

The SACGM Compendium of guidance

Part 1: Introduction to the legislation and general
health and safety issues

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Preface

This guidance has been prepared by HSE, in consultation with Defra and the Scottish Executive, and incorporates advice from the Scientific Advisory Committee on Genetic Modification (SACGM).

The SACGM was established in January 2004 to provide technical and scientific advice to the UK Competent Authorities for the European Directive on the Contained Use of Genetically Modified Organisms. SACGM advises on all aspects of the human and environmental risks relating to the contained use of genetically modified organisms (GMOs).

The SACGM was set up as a Government scientific advisory committee in accordance with the Office of Science and Technology's Code of Practice for scientific advisory committees and operates in accordance with the Nolan principles. Compliance with Government good practice relating to scientific advisory committees is intended to ensure that independent expert scientific advice is provided when considering key scientific issues relating to the contained use of GMOs.

Following this guidance is not compulsory and you are free to take other action. But if you do follow this guidance you will normally be doing enough to comply with the law. Health and safety inspectors seek to secure compliance with the law and may refer to this guidance as illustrating good practice.

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1.1 The SACGM Compendium of guidance for contained use activities involving genetic modification

Overview

1. The Health and Safety Executive (HSE), in conjunction with the Department for Environment, Food and Rural Affairs (Defra) and the Scottish Executive Environment and Rural Affairs Department (SEERAD) has prepared the Compendium of Guidance in consultation with the Scientific Advisory Committee for Genetic Modification (Contained Use) (SACGM). SACGM provides technical and scientific advice to the UK Competent Authorities on all aspects of the risks posed to human health and the environment regarding contained use activities with genetically modified organisms (GMOs).
2. The Compendium of Guidance is aimed at all those wishing to undertake activities with GMOs in containment. In particular, those with responsibility for assessing the risks associated with such work, and those who are required to appraise those risk assessments, are the intended users of this guidance.
3. The terms *containment* and *contained use* refer to activities with GMOs that employ control measures such as physical, chemical or biological barriers to limit their contact with humans and environment. These activities are regulated under the Genetically Modified Organisms (Contained Use) Regulations. This guidance covers what is required by law for contained use activities with GMOs and represents what is considered to be good practice by the committee. By following it, users will be doing enough to comply with the Contained Use Regulations, and other legislation that impinges upon work with GMOs. Inspectors from the Competent Authorities will seek compliance with all the relevant legislation and may refer to this and other relevant guidance as illustrating good practice.

Scope of the Compendium

4. The Compendium of Guidance is intended to cover all work with GMOs in containment. This includes work with Genetically Modified Microorganisms (GMMs) as well as GM plants and animals. A GMO is defined as an organism (with the exception of humans) in which 'the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination' using 'recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules, produced by whatever means outside an organism, into any virus, bacterial

plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation'. This is a broad definition and further information on what is covered by the GM Regulations can be found in *A guide to the Genetically Modified Organisms (Contained Use) Regulations 2000* L29 (Third edition) HSE Books 2000 ISBN 978 0 7176 1758 6. There has been interest in the construction of novel biological systems (sometimes termed 'Synthetic Biology') and some of these approaches may also be covered by the legislation. Further information on this subject can be found in Infobox 1.1.

5. The Compendium of Guidance is intended to cover work of all types in any setting. It specifically offers guidance on work that is to be carried out at any location with specific reference to laboratories, large-scale production facilities, animal houses and plant growth facilities. The general principles set out in the Compendium cover the requirements of the legislation and therefore will be applicable to all situations, such as waste inactivation and incineration plants. Specific guidance is given for those wishing to undertake activities involving the administration to humans of substances based upon GMMs, or 'clinical studies'.
 - **Part 1** contains guidance relating to general health and safety issues, such as management responsibilities, which are applicable to all relevant workplaces. It also offers a guide to the requirements of other legislation that comes to bear on the Contained Use Regulations and how this is related to work with GMOs.
 - **Part 2** contains general guidance on the preparation of risk assessments for activities with GMMs, except those that are associated with plants (see Part 4). It also contains specific guidance relating to commonly used GMM platforms and technologies.
 - **Part 3** sets out in broad terms approaches to the containment and control of GMMs in different situations. There is specific reference to activities in laboratories, large-scale production facilities and animal houses.
 - **Part 4** contains general guidance on the preparation of risk assessments for activities with GM plants and GMMs that are associated with plants. It also covers the general requirements of the Contained Use Regulations for the handling of GMMs in plant growth facilities, as well as advice with respect to measures that can be employed to contain GM plants.
 - **Part 5** contains general guidance on the preparation of risk assessments for activities with GM animals and also gives advice with respect to measures that can be employed to contain GM animals.
 - **Part 6** gives specific guidance on the risk assessment and handling of GMMs in a clinical environment under the Contained Use Regulations, as well as information on the legislation that may affect such studies.

