as a “GM worker” has a responsibility to:

- Complete the University’s online GM awareness Moodle training
- Not start any GM work until approved by the GMSC
- Use GMOs and associated equipment including PPE in accordance with the project risk assessment and training
- Not carry out any work unless authorised by your P! /supervisor to do so
- Report any near misses, incidents or defects in any equipment, etc. provided for safe use

# 6 Risk Assessment

A suitable and sufficient risk assessment must be carried out before any contained use involving GMOs is commenced. The risk assessment must take full account of all aspects of the planned work, including handling, transport, storage, work area decontamination, inactivation of GMMs, disposal and waste management.

The key aspects to consider include:

- identification of any potentially harmful effects.
- characteristics of the proposed activity.
- the severity of any potentially harmful effects.
- the likelihood of them occurring; and
- disposal of waste and effluent.

The amount of detail in the risk assessment should be proportionate, providing sufficient detail to assess the hazards (potential for harm), how the harm could be realised, the likelihood of this occurring and the control measures that are needed to prevent the harm being realised.

The key steps to take when completing a risk assessment include:

I. hazard identification (e.g. harmful properties of recipient and donor micro-organisms, vectors or inserted material, consulting the approved List of biological agents) and assigning a provisional level of risk associated with the GMO.
II. consideration of how and where the contained use will be undertaken (including any non-standard procedures or higher risk environments) and adjusting the provisional level of risk accordingly.
III. selection of the appropriate containment measures (from the most applicable table in Schedule 8 of L29) based on the provisional level of risk and assigning the contained use to the appropriate containment level and classifying the activity according to that level; and
IV. reviewing and reconsidering the classification based on the completed assessment.

It should be noted that contained use above Class 2 **CANNOT** be carried out at the University currently as we do not have the facilities or legislative approval by the HSE for work above this class.

For the assessment under the GMO(CU) Regulations for larger GMOs, there is no requirement to consult the containment tables in Schedule 8 or classify the contained use. However, the risk assessment should consider whether the larger GMO is more hazardous to human health than the non-modified parental organism. In addition, although these Regulations are only concerned with the risks to human health from contained use with larger GMOs, risks to the environment should also be considered to ensure compliance with the EPA 1990. This should include risks arising from the escape of animals or escape of viable pollen from plants, enabling users to adopt the most suitable containment and protective measures to minimise damage to the environment.

To aid in the risk assessment process and to ensure compliance with all appropriate legislation, the GMSC has produced risk assessment templates for each type of work. These must be used unless the GMSC agrees another format can be used. The questions asked on these templates ensure that all requirements identified above and in guidance documents are answered and have been recognised by the regulator as good practice. These can be found on the GM SharePoint site and include templates:

For contained use of GMMs:

- simple Class 1 only form (a 'fast track' assessment form for well-characterised cells and vectors)
- micro-organisms other than viruses (less straight forward projects)
- human and animal viruses and viral vectors
- plant viruses

For contained use of larger GMOs:

- Plants
- Animals

## 6.1 GMSC Approval Processes

The GMSC must approve all GM risk assessments and GM workers prior to GM work starting.

### 6.1.1 GM Risk Assessment

A draft risk assessment must be submitted to the GMSC by the GM Project owner for review via the gmsc@lists.bath.ac.uk email. Review comments will be collated by the BSO and sent back for incorporation. For a new lab undertaking GMO work, this may require a visit from members of the GMSC to check it is appropriate, i.e. for class 2 work.

An updated risk assessment should then be resubmitted. Once this has been accepted, the GM Project owner should sign and date and obtain the equivalent of their Head of Department where relevant. The Chair of the GMSC will then also sign and date as approving the risk assessment. The BSO then adds the risk assessment to the central register and will send back the approved assessment along with a sign on sheet and a review record sheet.

GMO work can only then begin once the approved risk assessment has been received. The exception is for projects that require notification to the HSE. Please see relevant section for additional requirements.

### 6.1.2 GM Personnel Form

A draft GM personnel form must be submitted to the GMSC by the GM worker or GM Project owner for review via the gmsc@lists.bath.ac.uk email. The GMSC will check that the GM awareness course has been completed, and the level of experience provided. The GM worker must also identify the GM project they will be working on. When this information is satisfactory, the GM worker will be informed to obtain the required signatures and send back.

The form will then be approved by the GMS chair and the GM worker logged on a central register by the BSO. The BSO will then return the approved form, at which point the GM worker may begin their work.

These documents should all be filed together in an easily accessible place, i.e. the lab where the GM work is being undertaken.

### 6.1.3 Risk Assessment Review

Risk assessments are to be reviewed when:

a) there is reason to suspect that the risk assessment is no longer valid; or
b) there has been a significant change in the contained use to which the risk assessment relates.

