INTRODUCTION

Biological safety can be separated into four main areas. Work involving dangerous pathogens, genetically modified organisms, animals and work with animal and plant pathogens. Separate regulations apply to each area, with work involving pathogenic organisms subject to the requirements of the COSHH Regulations 2002, while work involving the modification or manipulation of genetic material is subject to the control of the Genetically Modified Organisms (Contained Use) Regulations 2000. The welfare and housing of animals is covered by the Animal (Scientific Procedures) Act 1986 enforced by The Home Office. Animal allergy and zoonotic infections are subject to the requirements of the COSHH Regulations 2002. Work with animal and plant pathogens is subject to legislation enforced by National Agriculture and Fisheries Departments.

This Procedure covers the regulations in outline; sites specializing in this area will have substantially more detailed local procedures.

All accidents, incidents and near misses must be entered into the local accident reporting system.
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ROLES AND RESPONSIBILITIES

The person responsible for biological safety on site is the most senior scientist on site with the relevant expertise.

Safety Committee for Genetic Manipulation and Pathogens.

If any work with genetically modified organisms or viruses is to be carried out, a GM safety committee must be formed before work commences. It is a legal requirement that an intention to use premises for activities involving genetic modification for the first time is notified to the Health and Safety Executive. This must be done by the Biological Safety Officer after agreement of the local GM committee.

The GM safety committee advises the person responsible for biological safety on site, normally the most senior scientist with the relevant expertise, and its purpose is to:

- review, in detail, the risk assessment for any proposed work involving genetic manipulation, and ensure the proposed controls are suitable and sufficient;
- monitor health & safety in genetic manipulation laboratories, and identify necessary improvements in procedures or the need for additional training;
- investigate any accidents or incidents involving GM materials;
- provide advice on trends in relevant good practice and future changes in legislation;
- the GMSC includes general staff representatives as well as those with technical expertise;

Biological Safety Officer (BSO)

A biological safety officer must be appointed if any work with genetically modified organisms is to be carried out. If there is no GM work on site then the LSA could take on duties of BSO.

The suitably-qualified BSO is responsible to the most senior scientist on site with the relevant expertise, and duties will be:

- to ensure that risk assessments are in place and statutory notifications made to HSE.
- to ensure that local rules are drawn up and followed;
- to advise on training of personnel in appropriate microbiological practice;
- to investigate accidents spillage etc. and ensure appropriate action is taken;
- to ensure safe storage and transport of modified organisms and ensure records of these are kept;
- to ensure that control measures and waste disposal procedures are appropriate; and to provide technical support to the GM Safety Committee.

The BSO will be required to have experience relevant to the level of work being carried out at that site.
A risk assessment must be carried out before work commences by the scientist responsible for the work. A biological COSHH assessment form is shown in Appendix III.

**Laboratory Containment Level 1 Requirements**

Laboratory Containment Level 1 is suitable for work with agents in Group 1.

1. The laboratory must be easy to clean. Bench surfaces must be impervious to water and resistant to acids, alkalis, solvents and disinfectants.
2. Effective disinfectants must be available for immediate use in the event of spillage.
3. If the laboratory is mechanically ventilated, it is preferable to maintain an inward airflow while work is in progress by extracting room air to atmosphere.
4. All procedures must be performed so as to minimise the production of aerosols.
5. The laboratory door must be closed when work is in progress.
6. Laboratory coats or gowns must be worn in the laboratory and removed when leaving the laboratory suite.
7. Personal protective equipment, including protective clothing, must be:
   (a) stored in a well-defined place;
   (b) checked and cleaned at suitable intervals;
   (c) when discovered to be defective, repaired or replaced before further use.
8. Personal protective equipment which may be contaminated by biological agents must be:
   (a) removed on leaving the working area;
   (b) kept apart from uncontaminated clothing;
   (c) decontaminated and cleaned or, if necessary, destroyed.
9. Eating, chewing, drinking, taking medication, smoking, storing food and applying cosmetics is forbidden.
10. Mouth pipetting is forbidden.
11. The laboratory must contain a basin or sink that can be used for hand washing.
12. Exposed parts of the body must be decontaminated immediately when contamination is suspected and before leaving the laboratory.
13. Bench tops must be cleaned after use.
14. Used glassware and other materials awaiting disinfection must be stored in a safe manner. Pipettes, for example, if placed in disinfectant, must be totally immersed.
15. Contaminated materials whether for recycling or disposal, must be stored and transported in robust and leak proof containers without spillage.
16. All waste material, if not to be incinerated, must be disposed of safely by other appropriate means.
17. Accidents and incidents must be immediately reported to and recorded by the person responsible for the work or other delegated person.
Laboratory Containment Level 2 Requirements
Guidance on safe working practices can be found in The Management, Design and Operation of Microbiological Containment Laboratories, HSE books.

Additional requirements above containment level 1 are listed below.