INFOBOX – SYNTHETIC BIOLOGY

Introduction. Synthetic biology involves the redesign of natural biological systems for the creation of bioengineered microorganisms as well as the construction of functional ‘genetic circuits’ and metabolic pathways for practical purposes. The main difference between most GM activities and synthetic approaches, is the latter aspires to assembling novel microbial genomes from a set of ‘genetic components’ instead of the transfer of genes from a donor to a recipient organism. Therefore, synthetic technology could make it possible to rationally engineer microorganisms with modified or even customised properties.

Under the Contained Use Regulations, genetic modification is defined as meaning *the altering of the genetic material in that organism in a way that does not occur naturally...using recombinant nucleic acid techniques involving the formation of new combinations of genetic material...and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation*. Therefore, synthetic approaches are covered by the GM regulations and the risks to human health and the environment must be assessed accordingly.

Risk assessment. Successfully engineered microorganisms could be self-sustaining and able to evolve. Therefore, they pose potential risks to both human health and the environment. Due to the complexity of biological processes required to generate a synthetic microorganism, it might be expected that most successful constructions would be expected to be less viable than their natural counterparts. Therefore, they would not be expected to pose significant risk to human health unless they are based upon human pathogens or contain known pathogenic mechanisms. Similarly, it is not anticipated that they would pose a risk to animal or plant health, unless they had been engineered with those properties. In the event of a release, they would therefore be expected to die-out rapidly. These organisms would be unique, however, and could occupy a novel niche or out-compete another species.

Containment and control. Given that the goal of synthetic biology is to create novel microorganisms, many of the risks associated with such activities will be complex, indefinable and difficult to anticipate with any degree of precision. Like more traditional GM approaches, however, many of those risks could be estimated based upon knowledge of the microorganisms and biological processes on which they are based. It is important, however, to acknowledge uncertainty and to deal with it using the precautionary principle. Therefore, work of this type is likely to attract higher containment measures than would otherwise be applicable to the organisms on which they are based, or from which the genetic information has been derived.

1.2 Legislation relating to GMOs and biological agents

Overview

1. There are several key pieces of legislation specifically concerned with the contained use of genetically modified organisms (GMOs). The main piece of legislation, covering both human health and environmental aspects of work with genetically modified microorganisms (GMMs), is the Genetically Modified Organisms (Contained Use) Regulations 2000, as amended (referred to hereafter as the Contained Use Regulations). These Regulations also extend to cover aspects of human health when working with GM plants and animals. Users are also referred to the HSE publication *A guide to the Genetically Modified Organisms (Contained Use) Regulations 2000* L29 (Third edition) HSE Books 2000 ISBN 978 0 7176 1758 6, which provides specific guidance relating to interpretation of the legislation.
2. From the perspective of environmental protection, aspects relating to the contained use of GM plants and animals are covered by the Environmental Protection Act 1990 (EPA). Where GMOs are intentionally released from containment into the environment, such activities are regulated by The Genetically Modified Organisms (Deliberate Release) Regulations 2002. Further details on deliberate release and the EPA can be obtained from the Defra website at: www.defra.gov.uk and is further expanded upon in Section 1.4 of this document.
3. The Compendium provides guidance only on legal obligations under other legislation that relates to aspects of working with GMOs. This document should aid duty holders to fulfil their legal obligations to both GMO-specific, and other more general legislation, including:
 - General health and safety legislation, including the Health and Safety at Work etc Act 1974 and the Management of Health and Safety at Work Regulations 1999.
 - Plant and animal health legislation - for example, work with GMMs that are animal or plant pathogens, or GMOs that contain sequences derived from plant or animal pathogens may require licences under the relevant legislation.

The Contained Use Regulations and COSHH

4. The requirements of the Control of Substances Hazardous to Health (COSHH) Regulations 2002 (as amended) and the associated Approved Codes of Practice (ACOP) may apply to certain GM work. COSHH defines biological agents as 'any micro-organism, cell culture, or human endoparasite... which may cause any infection, allergy, toxicity or

otherwise create a hazard to human health including any that have been genetically modified'. Known human pathogens are assigned to one of four hazard groups (Hazard Groups 1 to 4), depending on the hazards posed to human health. These hazard groups correspond to four levels of containment (Containment Levels 1 to 4), for which there are prescribed specific control measures. Activities with these agents must, therefore, be handled at the correct containment level. The hazard group classification for known pathogenic microorganisms can be downloaded from the HSE website at: www.hse.gov.uk/pubns/misc208.pdf.