The GMSC stipulates that class 2 risk assessments as a minimum must be reviewed annually, while all others must be done 3 yearly.

In addition, changes such as location i.e. lab and project owner will require an update of the GM risk assessment submitted to the GMSC for reapproval.

The review must be recorded, even if nothing has changed (review record sheets are provided by the GMSC) to provide evidence that it has been done and kept for at least ten years after the contained use stops. These records should be readily accessible, preferably kept with the GM risk assessment.

# 7 Genetic Modification Safety Committee

Regulation 8 requires that expert advice on risk assessments be obtained. To meet this duty a Genetic Modification Safety Committee (GMSC) has been established. All risk assessments must be approved by the GMSC regardless of Class. The GMSC also approves GM workers via the registration process described on the GM SharePoint site and the online course. Terms of reference are in place for the GMSC. The GMSC regularly reviews risk assessments and answers queries via the GMSC email: gmsc@lists.bath.ac.uk. It meets annually to ratify the new projects and GM workers and identify areas for continual improvement. Any audits and inspections carried out during the previous year will also be tabled at this meeting.

The University has also appointed a Biological Safety Officer (BSO) who is a member of the Safety, Health and Employee Wellbeing team. This role provides advice on legislation compliance, acts as Secretary to the GMSC, and coordinates notifications as well as administering registration and project assessment forms.

Departments have also appointed local biological safety advisors where required to advice on the day-to-day safety management of GM work.

# 8 Regulatory Notifications

The University of Bath has a premises notification (GM85) with the Health and Safety Executive (HSE), the regulatory body for work with GMOs. There is then a further requirement to make additional notifications to the HSE for further contained use, as set out below. These notifications may require the completion of a form and a fee. The BSO coordinates these notifications with input from the GM project owners and the chair of the GMSC.

## 8.1 Notification of Class 2 contained use

Regulation 10 requires that all class 2 contained uses are notified before the contained use can begin. This must be done using the correct form CU2, submitted to the HSE, along with the approved risk assessment.

As mentioned above this will be coordinated by the BSO who will provide guidance on the process. It should be noted that a fee is payable to the HSE for this notification which is currently £1074 payable by the department.

Once a notification has been made then any changes to the information supplied need to be notified to the HSE. These could be administrative such as a change to the person responsible, location or cessation of the contained use (no fee) or a significant change affecting the risk (fee of £803). The GMSC should be notified of any such changes prior to them occurring and the risk assessment should be updated and approved. Again, the BSO will co-ordinate and provide support regarding the notification.

## 8.2 Notification of contained use involving larger GMOs

Regulation 12 requires the person responsible for a contained use involving larger GMOs to notify the competent authority where the larger GMO presents a greater risk to humans than the non-modified parental organism. Examples of risks of harm from larger GMOs include:

1. causing disease in humans, including allergenic or toxic effects.
2. acting as a reservoir or vector for micro-organisms affecting humans.
3. adverse effects on humans arising from changes in behaviour or in physical nature.

At present, there are a minimal number of projects involving larger GMOs at the University and none has required notification. The BSO and GMSC will again advise on the procedure if such a notification were required, the fee also applies.

## 8.3 Notification of significant and administration changes

There is also the requirement to notify any significant change affecting the risks associated with an ongoing contained use. Significant means where the changes increase or present different risks compared to the originally notified work and lead to the user having to change the way they work (e.g. containment or control measures).

We must notify changes to administrative details that have been previously notified. Administrative details do not affect the output of the risk assessment. This can include a change in location (building) or the person responsible for the contained use.

## 8.4 Principles of occupational and environmental safety

A fundamental requirement of the Regulations is to apply barriers to limit contact of GMOs with humans and the environment. The nature and extent of these barriers should be consistent with the level of risk, and exposure of humans or the environment must be reduced to the lowest level reasonably practicable. To achieve this, control measures must include the principles of good microbiological practice (GMP) and good occupational safety and hygiene (GOSH) which are set out in Schedule 7 of L29 and summarised in Appendix 1.

APPLICATION OF ALL THESE PRINCIPLES IS MANDATORY IN ALL CASES

## 8.5 Containment and control measures for contained use involving micro-organisms at CL2

In addition to applying the principles of GMP and GOSH, for contained use of Class 2 micro-organisms further containment measures are required as set out below. These are detailed in Regulation 19 and Schedule 8 of L29.