1. Access to the laboratory must be restricted to authorised persons.
2. There must be specified dis-infection procedures.
3. If the laboratory is mechanically ventilated air pressure must be maintained negative to atmosphere while work is in progress.
4. There must be safe storage of biological agents.
5. Laboratory procedures giving rise to infectious aerosols must be conducted in a microbiological safety cabinet.
6. There must be access to an incinerator for the disposal of infected clinical material.
7. There must be adequate space (24 m³) in the laboratory for each worker.
8. Laboratory coats or gowns, which must be side or back fastening, must be worn and removed when leaving the laboratory suite.
9. Separate storage for PPE (for example, pegs) apart from that provided for personal clothing must be provided in the laboratory suite.
10. Bench surfaces must be regularly decontaminated according to the pattern of the work.
11. The laboratory must contain a wash basin located near the laboratory exit. Taps must be of a type that can be operated without being touched by hand.
12. An autoclave for the sterilisation of waste materials must be readily accessible in the same building as the laboratory, preferably in the laboratory suite.
13. Materials for autoclaving must be transported to the autoclave in robust, spill-proof containers.

Laboratory Containment Level 3 Requirements
Work with Containment Level 3 pathogens must only be carried out in specialist facilities. Details of the requirements can be found in the Categorization of biological agents according to hazard and categories of containment. Fourth Edition, 1995 and The Management, design and operation of microbiological containment laboratories, HSE books.

Guidance on handling human samples can be found at:
http://www.hse.gov.uk/pubns/infection.pdf

Transport of infectious substances
The regulations covering the carriage of dangerous goods by road and rail are derived from European Directives (ADR (road) and RID (rail)). The requirements for air transport of dangerous
goods, both within Great Britain and overseas, are contained in the International Civil Aviation Organisation (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air. Information on the transport of infectious substances can be obtained from the NERC DGSA responsible for the transport of dangerous goods. Details on the transport of infectious substances can be found in Biological agents: Managing the risks in laboratories and healthcare premises, 2005, published by the HSE.

GENETICALLY MODIFIED ORGANISMS

It is a legal requirement that an intention to use premises for activities involving genetic modification for the first time is notified to the Health and Safety Executive. All notified GM centres must have a person designated as the centre's BSO, who is formally appointed by the most senior scientist with the relevant expertise on the site concerned. The role and duties of this key appointee are clearly set out in the HSE Compendium of Guidance, which is issued to each notified GM centre. The compendium also gives detailed guidance on the formulation and recording of GM risk assessments, and the requirement to have such assessments approved by a competent local GM Safety Committee. This guidance also outlines the criteria for deciding upon the hazard categorisation of the work in question, and the criteria which must be met for each laboratory, animal or plant containment level for GM work. Other issues such as instruction, training, supervision and health/medical surveillance are also dealt with in detail in the compendium.

Updates to the Compendium of Guidance, and to the series of HSE/ACGM Newsletters providing additional information and guidance to GM Centres, are automatically sent by HSE to the notified centre. The HSE Advisory Committee on Genetic Modification (ACGM) produces a full set of guidance notes as a compendium. Detailed risk assessments of work must be submitted to the local ACGM Committee for approval prior to the work commencing. Staff are advised that if they wish to supply genetically modified biological material to other laboratories they must at first confirm in writing that the recipient is allowed to handle the material by asking them to quote their registration number. ACGM/Health and Safety Executive (HSE) Note 8 sets out guidance and recommendations of good practice for genetic manipulation in the laboratory. Guidance on The Genetically Modified Organisms (Contained Use) Regulations 2000 and The Genetically Modified Organisms (Deliberate Release) Regulations 2000 are available from the BSO.
GENETICALLY MANIPULATED MICRO-ORGANISMS INCLUDING VIRUSES

WORKING WITH ANIMALS
The welfare and housing of animals is covered by the Animal (Scientific Procedures) Act 1986 enforced by The Home Office. Animal allergy and zoonotic infections are subject to the requirements of the COSHH Regulations 2002. The use of transgenic animals is subject to the control of the Genetically Modified Organisms (contained Use) Regulations 2000.

Laboratory Animal Allergy (LAA)
Laboratory animal allergy is an allergic response to repeated exposure to animal allergens. Common allergens are proteins from body tissue and excretions of most animals. Urine, fur, saliva and serum may all contain allergenic substances. The symptoms of LAA may be similar to those of hay fever. They include rhinitis (sneezing and runny nose), conjunctivitis (sore or watering eyes), eczema and asthma (chest tightness and wheezing). The commonest symptoms are rhinitis and conjunctivitis and the most important health problem is occupational asthma. All employees working with animals must be included in a surveillance program to monitor for sensitivity to animal allergens. Employees will be given an appointment to attend the Occupational Health Service for health assessment before work with animals is commenced. Further information can be found at:
Control of laboratory animal allergy. HSE Books 2002. ISBN 0717624501

Zoonotic Infections
Zoonoses are diseases naturally spread from animals to man. Animals may infect humans through aerosols, wound contamination, blood-borne transmission, or urine or faecal contact. Staff must be aware of which diseases animals can carry, how they can be transmitted and what the early diagnostic signs in humans are if infection occurs. This is particularly important for fieldworkers who must be aware of the potential risks depending on the environment in which they are working. If someone contracts a disease, it must be reported to NERC centrally even if it is not reportable to HSE under RIDDOR.
Further information can be found in the Prospect publication "A Working Guide to Zoonotic Infections", and The occupational zoonoses. HSE Books 1993. ISBN 0118863975
IMPORTATION AND KEEPING OF ANIMAL AND PLANT PATHOGENS