6. Classification of GMMs is based on risk assessment; this then determines the containment measures required to control the identified risks. The containment measures selected decide the classification of the activity and it is this classification that determines the notification requirements. The relationship between risk assessment and classification for notification purposes is illustrated in more detail in Figure 1.2.1 (GMMs) and Figure 1.2.2 (GMOs). This is intended as an outline of requirements only and does not give details of the detailed risk assessment process or managerial scrutiny of those assessments. Notification forms are available from the HSE or can be downloaded at: www.hse.gov.uk/biosafety/gmo/law.htm.

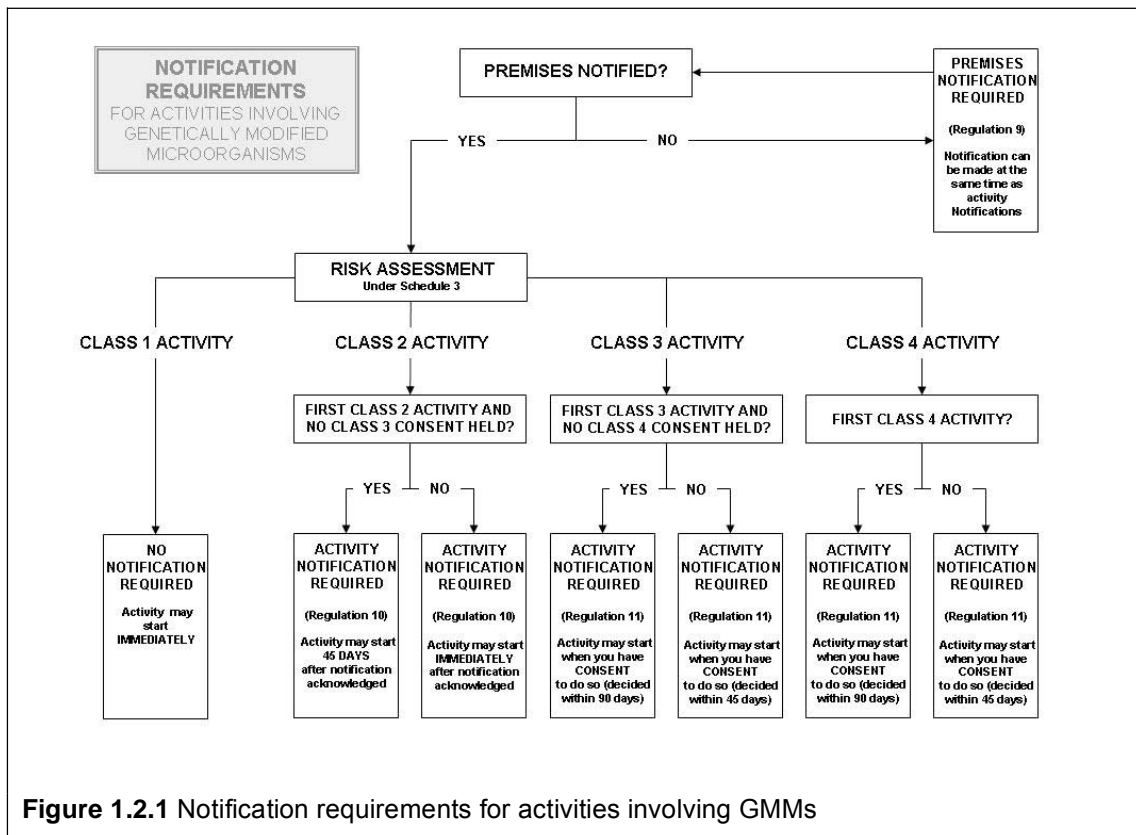
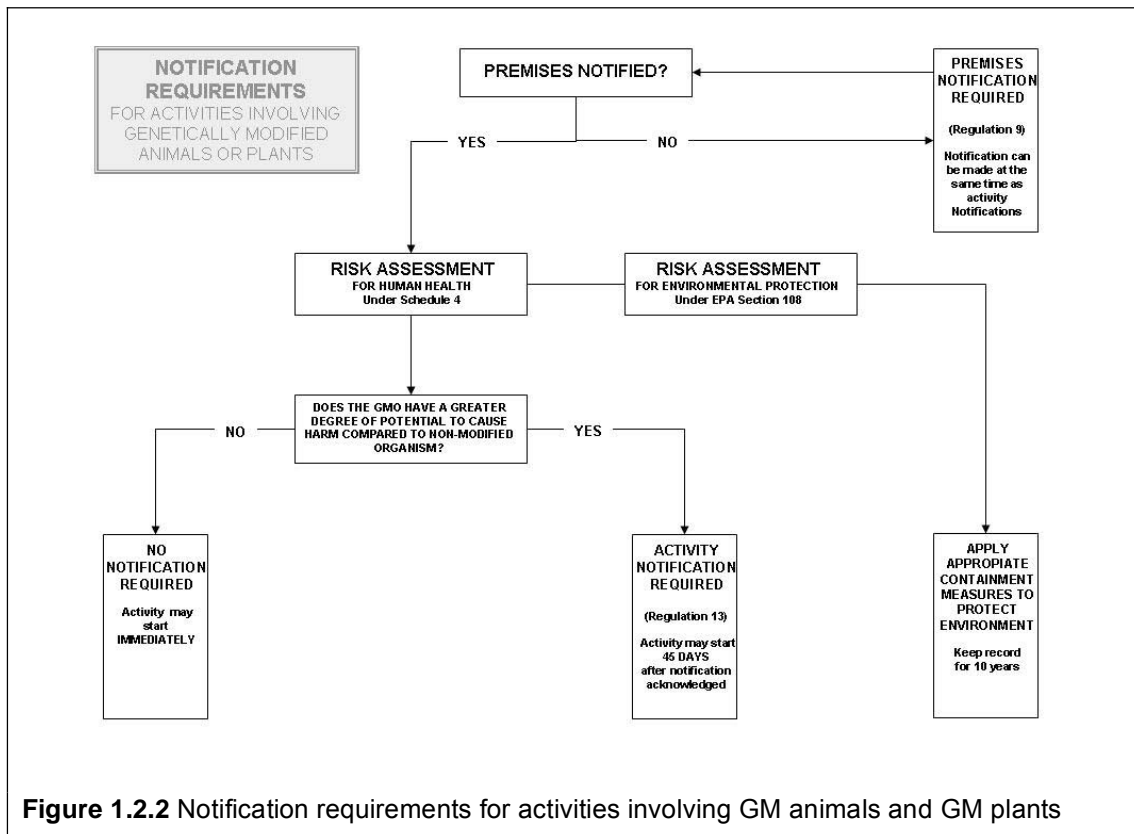