- **Bench surfaces** impervious to water, resistant to acids, alkalis, solvents, disinfectants and decontamination agents and easy to clean.
- Use of a **Microbiological Safety Cabinet** when the risk assessment shows there is a risk from inhalation.
- **Access restricted** to authorised personnel only.
- An **Autoclave** is required within the building.
- **Biohazard** sign on door, this is mandatory for laboratories operating at CL2.
- Specific measures are required to minimise **aerosol dissemination.**
- Provision of suitable **Protective Clothing**, as a minimum in CL2 laboratories a lab coat must be worn, preferably of the Howie style.
- **Gloves** to be worn when the risk assessment determines they are required.
- Efficient control of **disease vectors** (e.g. rodents and insects) which could **disseminate GMMs** is required, specific control measures are in place where required in animal facilities.
- **Inactivation** of GMMs in contaminated material and waste is required by validated means.
- **Safe Storage** of GMMs.
- Written **records of training.**

### 8.6 Containment and control measures for contained use involving larger GMOs

Appropriate containment and control measures should be identified within the risk assessment submitted to the GMSC. Further information on appropriate containment for larger GMOs can be found in *The SACGM compendium of guidance, part 4 for plants and part 5 for animals.*

The GMO(CU) Regulations do not cover environmental hazards arising from contained use with larger GMOs. However, environmental risk assessments are required under the EPA 1990 and suitable containment, and control measures must be applied to prevent escape and to protect the environment.

## 9 Information, Instruction and Training

All persons working in microbiological laboratories must have a clear understanding of any identifiable risks to their health arising from work and the actions to be taken in dealing with situations in which exposure may occur. The level of training provided should be appropriate to the level of risk and the complexity of work being undertaken and should include:

- information about the risks likely to be encountered in their work including the class of the GMOs and the containment level of the laboratory space.
- the principles and practice of infection control in the laboratory, as a minimum Good Microbiological Practice.
- the safe working practices and procedures for the specific GMO work as stated in the risk assessment.
- the appropriate procedures in the event of an emergency.

A record of training completed should be made and kept, along with a timeframe (every 3 years is recommended) for refresher training identified in local arrangements.

## 10 Accident and Emergency Procedures

All laboratories need to clearly set out the appropriate procedures in writing (i.e. written emergency plans or contingency arrangements) for dealing with incidents which may result in the release of GMOs. Staff must be instructed and trained in the procedures and spillages should be attended to promptly. Incidents should be reported via the university report a problem tool. If there has been a potential release and/or exposure, then an investigation should be carried out by appropriate persons in the department to determine the direct and root causes and identify any corrective action to be implemented to prevent reoccurrence. Depending on the severity of the incident, SHEW may also be involved in this investigation. Incidents are then discussed at the department H&S Committee for wider learning and sharing.

## Appendix 1: Containment levels and the corresponding risk classification

| Containment necessary to control the risk | Risk Classification |
|---|---|
| Level 1 | Class 1 |
| Level 1 with the addition of measures from Level 2<br><br>or<br><br>Level 2 (without additional measures) | Class 2 |
| Level 2 with the addition of measures from Level 3<br><br>or<br><br>Level 3 (without additional measures) | Class 3 |
| Level 3 with the addition of measures from Level 4<br><br>or<br><br>Level 4 (with or without additional measures) | Class 4 |

Ref: Regulation 5 Table 1 of HSE Guidance L29; The Genetically Modified Organisms (contained use) Regulations 2014

| Class | Description |
|---|---|
| 1 | Contained use of no or negligible risk, for which containment level 1 is appropriate to protect human health and the environment. |
| 2 | Contained use of low risk, for which containment level 2 is appropriate to protect human health and the environment. |
| 3 | Contained use of moderate risk, for which containment level 3 is appropriate to protect human health and the environment. |

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| 4 | Contained use of high risk, for which containment level 4 is appropriate to protect human health and the environment. |

Ref: Regulation 2(1) Schedule 1 of HSE Guidance L29; The Genetically Modified Organisms (contained use) Regulations 2014

## Appendix 2 General principles of good microbiological practice and of good occupational safety and hygiene

The general principles of good microbiological practice and of good occupational safety and hygiene are as follows

a. keeping workplace and environmental exposure to any genetically modified micro-organism to the lowest reasonably practicable level.
b. exercising engineering control measures at source and supplementing these with appropriate personal protective clothing and equipment where necessary.
c. testing adequately and maintaining control measures and equipment.
d. testing, where necessary, for the presence of viable process organisms outside the primary physical containment.
e. providing appropriate training of personnel.
f. establishing a genetic modification safety committee, if required.
g. formulating and implementing local codes of practice for the safety of personnel, as required.
h. displaying biohazard signs where appropriate.
i. providing washing and decontamination facilities for personnel.
j. keeping adequate records.
k. prohibiting in the work area eating, drinking, smoking, applying cosmetics or the storing of food for human consumption.
l. prohibiting mouth pipetting.
m. providing written standard operating procedures where appropriate to ensure safety.
n. having effective disinfectants and specified disinfection procedures available in case of spillage of genetically modified micro-organisms.
o. providing safe storage for contaminated laboratory equipment and materials where appropriate