Basis of the Department for Environment, Food and Rural Affairs (DEFRA) Classification of Animal Pathogens

DEFRA classify animal pathogens for the purposes of operating the Importation of Animal Pathogens Order (IAPO) 1980 and the Specified Animal Pathogens Order (SAPO) 1998. The classification is made for the purpose of protecting animal health from escapes of organisms from a laboratory and not protection of workers in that laboratory. Classification of organisms for the purposes of protecting employees under COSHH are given by the Advisory Committee on Dangerous Pathogens (ACDP), Categorisation of biological agents according to hazard and categories of containment. Fourth Edition, 1995. The DEFRA and the ACDP classifications are not complementary documents and must not be read as such.

The IAPO prohibits the importation of any animal pathogen, or any potential or actual carrier of an animal pathogen from outside the EU except under the authority of a licence.

Because the DEFRA and ACDP classifications are not complementary documents, compliance with one does not exempt employers from their responsibilities under the other.

The DEFRA classification is made on the following basis:

1. Group 1 Disease-producing organisms which are enzootic and do not produce notifiable disease.
2. Group 2 Disease producing organisms which are either exotic or produce notifiable disease, but have a low risk of spread from the laboratory.
3. Group 3 Disease producing organisms which are either exotic or produce notifiable disease and have a moderate risk of spread from the laboratory.
4. Group 4 Disease producing organisms which are either exotic or produce notifiable disease and have a high risk of spread from the laboratory.

Plant Pathogens

The Plant Health Order 1993 prohibits the importation from outside the EU of any plant pathogen or pest that is not already established in Great Britain. Controlled pathogens can only be imported for experimental purposes under a licence and the Order includes the control of genetically modified plant pests. Licence applications must be approved by the local safety committee.

This legislation applies to any materials that may harbour pathogens including soil, plants, waters, fibres. Agreement on importation must be obtained for every individual item i.e. a site-level import license is not general and must include every item imported. A site license can be modified in agreement with DEFRA (with payment of an additional charge).

If samples imported from outside the EU are suspected of carrying animal or plant pathogens, DEFRA must be contacted for advice on their handling and whether a licence is required.
REVIEW POLICY FOR UPDATING RISK ASSESSMENTS

It is the policy of the Local GM Safety Committee to review whether or not Risk Assessments need to be updated. This relates to Risk Assessments covering any aspect of work on NERC sites including work at Field Sites.

At each Committee Meeting, "updating Risk Assessments" appears as an item on the Agenda to ensure regular and high quality review.

The Local ACGM committee reviews Risk Assessments at every meeting and any proposed changes are discussed. Particular attention focuses on the need to ensure that projects have not progressed beyond the scope of the relevant Risk Assessment as major changes may require notification to HSE.
APPENDIX I: THE REGULATIONS

- Importation of Animal Pathogens Order 1980 (IAPO)
- Animal (Scientific Procedures) Act 1986
- The Plant Health Order 1993
- Specified Animal Pathogens Order 1998 (SAPO)
- The Genetically Modified Organisms (Contained Use) Regulations 2000
- Control of Substances Hazardous to Health (COSHH) Regulations 2002
- The Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2005
APPENDIX II: GENERAL GUIDANCE

- ACGM compendium of guidance, HSE 2000 ISBN 0717617637
- Blood-borne viruses in the work place. Guidance for employers and employees. HSE. ISBN 0171762062
- Biological agents: Managing the risks in laboratories and healthcare premises. HSE 2005.
- Control of laboratory animal allergy. HSE Books 2002. ISBN 0717624501
## COSHH Assessment Form for work with micro-organisms

<table>
<thead>
<tr>
<th>Name of micro-organism</th>
<th>Hazard group</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
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<tbody>
<tr>
<td>Location of work (room no.)</td>
<td>Person(s) involved</td>
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<td>Description of procedure</td>
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<td>If pathogenic specify consequences of infection</td>
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<td>Routes of infection</td>
<td>Ingestion / Inhalation / Percutaneous</td>
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<td>Could a less hazardous organism be used?</td>
<td>Yes / No</td>
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<td>Justify not using a less hazardous organism</td>
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<td>Control measures</td>
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<td>Containment level</td>
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<td>Additional precautions</td>
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<td>Gloves</td>
<td>Yes / No</td>
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<td>Avoid use of sharps</td>
<td>Yes / No</td>
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<td>Microbiological safety cabinet</td>
<td>Yes / No</td>
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<td>Other (specify)</td>
<td>Yes / No</td>
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<td>Is health surveillance required? yes/no</td>
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<td>Training requirements</td>
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<td>Disinfection procedures</td>
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<td>Waste disposal procedures</td>
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<td>Name and position of assessor</td>
<td>Signature</td>
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<td>Name of supervisor</td>
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<td>Assessment review date</td>
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