Figure 1.2.1 Notification requirements for activities involving GMMs



7. Furthermore, since COSHH only relates to GMMs that may present a hazard to human health, and does not consider any environmental risks, COSHH may not be applicable to all GMMs. Consequently, the containment and control requirements for a particular organism may differ between the two sets of legislation. However, the standards set in the four containment levels described in the Contained Use Regulations are broadly equivalent to those in COSHH (the minor differences which arise are a result of the genetic modification legislation encompassing environmental protection). It is worth emphasising that where risk assessment for the use of biological agents has been conducted for the purposes of the Contained Use Regulations, they will not need to be repeated for COSHH.

8. Additional guidance on biological agents can be found on the HSE website at: www.hse.gov.uk/biosafety.

Anti Terrorism, Crime and Security Act

9. Some GM materials will require safe storage under Part 7 of the Anti Terrorism, Crime and Security Act 2001 (ATCSA). Laboratories have a duty to ensure that the storage and use of dangerous pathogens and toxins listed within Schedule 5 of the Act are as secure

as reasonably practicable. Notes to this schedule include GM derivatives of listed pathogens and toxins, and sequences derived from such organisms.

10. In broad terms ATCSA requires laboratories to:

- Register with the Home Office their holdings of Schedule 5 substances. Inform the police of the security measures in place and the personnel who have access to the Schedule 5 substances.
- Ensure that Schedule 5 substances and the premises in which they are kept, stored, worked on and disposed of are secure.
- Ensure that access to said substances is authorised and controlled.

11. Further information is available by contacting the local Counter Terrorism Security Advisor or National Counter Terrorism Security Office (Tel: 020 7931 7142) or nactso@btopenworld.com.

1.3 Legislation relating to management responsibilities

Health and Safety at Work Act

1. The HSW Act and more specifically the Management of Health and Safety at Work Regulations (MHSWR) require that employers appoint competent persons to assist them in complying with health and safety legislation. In the context of the Contained Use Regulations, this requirement may be satisfied by the appointment of a biological safety officer (BSO). This managerial responsibility to ensure a safe working environment cannot be delegated to the workers, (including to the BSO).
2. Effective management should include monitoring the activities of the BSO and the Genetic Modification Safety Committees (GMSC) (see paragraph 19 of this section) set up to advise them on risk assessment. Management also have a duty to keep the safety policies under review, implement control measures and ensure that they are effective. It is particularly important that management afford the advice of BSOs and GMSCs due credence. To achieve this it is helpful if the BSOs and the GMSC can directly access senior management.
3. The Safety Representatives and Safety Committees Regulations 1977 state that where there are appointed safety representatives, management has a duty to consult them on matters relating to health and safety and take account of their views. Direct consultation with employees will be necessary if there are no appointed safety representatives.
4. It should be noted that in addition to the responsibility of management, employees have a duty to take reasonable care for both their own health and safety and that of others who may be affected by their acts or omissions at work.
5. The Contained Use Regulations place a number of statutory duties on employers in relation to both human health and environmental safety. The full details are outlined in the regulations and guidance, but one of the primary duties is to undertake a risk assessment covering both human health and safety and environmental safety.
6. The risk assessment for environmental safety for GMOs that are plants and animals is made under the EPA and the Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996, as amended. Further guidance can be found in Part 4 and Part 5 of the Compendium.

