

University of East Anglia

**THE CONTAINED USE OF
GENETICALLY MODIFIED
ORGANISMS RULES**

Sixth Edition, October 2008

*These Rules have been approved by
the Biological Hazards and Genetic Modification Committee*

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1. Legal Requirements

Experimental work involving the contained use of genetically modified organisms (GMOs) is subject to the Genetically Modified Organisms (Contained Use) Regulations 2000, the Environment Protection Act (1990) and the Genetic Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996, as amended by the Genetically Modified Organisms (Deliberate Release and Risk Assessment – Amendment) Regulations 1997. The Health and Safety Executive has published detailed guidance on the interpretation of the GMO (Contained Use) regulations (reference L29) - copies are held by Biological Safety Officer (GM) and Safety Services. More detailed guidance has been published by the Advisory Committee on Genetic Manipulation in the ACGM Compendium of Guidance, accessible on the web (access can be obtained via the Safety Services website).

No work involving deliberate release of genetically modified organisms is allowed at the University.

The Regulations define *genetic modification* in relation to any organism as "the altering of the genetic material in that organism by a way that does not occur naturally by mating or natural recombination or both". Illustrative examples of techniques constituting genetic modification, and techniques to which the regulations do not apply, are given in Schedule 2 to the Regulations.

Contained use is defined as any activity in which organisms are genetically modified or in which genetically modified organisms are cultured, stored, used, transported, destroyed or disposed of, and where physical barriers (possibly combined with chemical and/or biological barriers) are used to limit their contact with the general population and the environment.

2. Local Arrangements

Within the University, all work involving genetic manipulation is subject to the scrutiny of the Biological Hazards and Genetic Manipulation Committee, which reports to the University Health and Safety Executive. Also, a Biological Safety Officer, Genetic Modification (GM BSO) has been appointed to carry out the expert task of initially assessing applications to undertake genetic manipulation experiments and to enable work of low risk to be authorised without undue delay.

3. **Approval of Proposed Work**

A risk assessment for all proposed work with GMOs must be submitted to the Biological Hazards and Genetic Manipulation Committee (via the Director of Safety Services) for approval before a start can be made. Applications to Research Councils, etc. for funding work in this area should be discussed with the GM BSO before they leave the University. The risk assessment must be recorded on form USS/GM/F01. Further information can be obtained from the GM BSO or from the Safety Services.

All activities involving GMOs must be classified in accordance with the guidelines set out in the ACGM guidance. It is the responsibility of the member of faculty responsible for the project to carry out this risk assessment, which should be written up in sufficient detail, with references where appropriate, to be understood by the GM BSO, the scientifically competent members of the Committee and specialist inspectors from the Health and Safety Executive. The matters to be taken into account in undertaking the risk assessments are described in Schedules 3 and 4 to the Regulations. It is essential that the proposer is familiar with the guidance from ACGM.

The Regulations set out a framework for classifying work with genetically modified organisms into four classes:

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

Projects determined to be Class 2 and above will need to be notified to the Health and Safety Executive (HSE). The Director of Safety Services will carry out this notification on behalf of the University. The regulations stipulate differing time periods that must pass before different notified classes of projects can begin. Fees must be paid to the HSE for these notifications.

If a project is to involve the use of a host strain or vector that has been derived from a pathogen listed under Schedule 5 to the Anti Terrorism, Crime and Security Act 2001 (Modification) Order 2007, approval must be sought from University Safety Services prior to ordering of the host strain or vector.

If there is any intention to transport any GMO, host strain or vector from UEA to any other organisation for any reason, checks must be made, by the Principal Investigator, on the notification status of the premises prior to despatch. Any dispatch of CL3 or other high risk GMOs to an organisation outside of the United Kingdom shall only occur after the Principal Investigator has received written confirmation that the organisation is authorised, competent and suitably equipped to hold such material (the confirmation shall

be guaranteed by a signatory at institutional level). Documented records of these checks shall be retained.

4. **Projects that Require a DEFRA Licence for Work with Plant Pathogens or Specified Animal Pathogens**

The approval of such projects by the Biohazards and Genetic Manipulation Committee will be provisional until a final risk assessment quoting the DEFRA licence number has been submitted.

5. **Training of Personnel**

All staff and graduate students involved in the experimental work must be adequately trained in microbiological or other appropriate laboratory practice and must be familiar with the requirements of the Regulations and the guidance from the ACGM. All new entrants must be given a copy of these Rules.

6. **GMOs in Undergraduate Teaching**

The use of GMOs in undergraduate practical classes and by final year project students is also subject to the regulations and faculty should discuss the proposed experiments involving their use with the BSO and obtain prior approval before the practical class or project starts.

7. **Suitability of Laboratories**

All work with Genetically Modified Organisms should be carried out in laboratories which are equipped to the Containment Level defined in the approved risk assessment.

8. **Methods of Work**

All persons carrying out genetic manipulation work must be familiar with the UEA Microbiological Safety Rules. These rules must be followed, including the details recommendations for good laboratory practice which are included as Appendix B.

9. **Health Surveillance**

There are no special mandatory health surveillance requirements for persons carrying out experiments at Containment Levels 1 and 2. However, if, for personal reasons, you feel otherwise, please consult the Dean or Occupational Health.

10. **Completion of Projects**

Those staff who originally proposed an approved project involving work with genetically modified organisms must notify the GM BSO and the Director of Safety Services, in writing, as soon as all work covered under the risk assessment has been finally ended.