



Supervision of students undertaking GM work

1 GENERAL INTRODUCTION

This Safety Note deals with University procedures for ensuring compliance with the law for students engaged in activities involving genetically modified organisms (GMOs), whether they are genetically modified microorganisms (GMMs) or genetically modified higher organisms (GMHOs). (Note that the terms Class 1 and Class 2 used in this Note only refer to work with GMMs.)

Students on courses such as Microbiology, Biochemistry, Molecular Biology, *etc*, may be expected to acquire practical knowledge of modern molecular biological techniques. This may include work falling within the legal definition of “*an activity involving genetic modification*”. Everyone who is involved in such an activity (whether an employee or a student) must comply with the requirements of the GMO (Contained Use Regulations). Supervisors of practical classes and research projects have the major responsibility in law towards the students under their supervision, and must ensure that the students involved are given sufficient information to enable them to comply with the law. (Although the Note refers solely to undergraduates, the same requirements apply to postgraduates on taught courses, *eg*, M.Sc. courses, where there is a strong taught element to the course.)

2 TEACHING SITUATIONS

Undergraduates may be involved with GM work in two situations: during participation in either a fully supervised laboratory practical classes, or in an undergraduate research project which involves the use of GMOs. A project may be specifically designed for teaching use, or parts of previously-approved projects may be adapted for teaching use.

In all cases, the GM work must be on a project that has been approved by the University Sub-Committee for Biological Safety (SCBS) as being suitable for Undergraduates. Names of all Undergraduates must be notified to Health & Safety Services, together with details of the supervision arrangements.

2.1 Supervised laboratory practical classes

All supervised practicals that include “GM activities” must have been approved by SCBS. Such activities may be either “new” or previously approved GM projects. Participants need only be listed, but all supervisors must be registered as GM workers. (See below)

- **New project proposals**

Only Class 1 activities (or equivalent for higher organisms) are permitted for fully-supervised class practicals. Prospective project supervisors are urged to submit “low risk” project proposals, where the initial proposals must identify the range of potential techniques/plasmids, vectors, *etc*, to be used. (See Section 6.4, “Generic Assessments” in Safety Guide 15). If the project is approved, the supervisor must ensure that all such materials comply with the criteria for “low risk” (as indicated in the SAGM Compendium of Guidance). Changes that remain within the range of techniques *etc*. need not then be notified on an individual basis to SCBS.

New proposals to undertake teaching projects must be submitted in sufficient time to allow the project to be considered and approved **before** the laboratory class is due to start. In general, it takes approximately 4 weeks between submission and granting of “Biological Safety Officer (BSO) approval”. For Class 1 (or equivalent) projects, such temporary approval will apply, in that the BSO can give permission for the project to start, subject to a review of the risk assessment by an independent assessor. This approval is subject to ratification by the next scheduled meeting of SCBS (See SG15, Section 9.2).

Once the project has been approved, a list showing the names of the supervisors/demonstrators should be sent to Health & Safety Services **before** the series of practicals start. These details should include information on the experience of the supervisors and demonstrators in GM techniques. As the details of student numbers, *etc*, will change from year to year, the project proposer should state the minimum levels of demonstrator or supervisor numbers that will be required, and their required level of experience in GM techniques. (For projects involving GMMs (including the use of cell cultures), the recommended ratio is one demonstrator to 5 students. The class supervisor(s) is/are included in this ratio.)

- **Changes to existing approved projects**

Unless the original approved project was approved as a “low risk” project, changes to existing class teaching projects need to be notified to SCBS as an extension to an existing project. It would be advantageous to convert the project to a generic “low risk” project at this stage, to avoid the need to notify further changes.

- **Existing approved projects**

A copy of the list of the names of the student participants involved should be sent to the Health & Safety Services office (copied to the Area Health & Safety Co-ordinator or GM administrator) each year for record keeping purposes. Any changes in the allocated demonstrators, class supervisor(s), *etc*, should be similarly notified to the Health & Safety Services office before the class starts.

- **Annual review**

Project supervisors are reminded that all GM projects, including those specifically designed as teaching projects, are included in the Annual Review process. For details, see Safety Guide 15, section 9.8)

2.2 Undergraduate GM research projects

Undergraduates may participate in approved GM projects in their Department, or could (with appropriate guidance from a prospective supervisor) suggest their own project. Prospective supervisors should take note that such proposals must be submitted in good time to SCBS to allow the assessment and approval process to proceed (see below).

- **Existing approved projects**

Normally, undergraduates may only be involved with Class I GM projects (or the equivalent for higher organisms. Exceptionally, SCBS may approve (on a case-by-case basis) the involvement of undergraduates on **a previously-approved higher risk (Class 2) project**. The Project Supervisor must submit adequate documentation to support any such case that he/she wishes to make for such involvement. This documentation must provide evidence regarding the safe operation of the project, *i.e.*, to show that the risk assessment submitted with the project application remains valid. If SCBS were to approve, the Supervisor must ensure that any conditions attached to the approval by SCBS are fully observed, and enforced if necessary. Any students permitted to work on such projects must be demonstrably competent in basic “good microbiological practice techniques, and be subject to a high level of supervision. They must be subject to the full health registration and surveillance procedures.