Biological safety officers

7. The majority of requirements listed in the Contained Use Regulations will need to be delegated to a local level, as employers are unlikely to have all the relevant knowledge to meet these statutory requirements. Regulation 6 of the MHSWR requires every employer to appoint one or more 'competent persons' to assist them in undertaking the measures required to comply with the relevant statutory duties. Where GM work is undertaken, this role of 'competent persons' has traditionally been undertaken by a biological safety officer (BSO).
8. Whether or not employers appoint a BSO, or Biological Safety Adviser, will depend on the establishment and how they decide to meet their statutory duties. However, if appointed, a BSO must have sufficient training, experience or knowledge and other qualities to enable them properly to assist in undertaking the measures required to meet all of the relevant statutory provisions. In addition, the BSO must be allocated sufficient time and resources to do the job.
9. As well as advising on the containment and training aspects of the work, the BSO will normally advise on risk assessment and co-ordinate the notification procedures. In a small department/institution or company one person may undertake these tasks. However, in large institutions it may be impractical to have only one person carrying out this role in addition to other duties such as research and teaching. In such cases there may be a need to consider appointing more than one person to undertake the BSO role.
10. The appointed person(s) should ideally have experience of working within a containment laboratory or with similar practices, but the absence of such experience should not necessarily preclude the appointment of an individual who is otherwise well suited for the position. In such instances appropriate training and technical assistance should be provided as necessary. Where a BSO is not able to advise or assist employers to enable them to meet all their statutory duties other suitably qualified persons should also be appointed.
11. Examples of matters upon which the BSO may advise or assist the employer to enable them to meet the statutory requirements for work with GMOs, include:
 - Ensuring that local rules for the safety of personnel are drawn up and followed.
 - Ensuring appropriate training of personnel has been carried out.
 - Ensuring accidents/incidents spillages etc. in the laboratory (or other containment facility) are appropriately investigated and followed up (see paragraph 41 of this section).

- Advising on the safe storage, transport and disposal of genetically modified organisms/ harmful or potentially harmful material and ensuring that the records kept are current and accurate.
- Ensuring that laboratories are appropriately disinfected at the end of a project or before the entry of maintenance personnel. Appropriate disinfection could range from swabbing down work surfaces to complete fumigation and will be dependent on the risk assessment.
- Participating in locally organised inspections.
- Advising on appropriate methods for testing for the presence of viable process organisms outside the primary containment, if deemed necessary.
- Ensuring that control measures and equipment are tested and maintained at appropriate intervals.
- Providing technical support to the GMSC on risk assessment and classification.
- Ensuring all appropriate statutory notifications are made to HSE.
- Informing employers of any changes to the relevant regulations.
- Physical security of the laboratory.
- Liaising with National Counter Terrorism Security Office (NACTSO) where appropriate.

Training

12. Training is required under the Contained Use Regulations and also by COSHH and the MHSWR. It can be divided into:

- Induction training following recruitment, for example, training in good microbiological practice and familiarisation with the local rules before beginning work.
- Training when a significant change to work, equipment, work environment, work activity or responsibilities takes place, especially where increased or new risks may be involved.
- Refresher training (where appropriate) to maintain standards.
- Training in risk assessment procedures will often be useful (although this is not specifically required by the legislation).

13. The level of training provided should be appropriate to the level of risk or the complexity of the procedures being undertaken. In smaller groups or establishments training is often given on a one to one basis, with research supervisors, senior technicians or other safety advisors initially demonstrating techniques. Of course, the supervisors, technicians and advisors must themselves be appropriately trained, including refresher training where necessary. The new employee can then progress to performing the technique under

supervision. Once both supervisor and trainee are satisfied with the level of competence achieved the supervisor allows them to continue without constant supervision. The duration of this supervised training will clearly relate to the risk level and the complexity of the procedures being undertaken. Even fully competent individuals will require some level of monitoring to ensure that standards are being met consistently.

14. At Containment Level 3 and above, a more formal approach to training is required, with written records of training kept. It is also required to keep formal training records for some Containment Level 2 projects, depending on the risk assessment. It is good practice to retain and maintain records for all staff, whatever the level of work. Usually staff commencing work at Containment Level 3 or above will be assessed for their suitability, for example whether they work safely and competently at Containment Level 1 and 2.
15. One requirement of the Contained Use Regulations is that at Containment Levels 3 and 4, all work with live organisms must be carried out in a microbiological safety cabinet, therefore staff should be trained in the safe use of cabinets. Other aspects of working at Containment Level 3 and above that should be covered in training include safe transport and storage of organisms and waste management procedures. New workers should be trained in emergency procedures, for example, in the event of a culture spillage, employees should be familiar with the appropriate disinfection and fumigation procedures.

Supervision and monitoring of standards

16. Regulation 5 of the MHSWR covers the supervision of workers and the monitoring of standards. This states that arrangements must be made for the effective planning, organisation, control and monitoring of preventive and protective measures. The requirement to exert control in relation to health and safety issues expects management to ensure that decisions that have been made relating to health and safety are actively implemented. Management are therefore expected to ensure a progressive improvement in health and safety by reviewing actual standards and comparing them to what was planned.
17. Monitoring of health and safety standards by locally organised inspections is necessary because, even after safe working practices have been devised and implemented, with time standards can slip and employees sometimes deviate from agreed procedures. The level of monitoring will depend on the risks associated with the work and the competence of the workers. Fully competent individuals will still require some level of monitoring to ensure that standards are being met.

18. While issues relating to the environment are not covered by the MHSWR, it should be regarded as good practice to have comparable standards of supervision and monitoring for those aspects of genetic modification work that involve environmental hazards.

Genetic modification safety committees

19. As stated above, the Contained Use Regulations place a statutory obligation on anyone carrying out a risk assessment under those Regulations to establish a GMSC. Although the statutory purpose is solely to advise the management on the adequacy of any risk assessment, the GMSC can also provide a beneficial influence on ensuring good practice if there is full discussion with all those concerned, on safety, training and laboratory discipline. Members' local knowledge and expertise can be particularly important. GMSCs are often involved in the formation of local rules and in the consideration of accidents and incidents. SACGM and HSE attach great importance to the safety committee, which often plays a key role in the organisation of safety procedures.

20. Depending on the nature of the GM work being undertaken it may be necessary to have a range of representatives from various technical disciplines, representing both management and employees (eg Union reps), health and safety advisor(s) such as a BSO and, if necessary, input from clinicians.

21. While it is important to have the correct representation on the GMSC, centres should avoid having unnecessarily large and unwieldy committees. The composition can be tailored for different GM studies and outside expertise can be drafted-in where necessary.

22. SACGM places particular emphasis on the value of having a balanced committee representing both management and employees and the need for the committee to be run in such a way that all members' views are heard. Details about the GMSC must be submitted to the Competent Authority as part of the notification of first use of premises for genetic modification activities.

Health surveillance

23. Health surveillance is about putting in place procedures to detect adverse reactions or ill health among employees that are exposed to health risks as a part of their work. Ultimately, this is so that action can be taken to prevent further harm to those workers or others who may be exposed. There is no requirement for health surveillance under The

Contained Use Regulations, although more general regulations, such as the MHSWR and COSHH, might be applicable.

24. Health surveillance is required by COSHH (and MHSWR) if *all* of the following criteria apply:

- The work could result in harm to health in some way.
- There are safe and practical ways of detecting diseases or conditions associated with exposure.
- Damage to health may occur under particular conditions at work.
- Surveillance will benefit the employee or workforce.

25. The benefits of health surveillance are that it can:

- Provide information so you can detect harmful health effects at an early stage, so protecting employees and confirming whether they are still fit to do their jobs.
- Provide data, by means of health records, to detect and evaluate health risks.
- Provide an opportunity to train and instruct employees further in safe and healthy working practices (eg how to use personal protective equipment (PPE) properly).
- Give employees the chance to raise any concerns about the effect of their work on their health.

26. In practice, health surveillance for most activities with GMOs and GMMs will not be required. The circumstances where it could be useful might be where the agent causes serious disease that may have an insidious onset, and where there is an effective treatment available. However, in the case of work with GMOs and GMMs, the risks may be less well defined compared to the organism from which it is derived, or arise as a direct result of the modification. Users should consider whether the organism being modified - or the modification itself - gives rise to a significant risk to health and consequently, whether surveillance would be beneficial.

27. Many GMMs will pose no identifiable risk to human health and there will be no need for health surveillance under COSHH or MHSWR in most cases. However, some work will involve GMMs where there are both a potential risk to health and methods to detect adverse events. In such cases, some form of health surveillance may be appropriate. Examples of GM work where health surveillance may need to be considered are:

- GMMs derived from biological agents classified in ACDP hazard groups 2 - 4, or assigned to GM activity class 2 – 4 on the basis of human health protection. In practice, the majority of organisms assigned to GM activity class 2 will not require

health surveillance. Examples of when it might be required include GMMs with altered tissue tropism/host range, where the GMM is less susceptible to prophylaxis, or where a vaccine may not confer full protection against the GM form of an agent.