Under no circumstances would undergraduates be permitted to work on a Class 3 project.

- **New or revised project proposals**

A student may suggest his/her own Class 1 GM project for a final-year research project. In this case, the details of the project must be fully discussed by the student with his/her supervisor, taking into account cost and space implications as well as the timescale of the approval process. The supervisor would be named as the project supervisor on the application form, and would be deemed to be in day-to-day control of the research project. A minimum of **4 weeks** must be allowed to allow the assessment process to be completed. All low risk GM projects can be given “BSO approval pending the next full meeting of SSGM.

- **Supervision**

All undergraduate students involved on GM research projects must be directly supervised by a

properly trained and competent member of the project team. The named Project Supervisor retains overall responsibility for the work of the student on the project. Students must be given instruction on the legal requirements for GM work as well as copies of appropriate guidance documents and the local rules in force for the project. (Attendance at one of the annual GM training seminars would be deemed to satisfy the need for instruction on the legal requirements.) The supervisor must ensure that the work undertaken by the student remains within the bounds of the risk assessment agreed for the project.

3 STUDENT REGISTRATION PROCEDURES

3.1 Fully supervised laboratory practical classes

Students are not **required** to go through the full registration process if they are only taking part in fully supervised class practicals. The supervisor is required to send a list of the class participants to the Health & Safety Services office before the (series of) practical class(es) starts - however, see below.

Certain medical conditions or treatments may compromise the ability of the body to fight infections. Class supervisors should highlight the following contraindication categories before the classes begin. Anyone who is:

- pregnant, or attempting to conceive;
- under any form of immunosuppressive treatment (including topical steroid treatment), or they are suffering from HIV infection;
- suffering from eczema, or other skin disorder; or
- receiving antibiotic or antifungal treatment for infections;

should be recommended to consult his/her own GP regarding the advisability of undertaking GM work or work with microorganisms. Anyone who is medically advised not to undertake such work should inform the class supervisor **in confidence**, although the reason for non-participation need not be given.

Student participants in the practicals must be recorded on a list each year as above. However, the project supervisor may, at his or her discretion, require students to complete the full registration process. This would be appropriate if there was a significant amount of GM work involved, for example a mini-project of several weeks duration. In addition, supervisors may consider that having all students complete the registration process for taught projects emphasises the importance of the registration process and compliance with the GM Regulations. By contrast, where the amount of GM work involved was limited to one or two practical classes, it would be inappropriate in terms of the time, expense and effort involved to require students to register as Undergraduate GM workers.

3.2 Research projects

Students involved with GM research projects are required to register in the normal way (Safety Guide 15, section 7), using the “Low Risk” GM worker registration form, [ref. GM02LR]. This is available via the “forms” page of the Health & Safety Services office web site. The form should be completed and returned (preferably as an e-mail attachment) to the BSO at Health & Safety Services [safety@rdg.ac.uk].

Exceptionally, any student who is approved by SSGM for work on a **Class 2 project** must go through the full registration procedures, which include being subject to health surveillance, and being given medical approval before they can start work. They must have submitted a completed Occupational Health questionnaire and the “standard” GM worker registration form to Occupational Health, and must attend a medical interview if required, before they can obtain approval to commence work. The “approval to start work” letter is issued by the BSO, and is in the form of a conditional approval. Failure to observe the conditions of approval may result in the approval being suspended or withdrawn.

4 PROCEDURAL SUMMARY

1. A GM project intended for undergraduate use must have been approved by SCBS as being suitable for this purpose. Normally, such projects would be Class 1 for GMMs or the equivalent for higher organisms.
2. Only low-risk projects (Class 1 for GMMs, or equivalent for higher organisms) are suitable for fully-supervised class practical classes. There must be a high level of supervision by staff with previous experience of genetic modification work.
3. Student involvement in GM research projects is normally limited to low-risk projects. All students involved on research projects must be registered as undergraduate GM workers and subject (where required) to the full University requirements for health surveillance.
4. In exceptional circumstances, SCBS may approve the involvement of undergraduates on higher risk projects, but any such approval would be on a case-by-case basis. Any conditions attached to such an approval by SCBS must be fully observed, and enforced by the Supervisor if necessary.
5. Under no circumstances will undergraduates be permitted to work on a Class 3 GM project.
6. All students involved with GM activities must be given sufficient information, instruction and training to enable them to comply with the law. If an individual is unable to attend one of the training sessions organised by Health & Safety Services (for example, because of time constraints), the responsibility for ensuring that he/ she is familiar both with legal requirements and University procedures is devolved to the Supervisor.
7. Students must be listed, or registered with Health and Safety Services as “undergraduate GM workers” as appropriate.

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