- Organisms expressing sequences/genes with known biological effects (such as oncogenes, enzymes, hormones, toxins) which may pose risks to health.
 - Work with a potential for exposure to cloned human genes which may lead to an immune response and subsequent auto-immune type disease.
 - Work that may cause respiratory sensitisation, especially at large scale and with the possibility that fusion proteins or inclusion bodies may enhance sensitisation.
28. Employees should be familiar with the clinical manifestations resulting from infection with the organisms being worked with (for example, Vaccinia virus lesions), and the correct procedures for reporting instances of disease/ill health to their employer.
29. The occupational health provider should be alert to unusual patterns of disease or ill health within the workforce, irrespective of the control/containment measures being used.
30. It may be possible to check the immune status of workers to see if they have protection against a potential infectious agent they could be exposed to in the course of their work. This could be carried out as part of pre-employment screening, or else by making checks on immunity following a course of vaccination (eg Hepatitis B; Measles). Immunity could also be screened following an exposure incident or used to confirm that control measures are working (for example, by checking for a sero-conversion event). This can be a useful feedback on risk assessments, indicating if further controls might be needed and what that might entail. Such procedures should ensure that those who may be at additional risk are identified so that additional controls can be put in place to protect them.
31. COSHH requires that, if the risk assessment shows there to be a risk of exposure to biological agents for which effective vaccines exist, these should be offered if the employee is not already immune. The advantages and disadvantages of immunisation versus non-immunisation should be fully explained when making the offer.
32. The Health and Safety at Work Act requires that protective measures such as immunisation be provided to workers free of charge. Employees may not wish to take up the offer of immunisation, or else do not respond to a vaccine. If so, employers should carry out a local assessment to determine the likelihood of that particular individual being exposed and acquiring an infection. If existing controls are deemed to be inadequate, then controls should be implemented to allow them to work safely. This might include the provision of extra PPE.

33. Immunisation should only be seen as a useful supplement to control measures required to prevent exposure and should never be relied upon for worker protection.
34. Information about vaccines available in the UK can be found in a Joint Committee on Vaccination and Immunisation publication *Immunisation against infectious disease*. Some vaccines may not be licensed for use in the UK but may be available on a named patient basis.
35. Any health surveillance programme that is undertaken should include keeping a health record for each individual. The health record is different from a clinical record. The health record should be about the individual's fitness for work or any specific precautions that should be taken. It should not include any confidential clinical data. The elements of a health record are given in the Appendix to COSHH and include:
- Personal details of the individual.
 - An historical exposure record (it may be sensible to combine this with any list of workers' exposure to a Hazard Group 3 or 4 biological agents - see below) and a record of any immunisations and the conclusions of any checks on immunity.
 - The health record and any list of exposed workers needs to be accessible by the employer in order to monitor control measures that are in place and to ensure that employees are not at risk. Records which include medical information arising from clinical examination are held in confidence by the doctor or nurse and can only be released with the written consent of the individual.
36. The COSHH ACOP contains further interpretation on the need for health surveillance and the Biological Agents ACOP gives interpretation specific to work with biological agents. Further general guidance on health surveillance can be found in the HSE publication *Health surveillance at work* HSG61 (Second edition) HSE Books 1999 ISBN 978 0 7176 1705 0 and the free HSE leaflet *Understanding health surveillance at work: An introduction for employers* Leaflet INDG304 HSE Books 1999 (single copy free or priced packs of 15 ISBN 978 0 7176 1712 8) Web version: www.hse.gov.uk/pubns/indg304.pdf.

Records of exposure

37. An exposure record is not the same as a health record required for the purposes of health surveillance under COSHH or the Management of Health and Safety at Work Regulations. However, exposure records must be available to any individual appointed for health surveillance (eg the local occupational health physician). It must also be available

to any employee specifically responsible for health and safety (such as a safety manager).

38. Each employee must have access to the information that relates to him or her personally. If records are kept (computerised or manual) about individuals in connection with health and safety legislation, the requirements of the Data Protection Act 1998 may apply. These requirements include informing people that certain information is held about them and granting them access to that information, should they request it. Guidance on the Act can be requested from the Data Protection Commissioner, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
39. In practice the exposure record might best be kept with other transferable confidential information (eg information accessible only by authorised individuals) in the employee's occupational health record. COSHH requires that records of exposure be kept for work with certain biological agents. Exposure in this context means working with the agent, not accidental exposure/loss of containment. These include all biological agents classified in Hazard Groups 3 and 4, for which records should be kept for 40 years after work ceases.
40. Retaining exposure records of individuals who have worked with oncogenes would be of value. However, the nature of 'infection' with such material does not lend itself to traditional formal Health Surveillance. Any such records should be stored securely. Upon termination of a contract, a copy of the records should be given to the worker so that they may be given to the next employer. This may be particularly important for researchers undertaking a number of short-term contracts.

Emergency procedures and notification of accidents

41. Although the Contained Use Regulations require emergency plans to be prepared, they are only necessary if risk assessment indicates that the health and safety of people outside premises, or the wider environment, may be affected.
42. COSHH requires employers to draw up plans for dealing with accidents involving biological agents. There should be clear instructions about the procedures to be followed if there is a significant incident when working with biological agents, for example, in the event of a significant spill involving hazard group 3 organisms. Additionally, the MHSWR require procedures to be in place for responding to serious and imminent danger, eg fire or flooding. The risk assessment should identify all the foreseeable incidents to be covered by the emergency procedures. The MHSWR also require that the emergency

services have sufficient knowledge of the hazards within the containment facility should they have to enter the premises to respond to an emergency situation.

43. 'Accident' is defined in the Contained Use Regulations as 'a significant and unintended release, either within the containment facility or to the environment, of GMOs which could cause harm to humans or the environment'. The competent authority must be notified of such accidents by reporting them to HSE using form CU3, which can be downloaded at <https://www.hse.gov.uk/forms/genetic/index.htm>. Following receipt of a CU3 form, HSE is obliged to investigate the accident and send a report to the European Commission. In practice, the large majority of accidents will not meet the level of severity that would trigger a notification requirement. However, such accidents may require notification under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 1995.
44. RIDDOR requires the reporting of any infection reliably attributable to work with live or dead humans or animals, exposure to blood or body fluids or any potentially infected material derived from any of the above. There is also the separate need to report any accident or incident which resulted or could have resulted in the release or escape of biological agent which is likely to cause severe human disease (hazard group 3 or 4 biological agents or Class group 3 or 4 GMMs - where the classification is based on hazard to human health).
45. In order to help those responsible for safety to check the effectiveness (and where appropriate, alter) safety precautions within the containment facility it is recommended that a local record is made of all accidents and occurrences with GMMs/GMOs (including near misses). This record should cover a range of incidents wider than would be covered by the statutory schemes such as the RIDDOR.

1.4 Legislation relating to environmental protection

Environmental Protection Act

1. The Contained Use Regulations require the risk assessment for work with GMMs to cover environmental hazards, but they do not require such an assessment to be conducted for work with GM animals or plants. There are, however, requirements under environmental protection legislation, which call for this assessment to be carried out. Environmental protection aspects relating to the contained use of GM plants and animals are covered by the Environmental Protection Act 1990 (EPA), and specifically under the Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996, except where GMOs are intentionally released from containment into the environment. Under Part VI of the Environmental Protection Act 1990, it is an offence to deliberately release any genetically modified organism into the environment or allow it to escape without prior consent of the Secretary of State or equivalent in devolved administrations. Such activities are regulated by The Genetically Modified Organisms (Deliberate Release) Regulations 2002. Further details on the Deliberate Release regime, notes on the application format and procedures can be found at: www.defra.gov.uk/environment/gm/regulation.

2. Applicants can also contact the GM Science, Policy and Regulation Team in Defra at:

GM Controls and ACRE Secretariat
Defra
Area 4D
Nobel House
17 Smith Square
London SW1P 3JR
E-mail: gm-regulation@defra.gsi.gov.uk

3. The EPA requires risk assessment of all GMOs in containment. In practice, GMMs are covered by risk assessments required under the Contained Use Regulations. The EPA, together with the Records and Exemptions Regulations, require that anyone keeping genetically modified animals or plants must carry out an assessment of the risks to the environment. The assessment must include risks arising from the escape of the animals or plants, including escape of viable pollen. The assessment enables the keeper of the GMOs to put suitable containment measures in place to minimise damage to the environment resulting from any such escape. Records of the assessment must be kept for 10 years.

Disposal of waste

4. Prior to off-site disposal of waste from contained use activities, any risks to humans or the environment associated with the GMOs must be removed using validated inactivation methods. The only exception to this is if the user has the explicit agreement of the competent authority to the Contained Use Regulations to dispose of waste without inactivation (see Part 3, Section 3.5 for further information). Once GM waste has been inactivated and disposed of it no longer comes under the Contained Use Regulations. However, it will be subject to the relevant waste and pollution legislation that applies to any waste. Specific guidance on the safe disposal of clinical waste containing biological agents has been published by the Department of Health (*Environment and sustainability – Health Technical Memorandum 07-01: Safe management of healthcare waste*), and is available as a priced publication from the Stationary Office (www.tsoshop.co.uk).

Further information

HSE priced and free publications are available by mail order from HSE Books, PO Box 1999, Sudbury, Suffolk CO10 2WA Tel: 01787 881165 Fax: 01787 313995 Website: www.hsebooks.co.uk (HSE priced publications are also available from bookshops and free leaflets can be downloaded from HSE's website: www.hse.gov.uk.)

This document contains notes on good practice which are not compulsory but which you may find helpful in considering what you need to do.

This document is available web only at: www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp

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